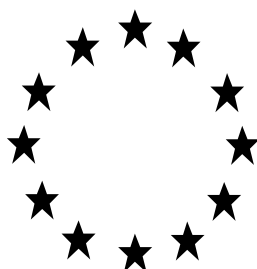


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT
OF A BIOCIDAL PRODUCT FOR
NATIONAL AUTHORISATION APPLICATIONS**



Product identifier in R4BP	Vertex 25 Oktablok (red)
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-GR029540-33
Asset No. in R4BP	IE-0016001-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	IE/BPA 70505
Date	14-03-2018 (NA-RNL Renewal)

Version 3.1

1 Version History

Date	Version	Reason for revision
2013/07/18	Version 1.0	Initial PAR
2018/01/09	Version 1.1	MAC PAR
2018/03/14	Version 2.0	Updated at 1 st Renewal of authorisation RNL
2021/02	Version 3.0	Updated for minor change to professional and Trained professional pack sizes.
2023/10	Version 3.1	Reduction of non-active substance preservative Nuosept OB 03 concentration from 0.125% to 0.11%. Update of EUH208 hazard statements.

2 Overview of applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
National Authorisation Dir 98/8/EC	IE	n/a	2013/07/18	2013/07/18	111
NA-MAC	IE	BC-YL028939-03	2018/01/09	2018/01/09	537
NA-RNL	IE	BC-GR029540-33	2018/03/14	2018/03/14	36
NA-MIC	IE	BC-EP061302-43			52-89
NA-MIC	IE	BC-WM073987-97			3-5

3 Minor changes

NA-MIC BC-EP061302-43

On the 06/08/2020 the Authorisation Holder submitted a Minor Change application to change allowed pack sizes for Professional and Trained Professional users in the cMS Greece. They asked the RefMS Ireland to evaluate these changes to ensure there would be no future issues during renewals of the product. However due to National Legislation Ireland only allows a minimum packsize for rodenticide products for Trained and Trained Professional of 2.5Kg. Therefore, the evaluated packsizes will not be authorised for the Irish market. After consultation with the only cMS, Greece, they confirmed they also will not allow these pack sizes onto the market.

The application was found to meet the criteria for a minor change to packaging:

- New range is consistent with the dose rate and instructions for use as approved in the summary of the biocidal product characteristics
- No change is user category
- The same risk-mitigation measures apply

Ireland has assessed the application and are of the viewpoint that the change to the packaging size does not affect the prescribed dose rate or instructions for use as per the SPC. No change in user category has been made and the same risk-mitigation measures apply. The constituents of the

packaging were assessed against the packaging originally approved and has not changed either. The only change has been to the size of the pack allowed for Professional and Trained Professional users. As the IE CA or the cMS do not allow the assessed pack sizes on the market we have updated the PAR to conclude on the evaluation of the additional pack sizes but this conclusion will not affect a change to the current SPC

NA-MIC BC-WM073987-97

The IE CA has processed an application for the minor change of a national authorisation (NA-MIC) for the biocidal product Vertox 25 Oktablok (red). The proposed minor change to the formulation is a reduction in the content of the fungicidal preservative [REDACTED] from 0.125% w/w to 0.11% w/w. Nuosept OB03 is added to the formulation to prevent mould growth in damp sewer conditions.

a) Physical, chemical, & technical properties

The storage stability of the wax block formulation has been previously established and new studies are not submitted. The preservative does not act as a stabiliser for the active ingredient, therefore the proposed reduction in its content is not expected to affect the active substance concentration in the formulation during storage. The mass difference is substituted with an inert filler ingredient (wholewheat flour), ensuring that the content of the active substance remains unaffected.

A statement from the manufacturer of the preservative indicates that the magnitude of the proposed formulation change has been found to have a negligible impact on the preservative's efficacy. It is also stated that the proposed preservative content remains above the minimum inhibition concentrations for a range of target fungi species and within typical use levels in products (0.1 – 0.3% w/w). The reduced preservative content is therefore expected to uphold resistance of the product to mould and maintain the integrity of the formulation.

The physicochemical properties and shelf-life of the product are not expected to be affected by the minor change to the formulation.

a) Efficacy and palatability

Vertox 25 Oktablok (red) is a ready to use bait formulation for the control of house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*) in indoor and outdoor settings. They are intended for use by the general public, professionals and trained professionals. The applicant wishes to change the formulation of the product by lowering the concentration of the preservative [REDACTED] from 0.125% to 0.11%. The lowered preservative concentration in the formulation will be replaced with the corresponding amount of wheat flour. [REDACTED] is included in the formulation to maintain the integrity of the product when used in 'extreme' sewer conditions. The applicant postulates that lowering the amount of preservative in the formulation will not impact the palatability and efficacy of the product.

In support of this 'minor change' the applicant asks that the study 'Palatability of Whole Wheat Rodenticide with [REDACTED] Preservative' (Davies, S. 2021) be considered. This study compared the palatability of three bait formulations; a whole wheat bait formulation containing 0 ppm of active substance, treated with either 0.25% (w/w) or 0.5% (w/w) [REDACTED], and a third (identical) whole wheat bait formulation containing 0 ppm of active material and no preservative.

37% of the 0.25% (w/w) Nuosept OB03 bait treatment was consumed, compared with 67% of the untreated whole wheat bait treatment (contains zero preservative). When bait uptake between the untreated whole wheat bait and the whole wheat bait containing 0.5% [REDACTED] was compared, 26% of the bait consumed contained 0.5% (w/w) [REDACTED] versus 74% bait consumption for the untreated whole wheat bait formulation. It was therefore concluded that bait treated with [REDACTED] is less palatable than untreated bait, and that increasing the concentration of [REDACTED] corresponds to a reduction in bait uptake.

A comparison between the palatability of untreated whole wheat bait and untreated cut wheat formulations was also conducted as part of this study. In this comparison, 52% of the bait consumed was the untreated whole wheat formulation compared with 48% for the untreated cut wheat formulation. The palatability of both formulations was therefore comparable. Based on the Davies study (Davis, S. 2021), it can be concluded that the reduction of the [REDACTED] preservative from 0.125% (w/w) to 0.11% (w/w) should have no adverse effect on the palatability of the Vertox 25 Oktablok.

Additionally, as supplementary data, the applicant wishes to consider a study on aged product completed for a similar product Rodex Pellet bait [REDACTED] to demonstrate the efficacy of aged (2 year old) product on *Rattus norvegicus*. Rodex Pellet Bait – a similar product to Vertox 25 Oktablok (red) containing bromadiolone instead of brodifacoum; 50ppm active substance concentration, similar inert fillers/bait materials, but no preservative was used in the study. A main component of both formulations was wheat. Mean bait consumption was 47.2% of the total food consumption with 100% mortality 7-9 days after exposure to the bait. Rodex Pellet bait contained wheat flour, sugar, water and milk powder but no preservative, yet mould growth was resisted, and the product remained palatable and efficacious.

The IE CA acknowledges the applicability of the study and confirms that the data demonstrates an acceptable level of palatability and mortality at the end of the 2-year shelf life.

Furthermore, it is important to note that the concentration of the preservative is being reduced from 0.125% to 0.11% - a minor difference of 0.015%, and (at this concentration) is still within the recommended preservative limits set by the manufacturer, which are within the typical use levels for [REDACTED] (0.1% - 0.3%). An addition rate of 0.11% is within this range and still significantly above the minimum inhibitory concentration for a range of target fungi species (Troy Chemie GmbH). As a

result, the reduced concentration of the preservative is not thought to negatively influence effectiveness against mould growth.

In addition, Vertox 25 Oktablok also contains [REDACTED] - a preservative ingredient which offers protection against mould growth (used as a coating agent to enhance stability and preservation). Therefore, the previously evaluated data for Vertox 25 Oktablok (red), remains applicable.

In order to minimize the number of experiments on animals, the IE CA accepts the additional studies provided by [REDACTED] (2021) and [REDACTED] (2005) and the previously submitted efficacy data package for Vertox 25 Oktablok (red) as sufficient to demonstrate efficacy and palatability of the product with the reduced concentration of the preservative [REDACTED].

List of studies and documents:

Author(s)	Year	Title. Source (where different from company) GLP /(Un)published	Data Protection Claimed (Yes/No)	Owner
[REDACTED]	2021	Palatability of Whole Wheat Grain with or without [REDACTED] Preservative [REDACTED] Summary Report Not GLP, Unpublished	Yes	[REDACTED]
[REDACTED]	2005	Palatability and Efficacy of Aged Rodex Pellet Bait Formulation in Laboratory Rats. [REDACTED] 16/2005 No / Unpublished	Yes	[REDACTED]
Heuer, T	2022	Nuosept™ OB03 Fungicidal efficacy in wet state preservation (BPR PT6) N/A / Published	No	Troy Chemie GmbH
Withall, A	2022	Statement regarding reduction of preservative in 25ppm wax block baits N/A / Unpublished	No	PelGar International Ltd.

TABLE OF CONTENTS

1	Version History	2
2	Overview of applications	2
	1st Renewal PAR – March 2018	39
1	Conclusion	41
2	Summary of the product assessment	45
2.1	Administrative information	45
2.1.1	<i>IDENTIFIER IN R4BP</i>	45
2.1.2	<i>AUTHORISATION HOLDER</i>	45
2.1.3	<i>MANUFACTURER(S) OF THE PRODUCT</i>	45
2.1.4	<i>MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)</i>	46
2.2	Product composition and formulation	46
2.2.1	<i>QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION</i>	46
2.2.2	<i>INFORMATION ON THE SUBSTANCE(S) OF CONCERN</i>	47
2.2.3	<i>CANDIDATE(S) FOR SUBSTITUTION</i>	47
2.2.4	<i>TYPE OF FORMULATION</i>	47
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008	47
2.4	Use(s) appropriate after renewal of the authorisation	49
2.4.1	<i>USE 1 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – HOUSE MICE – GENERAL PUBLIC – INDOOR</i>	49
2.4.2	<i>USE 2 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – RATS – GENERAL PUBLIC – INDOOR</i>	51
2.4.3	<i>USE 3 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – RATS – GENERAL PUBLIC – OUTDOOR AROUND BUILDINGS</i>	53
2.4.4	<i>USE 4 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – HOUSE MICE – PROFESSIONALS – INDOOR</i>	55
2.4.5	<i>USE 5 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – RATS – PROFESSIONALS – INDOOR</i>	59
2.4.6	<i>USE 6 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – HOUSE MICE AND/OR RATS – PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	62
2.4.7	<i>USE 7 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – INDOOR</i>	65
2.4.8	<i>USE 8 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	69
2.4.9	<i>USE 9 APPROPRIATE AFTER RENEWAL OF THE AUTHORISATION – RATS – TRAINED PROFESSIONALS – SEWERS</i>	74
2.5	General directions for use	77
2.5.1	<i>INSTRUCTIONS FOR USE</i>	77
2.5.2	<i>RISK MITIGATION MEASURES</i>	78
2.5.3	<i>PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT</i>	78
2.5.4	<i>INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING</i>	79
2.5.5	<i>CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE</i>	79
2.5.6	<i>OTHER INFORMATION</i>	79
2.5.7	<i>DOCUMENTATION</i>	79
3	Assessment of the product	80
3.1	Proposed Uses	80
3.1.1	<i>USE 1 – HOUSE MICE – GENERAL PUBLIC – INDOOR</i>	80
3.1.2	<i>USE 2 – RATS – GENERAL PUBLIC – INDOOR</i>	81
3.1.3	<i>USE 3 – RATS – GENERAL PUBLIC – OUTDOOR AROUND BUILDINGS</i>	82
3.1.4	<i>USE 4 – HOUSE MICE – PROFESSIONALS – INDOOR</i>	83
3.1.5	<i>USE 5 – RATS – PROFESSIONALS – INDOOR</i>	84
3.1.6	<i>USE 6 – HOUSE MICE AND/OR RATS – PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	86
3.1.7	<i>USE 7 – HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – INDOOR</i>	88

3.1.8	USE 8 - HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – OUTDOOR AROUND BUILDINGS	90
3.1.9	USE 9 - RATS – TRAINED PROFESSIONALS – SEWERS	92
3.2	Physical, chemical and technical properties	94
3.3	Physical hazards and respective characteristics	94
3.4	Methods for detection and identification	94
3.5	Efficacy against target organisms	94
3.6	Risk assessment for human health	98
3.6.1	ASSESSMENT OF EFFECTS OF THE ACTIVE SUBSTANCE ON HUMAN HEALTH	98
3.6.2	ASSESSMENT OF EFFECTS OF THE PRODUCT ON HUMAN HEALTH	98
3.6.3	EXPOSURE ASSESSMENT	98
3.6.4	RISK CHARACTERISATION FOR HUMAN HEALTH	100
3.7	Risk assessment for animal health	101
3.8	Risk assessment for the environment	102
3.9	Assessment of a combination of biocidal products	106
3.10	Comparative assessment	106
4	General Annexes	108
4.1	List of studies for the biocidal product (family)	108
4.2	Output tables from exposure assessment tools	109
4.3	New information on the active substance	109
4.4	Residue behaviour	109
4.5	Summaries of the efficacy studies (B.5.10.1-xx)	110
4.6	Other	112
5	Confidential annex (Access level: “Restricted” to applicant and authority)	113
5.1	Full composition of the product	113
	Annex 1 - Initial PAR – July 2013	114
1.	General information about the product application	116
1.1.	Applicant/ Authorization Holder	116
1.2.	Marketing/Distributing Company (where applicable)	116
1.3.	General Information on the Biocidal Product	116
1.4.	Information on active substance(s)	117
1.5.	Information on the intended use(s) of the biocidal product	118
1.6.	Documentation	120
	DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION	120
	ACCESS TO DOCUMENTATION	120
2	Classification, labelling and packaging	121
2.1.	Harmonised classification of the active substance	121
2.2.	Harmonised classification and labelling of the biocidal product	122
2.3.	Packaging	125
3.0.	Summary of the product assessment	136
3.1.	Physico/chemical properties and analytical methods	136
3.1.1.	Identity related issues	136
3.1.2.	PHYSICO-CHEMICAL PROPERTIES	137
3.1.3.	Physical, Chemical and Technical Properties of the Biocidal Product	138
3.1.4.	ANALYTICAL METHODS	147
3.1.5.	ANALYTICAL METHOD FOR THE RELEVANT IMPURITIES, ISOMERS AND CO-FORMULANTS IN THE BIOCIDAL PRODUCT	148
3.2.	Efficacy of the Biocidal Product	149
3.2.1.	FUNCTION/FIELD OF USE	149
3.2.2.	ORGANISMS TO BE CONTROLLED	149
3.2.3.	DOSE/MODE OF ACTION	149
3.2.4.	EFFECTS ON THE TARGET ORGANISMS (EFFICACY)	149
3.2.5.	KNOWN LIMITATIONS (E.G. RESISTANCE)	151
3.2.6.	HUMANENESS	154
3.3.	Biocidal Product Risk Assessment (Human Health and the Environment)	155
3.3.1.	DESCRIPTION OF THE INTENDED USE(S)	155
3.3.2.	HAZARD ASSESSMENT FOR HUMAN HEALTH	155

3.3.3	EXPOSURE ASSESSMENT FOR HUMAN HEALTH	163
3.3.4	RISK CHARACTERISATION FOR HUMAN HEALTH.....	171
3.3.5	EFFECT AND EXPOSURE ASSESSMENT FOR THE ENVIRONMENT	174
3.3.6	EXPOSURE ASSESSMENT FOR THE ENVIRONMENT.....	182
3.3.7	RISK CHARACTERISATION FOR THE ENVIRONMENT	192
	NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN	194
3.4.	Measures to protect man, animals and the environment	202
3.4.1	METHODS AND PRECAUTIONS CONCERNING HANDLING, USE, STORAGE, TRANSPORT OR FIRE 202	
3.4.2	SPECIFIC PRECAUTIONS AND TREATMENT IN CASE OF AN ACCIDENT	203
3.4.3	PROCEDURES FOR CLEANING APPLICATION EQUIPMENT	205
3.4.4	IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE	206
3.4.5	PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING ...	206
3.4.6	POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING ACCIDENTAL RELEASE ...	206
3.4.7	UNDESIRABLE OR UNINTENDED SIDE-EFFECTS.....	206
3.4.8	POISON CONTROL MEASURES.....	206
4.	Proposal for Decision.....	208
	ANNEXES to Initial PAR - July 2013.....	212
1.1	Reference	215
1.2	Data protection.....	215
1.2.1	DATA OWNER	215
1.2.2	CRITERIA FOR DATA PROTECTION	215
2	Guidelines and Quality Assurance	215
2.1	Guideline Study	215
2.2	GLP	215
2.3	Deviations	215
3	Materials and Methods	215
3.1	Preliminary treatment	215
3.1.1	ENRICHMENT	215
3.1.2	CLEANUP	215
3.2	Detection.....	215
3.2.1	SEPARATION METHOD.....	215
3.2.2	DETECTOR.....	216
3.2.3	STANDARD(S).....	216
3.2.4	INTERFERING SUBSTANCE(S).....	216
3.3	Linearity.....	216
3.3.1	CALIBRATION RANGE	216
3.3.2	NUMBER OF MEASUREMENTS	217
3.3.3	LINEARITY	217
3.4	Specificity: interfering substances	217
3.5	Recovery rates at different levels	217
3.5.1	RELATIVE STANDARD DEVIATION	217
3.6	Limit of determination	217
3.7	Precision	217
3.7.1	REPEATABILITY	217
3.7.2	ACCURACY	218
	The analytical methods for AS and impurities are as used in the original 5-batch analysis completed at a different laboratory.....	218
4	Applicant's Summary And Conclusion	218
4.1	Materials and methods	219
4.2	Conclusion	226
4.2.1	RELIABILITY.....	226
4.2.2	DEFICIENCIES	226
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	226

COMMENTS FROM OTHER MEMBER STATES (<i>specify</i>)	226
EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	239
None	239
COMMENTS FROM REFERENCE MEMBER STATES (IRELAND)	239
1 Reference	253
1.1 Reference	253
1.2 Data protection.....	253
1.2.1 DATA OWNER	253
1.2.2 COMPANIES WITH LETTER OF ACCESS	253
1.2.3 CRITERIA FOR DATA PROTECTION	253
2 GUIDELINES AND QUALITY ASSURANCE	253
2.1 Guideline study	253
2.2 GLP	253
2.3 Deviations	253
3 MATERIALS AND MethodS	253
3.1 Preliminary treatment	254
3.1.1 ENRICHMENT	254
3.1.2 CLEANUP	254
3.2 Detection	254
3.2.1 SEPARATION METHOD.....	254
3.2.2 DETECTOR.....	254
3.2.3 STANDARD(S)	255
3.2.4 INTERFERING SUBSTANCE(S).....	255
3.3 Linearity.....	255
3.3.1 CALIBRATION RANGE	255
3.3.2 NUMBER OF MEASUREMENTS	255
3.3.3 LINEARITY	255
3.4 Specificity: interfering substances	256
3.5 Recovery rates at different levels	257
3.5.1 RELATIVE STANDARD DEVIATION	257
3.6 Limit of determination	257
3.7 Precision	257
3.7.1 REPEATABILITY	258
3.7.2 INDEPENDENT LABORATORY VALIDATION	258
4 Applicant's Summary and conclusion	258
4.1 Materials and methods	258
4.2 Conclusion	258
4.2.1 RELIABILITY.....	259
4.2.2 DEFICIENCIES	259
Evaluation by Rapporteur Member State (ITALY)	259
EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	261
COMMENTS FROM OTHER MEMBER STATE (<i>specify</i>)	262
Date	281
Materials and methods.....	281
Conclusion	281
Reliability.....	281
Acceptability	281
Remarks	281
Comments from	281
Date	281
Results and discussion	281

Conclusion	281
Reliability.....	281
Acceptability	281
Remarks	281
REFERENCE	284
Reference	284
Data protection	284
<i>DATA OWNER</i>	284
<i>COMPANIES WITH LETTER OF ACCESS</i>	284
<i>CRITERIA FOR DATA PROTECTION</i>	284
Guideline study.....	284
Deviations	284
Method	284
Test Substance (Biocidal Product)	284
<i>TRADE NAME/ PROPOSED TRADE NAME</i>	284
<i>COMPOSITION OF PRODUCT TESTED</i>	284
<i>PHYSICAL STATE AND NATURE</i>	284
<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	284
<i>METHOD OF ANALYSIS</i>	284
Reference substance	284
<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	285
Testing procedure.....	285
<i>TEST POPULATION/ INOCULUM/ TEST ORGANISM</i>	285
<i>TEST SYSTEM</i>	285
<i>APPLICATION OF TS</i>	285
<i>TEST CONDITIONS</i>	285
<i>DURATION OF THE TEST/ EXPOSURE TIME</i>	285
<i>NUMBER OF REPLICATES PERFORMED</i>	285
<i>CONTROLS</i>	285
Examination	285
<i>EFFECT INVESTIGATED</i>	285
<i>METHOD FOR RECORDING/ SCORING OF THE EFFECT</i>	285
<i>INTERVALS OF EXAMINATION</i>	285
<i>STATISTICS</i>	285
<i>POST MONITORING OF THE TEST ORGANISM</i>	285
Results	285
Efficacy.....	285
<i>DOSE/EFFICACY CURVE</i>	286
<i>BEGIN AND DURATION OF EFFECTS</i>	286
<i>OBSERVED EFFECTS IN THE POST MONITORING PHASE</i>	286
Effects against organisms or objects to be protected	286
Other effects	286
Efficacy of the reference substance	286
Tabular and/or graphical presentation of the summarised results	286
Efficacy limiting factors	286
<i>OCCURRENCES OF RESISTANCES</i>	286
<i>OTHER LIMITING FACTORS</i>	286
Relevance of the results compared to field conditions	286
Reasons for laboratory testing	286
Intended actual scale of biocide application	286
Relevance compared to field conditions	286
<i>APPLICATION METHOD</i>	286
<i>TEST ORGANISM</i>	286
<i>OBSERVED EFFECT</i>	286
Relevance for read-across	286

Applicant's Summary and conclusion	287
Materials and methods.....	287
1.1 Reliability.....	287
1.2 Assessment of efficacy, data analysis and interpretation	287
1.3 Conclusion	287
1.4 Proposed efficacy specification	287
Evaluation by Rapporteur Member State	287
Date	287
Materials and Methods	287
Results and discussion	287
Conclusion	287
Reliability	287
Acceptability	287
Remarks	287
COMMENTS FROM	287
Date	287
Materials and Methods	288
Results and discussion	288
Conclusion	288
Reliability	288
Acceptability	288
Remarks	288
Tables for Method	289
1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)	289
1.2 Test organism (if applicable)	289
<i>SPECIES</i>	289
<i>STRAIN</i>	289
<i>SOURCE</i>	289
<i>LABORATORY CULTURE</i>	289
<i>STAGE OF LIFE CYCLE AND STAGE OF STADIA</i>	289
<i>MIXED AGE POPULATION</i>	289
<i>OTHER SPECIFICATION</i>	289
<i>NUMBER OF ORGANISMS TESTED</i>	289
<i>METHOD OF CULTIVATION</i>	289
<i>PRETREATMENT OF TEST ORGANISMS BEFORE EXPOSURE</i>	289
<i>INITIAL DENSITY/NUMBER OF TEST ORGANISMS IN THE TEST SYSTEM</i>	289
<i>CULTURING APPARATUS / TEST CHAMBER</i>	290
<i>NUMBER OF VESSELS / CONCENTRATION</i>	290
<i>TEST CULTURE MEDIA AND/OR CARRIER MATERIAL</i>	290
<i>NUTRIENT SUPPLY</i>	290
<i>MEASURING EQUIPMENT</i>	290
1.4 Application of test substance	291
1.5 Test conditions	291
<i>SUBSTRATE</i>	291
<i>INCUBATION TEMPERATURE</i>	291
<i>MOISTURE</i>	291
<i>AERATION</i>	291
<i>METHOD OF EXPOSURE</i>	291
<i>AGING OF SAMPLES</i>	291
<i>OTHER CONDITIONS</i>	291
1 Reference	293
1.1 Reference	293

1.2	Data protection.....	293
1.2.1	DATA OWNER	293
1.2.2	COMPANIES WITH LETTER OF ACCESS.....	293
1.2.3	CRITERIA FOR DATA PROTECTION	293
1.3	Guideline study.....	293
1.4	Deviations	293
2	Method	293
2.1	Test Substance (Biocidal Product)	293
2.1.1	TRADE NAME/ PROPOSED TRADE NAME	293
2.1.2	COMPOSITION OF PRODUCT TESTED.....	293
2.1.3	PHYSICAL STATE AND NATURE	293
2.1.4	MONITORING OF ACTIVE SUBSTANCE CONCENTRATION	293
2.1.5	METHOD OF ANALYSIS	293
2.2	Reference substance	293
2.2.1	METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE	294
2.3	Testing procedure.....	294
2.3.1	TEST POPULATION/ INOCULUM / TEST ORGANISM	294
2.3.2	TEST SYSTEM.....	294
2.3.3	APPLICATION OF TS	294
2.3.4	TEST CONDITIONS	294
2.3.5	DURATION OF THE TEST / EXPOSURE TIME	294
2.3.6	NUMBER OF REPLICATES PERFORMED.....	294
2.3.7	CONTROLS.....	294
2.4	Examination	294
2.4.1	EFFECT INVESTIGATED	294
2.4.2	METHOD FOR RECORDING / SCORING OF THE EFFECT.....	294
2.4.3	INTERVALS OF EXAMINATION	294
2.4.4	STATISTICS.....	294
2.4.5	POST MONITORING OF THE TEST ORGANISM.....	294
3	Results	295
3.1	Efficacy.....	295
3.1.1	DOSE/EFFICACY CURVE.....	295
3.1.2	BEGIN AND DURATION OF EFFECTS.....	295
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	295
3.2	Effects against organisms or objects to be protected	295
3.3	Other effects	295
3.4	Efficacy of the reference substance	295
3.5	Tabular and/or graphical presentation of the summarised results.....	295
3.6	Efficacy limiting factors.....	295
3.6.1	OCCURRENCES OF RESISTANCES.....	295
3.6.2	OTHER LIMITING FACTORS	295
4	Relevance of the results compared to field conditions	295
4.1	Reasons for laboratory testing	295
4.2	Intended actual scale of biocide application	295
4.3	Relevance compared to field conditions	295
4.3.1	APPLICATION METHOD	295
4.3.2	TEST ORGANISM.....	295
4.3.3	OBSERVED EFFECT	296
4.4	Relevance for read-across	296
5	Applicant's Summary and conclusion	296
5.1	Materials and methods	296
5.2	Reliability.....	296
5.3	Assessment of efficacy, data analysis and interpretation	296
5.4	Conclusion	296
5.5	Proposed efficacy specification	296

4	Evaluation by Rapporteur Member State	296
	Date	296
	Materials and Methods	296
	Results and discussion	297
	Conclusion	297
	Reliability	297
	Acceptability	297
	Remarks	297
	COMMENTS FROM	297
	Date	297
	Materials and Methods	297
	Results and discussion	297
	Conclusion	297
	Reliability	297
	Acceptability	297
	Remarks	297
1.1	(mixed) Population / Inoculum (if necessary; include separate table for different samples).....	298
1.2	Test organism (if applicable)	298
	<i>SPECIES</i>	298
	<i>STRAIN</i>	298
	<i>SOURCE.....</i>	298
	<i>LABORATORY CULTURE</i>	298
	<i>STAGE OF LIFE CYCLE AND STAGE OF STADIA</i>	298
	<i>MIXED AGE POPULATION.....</i>	298
	<i>OTHER SPECIFICATION.....</i>	298
	<i>NUMBER OF ORGANISMS TESTED.....</i>	298
	<i>METHOD OF CULTIVATION.....</i>	298
	<i>PRETREATMENT OF TEST ORGANISMS BEFORE EXPOSURE</i>	298
	<i>INITIAL DENSITY/NUMBER OF TEST ORGANISMS IN THE TEST SYSTEM.....</i>	298
	<i>CULTURING APPARATUS / TEST CHAMBER</i>	299
	<i>NUMBER OF VESSELS / CONCENTRATION.....</i>	299
	<i>TEST CULTURE MEDIA AND/OR CARRIER MATERIAL.....</i>	299
	<i>NUTRIENT SUPPLY</i>	299
	<i>MEASURING EQUIPMENT</i>	299
1.4	Application of test substance	300
1.5	Test conditions.....	300
	<i>SUBSTRATE.....</i>	300
	<i>INCUBATION TEMPERATURE</i>	300
	<i>MOISTURE</i>	300
	<i>AERATION</i>	300
	<i>METHOD OF EXPOSURE</i>	300
	<i>AGING OF SAMPLES</i>	300
	<i>OTHER CONDITIONS.....</i>	300
1	Reference.....	302
1.1	Reference	302
1.2	Data protection.....	302
1.2.1	DATA OWNER	302
1.2.2	COMPANIES WITH LETTER OF ACCESS	302
1.2.3	CRITERIA FOR DATA PROTECTION	302
1.3	Guideline study.....	302
1.4	Deviations	302
2	Method	302

2.1	Test Substance (Biocidal Product)	302
2.1.1	TRADE NAME/ PROPOSED TRADE NAME	302
2.1.2	COMPOSITION OF PRODUCT TESTED	302
2.1.3	PHYSICAL STATE AND NATURE	302
2.1.4	MONITORING OF ACTIVE SUBSTANCE CONCENTRATION	302
2.1.5	METHOD OF ANALYSIS	302
2.2	Reference substance	302
2.2.1	METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE	303
2.3	Testing procedure	303
2.3.1	TEST POPULATION/ INOCULUM/ TEST ORGANISM	303
2.3.2	TEST SYSTEM	303
2.3.3	APPLICATION OF TS	303
2.3.4	TEST CONDITIONS	303
2.3.5	DURATION OF THE TEST/ EXPOSURE TIME	303
2.3.6	NUMBER OF REPLICATES PERFORMED	303
2.3.7	CONTROLS	303
2.4	Examination	303
2.4.1	EFFECT INVESTIGATED	303
2.4.2	METHOD FOR RECORDING/ SCORING OF THE EFFECT	303
2.4.3	INTERVALS OF EXAMINATION	303
2.4.4	STATISTICS	303
2.4.5	POST MONITORING OF THE TEST ORGANISM	303
3	Results	304
3.1	Efficacy	304
3.1.1	DOSE/EFFICACY CURVE	304
3.1.2	BEGIN AND DURATION OF EFFECTS	304
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	304
3.2	Effects against organisms or objects to be protected	304
3.3	Other effects	304
3.4	Efficacy of the reference substance	304
3.5	Tabular and/or graphical presentation of the summarised results	304
3.6	Efficacy limiting factors	304
3.6.1	OCCURRENCES OF RESISTANCES	304
3.6.2	OTHER LIMITING FACTORS	304
4	Relevance of the results compared to field conditions	304
4.1	Reasons for laboratory testing	304
4.2	Intended actual scale of biocide application	304
4.3	Relevance compared to field conditions	304
4.3.1	APPLICATION METHOD	305
4.3.2	TEST ORGANISM	305
4.3.3	OBSERVED EFFECT	305
4.4	Relevance for read-across	305
5	Applicant's Summary and conclusion	305
5.1	Materials and methods	305
5.2	Reliability	305
5	1	305
5.3	Assessment of efficacy, data analysis and interpretation	305
5.4	Conclusion	305
6	Product is palatable to rats and effective in killing them.	305
5.5	Proposed efficacy specification	305
7	100% effective against rats	305
8	Evaluation by Competent Authorities	305
9		305

10	Evaluation by Rapporteur Member State	306
	Date	306
	Materials and Methods	306
	Results and discussion	306
	Conclusion	306
	Reliability	306
	Acceptability	306
	Remarks	306
	COMMENTS FROM	306
	Date	306
	Materials and Methods	306
	Results and discussion	306
	Conclusion	306
	Reliability	306
	Acceptability	306
	Remarks	306
1.1	(mixed) Population / Inoculum (if necessary; include separate table for different samples)	307
1.2	Test organism (if applicable)	307
	<i>SPECIES</i>	307
	<i>STRAIN</i>	307
	<i>SOURCE</i>	307
	<i>LABORATORY CULTURE</i>	307
	<i>STAGE OF LIFE CYCLE AND STAGE OF STADIA</i>	307
	<i>MIXED AGE POPULATION</i>	307
	<i>OTHER SPECIFICATION</i>	307
	<i>NUMBER OF ORGANISMS TESTED</i>	307
	<i>METHOD OF CULTIVATION</i>	307
	<i>PRETREATMENT OF TEST ORGANISMS BEFORE EXPOSURE</i>	307
	<i>INITIAL DENSITY/NUMBER OF TEST ORGANISMS IN THE TEST SYSTEM</i>	307
	<i>CULTURING APPARATUS / TEST CHAMBER</i>	308
	<i>NUMBER OF VESSELS / CONCENTRATION</i>	308
	<i>TEST CULTURE MEDIA AND/OR CARRIER MATERIAL</i>	308
	<i>NUTRIENT SUPPLY</i>	308
	<i>MEASURING EQUIPMENT</i>	308
1	Reference	309
1.1	Reference	309
1.2	Data protection	309
1.2.1	<i>DATA OWNER</i>	309
1.2.2	<i>COMPANIES WITH LETTER OF ACCESS</i>	309
1.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	309
1.3	Guideline study	309
1.4	Deviations	309
2	Method	309
2.1	Test Substance (Biocidal Product)	309
2.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	309
2.1.2	<i>COMPOSITION OF PRODUCT TESTED</i>	309
2.1.3	<i>PHYSICAL STATE AND NATURE</i>	309
2.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	309
2.1.5	<i>METHOD OF ANALYSIS</i>	309
2.2	Reference substance	309
2.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	310
2.3	Testing procedure	310
2.3.1	<i>TEST POPULATION / INOCULUM / TEST ORGANISM</i>	310
2.3.2	<i>TEST SYSTEM</i>	310

2.3.3	APPLICATION OF TS	310
2.3.4	TEST CONDITIONS	310
2.3.5	DURATION OF THE TEST / EXPOSURE TIME	310
2.3.6	NUMBER OF REPLICATES PERFORMED	310
2.3.7	CONTROLS	310
2.4	Examination	310
2.4.1	EFFECT INVESTIGATED	310
2.4.2	METHOD FOR RECORDING / SCORING OF THE EFFECT	310
2.4.3	INTERVALS OF EXAMINATION	310
2.4.4	STATISTICS	310
2.4.5	POST MONITORING OF THE TEST ORGANISM	310
3	Results	310
3.1	Efficacy	310
3.1.1	DOSE/EFFICACY CURVE	311
3.1.2	BEGIN AND DURATION OF EFFECTS	311
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	311
3.2	Effects against organisms or objects to be protected	311
3.3	Other effects	311
3.4	Efficacy of the reference substance	311
3.5	Tabular and/or graphical presentation of the summarised results	311
3.6	Efficacy limiting factors	311
3.6.1	OCCURRENCES OF RESISTANCES	311
3.6.2	OTHER LIMITING FACTORS	311
4	Relevance of the results compared to field conditions	311
4.1	Reasons for laboratory testing	311
4.2	Intended actual scale of biocide application	311
4.3	Relevance compared to field conditions	311
4.3.1	APPLICATION METHOD	311
4.3.2	TEST ORGANISM	311
4.3.3	OBSERVED EFFECT	311
4.4	Relevance for read-across	311
5	Applicant's Summary and conclusion	312
5.1	Materials and methods	312
5.2	Reliability	312
5.3	Assessment of efficacy, data analysis and interpretation	312
5.4	Conclusion	312
5.5	Proposed efficacy specification	312
11	Evaluation by Rapporteur Member State	312
	Date	312
	Materials and Methods	312
	Results and discussion	312
	Conclusion	312
	Reliability	312
	Acceptability	313
	Remarks	313
	COMMENTS FROM	313
	Date	313
	Materials and Methods	313
	Results and discussion	313
	Conclusion	313
	Reliability	313
	Acceptability	313
	Remarks	313
1.4	Application of test substance	313

1.5	Test conditions	314
	<i>SUBSTRATE</i>	314
	<i>INCUBATION TEMPERATURE</i>	314
	<i>MOISTURE</i>	314
	<i>AERATION</i>	314
	<i>METHOD OF EXPOSURE</i>	314
	<i>AGING OF SAMPLES</i>	314
	<i>OTHER CONDITIONS</i>	314
	Tables for Method	316
1.1	(mixed) Population / Inoculum (if necessary; include separate table for different samples)	316
1.2	Test organism (if applicable)	316
	<i>SPECIES</i>	316
	<i>STRAIN</i>	316
	<i>SOURCE</i>	316
	<i>LABORATORY CULTURE</i>	316
	<i>STAGE OF LIFE CYCLE AND STAGE OF STADIA</i>	316
	<i>MIXED AGE POPULATION</i>	316
	<i>OTHER SPECIFICATION</i>	316
	<i>NUMBER OF ORGANISMS TESTED</i>	316
	<i>METHOD OF CULTIVATION</i>	316
	<i>PRETREATMENT OF TEST ORGANISMS BEFORE EXPOSURE</i>	316
	<i>INITIAL DENSITY/NUMBER OF TEST ORGANISMS IN THE TEST SYSTEM</i>	316
	<i>CULTURING APPARATUS / TEST CHAMBER</i>	317
	<i>NUMBER OF VESSELS / CONCENTRATION</i>	317
	<i>TEST CULTURE MEDIA AND/OR CARRIER MATERIAL</i>	317
	<i>NUTRIENT SUPPLY</i>	317
	<i>MEASURING EQUIPMENT</i>	317
1.5	Test conditions	318
	<i>SUBSTRATE</i>	318
	<i>INCUBATION TEMPERATURE</i>	318
	<i>MOISTURE</i>	318
	<i>AERATION</i>	318
	<i>METHOD OF EXPOSURE</i>	318
	<i>AGING OF SAMPLES</i>	318
	<i>OTHER CONDITIONS</i>	318
1	Reference	320
1.1	Reference	320
1.2	Data protection	320
1.2.1	<i>DATA OWNER</i>	320
1.2.2	<i>COMPANIES WITH LETTER OF ACCESS</i>	320
1.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	320
1.3	Guideline study	320
1.4	Deviations	320
2	Method	320
2.1	Test Substance (Biocidal Product)	320
2.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	320
2.1.2	<i>COMPOSITION OF PRODUCT TESTED</i>	320
2.1.3	<i>PHYSICAL STATE AND NATURE</i>	320
2.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	320
2.1.5	<i>METHOD OF ANALYSIS</i>	320
2.2	Reference substance	320
2.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	321
2.3	Testing procedure	321

2.3.1	TEST POPULATION / INOCULUM / TEST ORGANISM	322
2.3.2	TEST SYSTEM	323
2.3.3	APPLICATION OF TS	323
2.3.4	TEST CONDITIONS	323
2.3.5	DURATION OF THE TEST / EXPOSURE TIME	324
2.3.6	NUMBER OF REPLICATES PERFORMED	324
2.3.7	CONTROLS	324
2.4	Examination	324
2.4.1	EFFECT INVESTIGATED	324
2.4.2	METHOD FOR RECORDING / SCORING OF THE EFFECT	324
2.4.3	INTERVALS OF EXAMINATION	324
2.4.4	STATISTICS	324
2.4.5	POST MONITORING OF THE TEST ORGANISM	324
3	Results	324
3.1	Efficacy	324
3.1.1	DOSE/EFFICACY CURVE	325
3.1.2	BEGIN AND DURATION OF EFFECTS	325
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	325
3.2	Effects against organisms or objects to be protected	325
3.3	Other effects	325
3.4	Efficacy of the reference substance	325
3.5	Tabular and/or graphical presentation of the summarised results	325
3.6	Efficacy limiting factors	325
3.6.1	OCCURRENCES OF RESISTANCES	326
3.6.2	OTHER LIMITING FACTORS	326
4	Relevance of the results compared to field conditions	326
4.1	Reasons for laboratory testing	326
11.1	Intended actual scale of biocide application	326
11.2	Relevance compared to field conditions	326
4.1.1	APPLICATION METHOD	326
4.1.2	TEST ORGANISM	326
4.1.3	OBSERVED EFFECT	326
11.3	Relevance for read-across	326
5	Applicant's Summary and conclusion	326
5.1	Materials and methods	326
5.2	Reliability	328
5.3	Assessment of efficacy, data analysis and interpretation	328
5.4	Conclusion	328
5.5	Proposed efficacy specification	328
12	Evaluation by Rapporteur Member State	329
	Date	329
	Materials and Methods	329
	Results and discussion	329
	Conclusion	329
	Reliability	329
	Acceptability	329
	Remarks	329
	COMMENTS FROM	329
	Date	329
	Materials and Methods	329
	Results and discussion	329
	Conclusion	329
	Reliability	329
	Acceptability	329
	Remarks	329

1	Reference.....	330
1.1	Reference	330
1.2	Data protection.....	330
1.2.1	<i>DATA OWNER</i>	330
1.2.2	<i>COMPANIES WITH LETTER OF ACCESS</i>	330
1.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	330
1.3	Guideline study.....	330
1.4	Deviations	330
2	Method	330
2.1	Test Substance (Biocidal Product)	330
2.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	330
2.1.2	<i>COMPOSITION OF PRODUCT TESTED</i>	330
2.1.3	<i>PHYSICAL STATE AND NATURE</i>	330
2.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	330
2.1.5	<i>METHOD OF ANALYSIS</i>	330
2.2	Reference substance	330
2.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	331
2.3	Testing procedure.....	331
2.3.1	<i>TEST POPULATION / INOCULUM / TEST ORGANISM</i>	332
2.3.2	<i>TEST SYSTEM</i>	333
2.3.3	<i>APPLICATION OF TS</i>	334
2.3.4	<i>TEST CONDITIONS</i>	334
2.3.5	<i>DURATION OF THE TEST / EXPOSURE TIME</i>	334
2.3.6	<i>NUMBER OF REPLICATES PERFORMED</i>	334
2.3.7	<i>CONTROLS</i>	334
2.4	Examination	334
2.4.1	<i>EFFECT INVESTIGATED</i>	334
2.4.2	<i>METHOD FOR RECORDING / SCORING OF THE EFFECT</i>	334
2.4.3	<i>INTERVALS OF EXAMINATION</i>	334
2.4.4	<i>STATISTICS</i>	334
2.4.5	<i>POST MONITORING OF THE TEST ORGANISM</i>	334
3	Results.....	334
3.1	Efficacy.....	335
3.1.1	<i>DOSE/EFFICACY CURVE</i>	335
3.1.2	<i>BEGIN AND DURATION OF EFFECTS</i>	335
3.1.3	<i>OBSERVED EFFECTS IN THE POST MONITORING PHASE</i>	335
3.2	Effects against organisms or objects to be protected	335
3.3	Other effects	335
3.4	Efficacy of the reference substance	335
3.5	Tabular and/or graphical presentation of the summarised results.....	336
3.6	Efficacy limiting factors.....	336
3.6.1	<i>OCCURRENCES OF RESISTANCES</i>	336
3.6.2	<i>OTHER LIMITING FACTORS</i>	336
4	Relevance of the results compared to field conditions.....	336
4.1	Reasons for laboratory testing	336
12.1	Intended actual scale of biocide application	336
12.2	Relevance compared to field conditions	336
4.1.1	<i>APPLICATION METHOD</i>	337
4.1.2	<i>TEST ORGANISM</i>	337
4.1.3	<i>OBSERVED EFFECT</i>	337
12.3	Relevance for read-across	337
5	Applicant's Summary and conclusion	337
5.1	Materials and methods	337
5.2	Reliability.....	338
5.3	Assessment of efficacy, data analysis and interpretation	338

5.4	Conclusion	339
5.5	Proposed efficacy specification	339
13	Evaluation by Rapporteur Member State.....	339
	Date	339
	Materials and Methods.....	339
	Results and discussion	339
	Conclusion	339
	Reliability.....	339
	Acceptability	339
	Remarks.....	339
	COMMENTS FROM	340
	Date	340
	Materials and Methods.....	340
	Results and discussion	340
	Conclusion	340
	Reliability.....	340
	Acceptability	340
	Remarks.....	340
1	Reference.....	341
1.1	Reference	341
1.2	Data protection.....	341
1.2.1	<i>DATA OWNER</i>	<i>341</i>
1.2.2	<i>COMPANIES WITH LETTER OF ACCESS.....</i>	<i>341</i>
1.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	<i>341</i>
1.3	Guideline study.....	341
1.4	Deviations	341
2	Method	341
2.1	Test Substance (Biocidal Product)	341
2.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	<i>341</i>
2.1.2	<i>COMPOSITION OF PRODUCT TESTED.....</i>	<i>341</i>
2.1.3	<i>PHYSICAL STATE AND NATURE</i>	<i>341</i>
2.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	<i>341</i>
2.1.5	<i>METHOD OF ANALYSIS</i>	<i>341</i>
2.2	Reference substance	341
2.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	<i>342</i>
2.3	Testing procedure.....	342
2.3.1	<i>TEST POPULATION/ INOCULUM/ TEST ORGANISM</i>	<i>343</i>
2.3.2	<i>TEST SYSTEM.....</i>	<i>344</i>
2.3.3	<i>APPLICATION OF TS.....</i>	<i>345</i>
2.3.4	<i>TEST CONDITIONS</i>	<i>345</i>
2.3.5	<i>DURATION OF THE TEST/ EXPOSURE TIME</i>	<i>345</i>
2.3.6	<i>NUMBER OF REPLICATES PERFORMED.....</i>	<i>345</i>
2.3.7	<i>CONTROLS.....</i>	<i>345</i>
2.4	Examination	345
2.4.1	<i>EFFECT INVESTIGATED</i>	<i>346</i>
2.4.2	<i>METHOD FOR RECORDING / SCORING OF THE EFFECT.....</i>	<i>346</i>
2.4.3	<i>INTERVALS OF EXAMINATION</i>	<i>346</i>
2.4.4	<i>STATISTICS.....</i>	<i>346</i>
2.4.5	<i>POST MONITORING OF THE TEST ORGANISM.....</i>	<i>346</i>
3	Results.....	346
3.1	Efficacy.....	346
3.1.1	<i>DOSE/EFFICACY CURVE.....</i>	<i>347</i>
3.1.2	<i>BEGIN AND DURATION OF EFFECTS.....</i>	<i>347</i>
3.1.3	<i>OBSERVED EFFECTS IN THE POST MONITORING PHASE</i>	<i>347</i>
3.2	Effects against organisms or objects to be protected	347

3.3	Other effects	347
3.4	Efficacy of the reference substance	347
3.5	Tabular and/or graphical presentation of the summarised results.....	348
3.6	Efficacy limiting factors.....	348
3.6.1	<i>OCCURRENCES OF RESISTANCES</i>	348
3.6.2	<i>OTHER LIMITING FACTORS</i>	348
4	Relevance of the results compared to field conditions.....	348
4.1	Reasons for laboratory testing	348
13.1	Intended actual scale of biocide application	348
13.2	Relevance compared to field conditions	348
4.1.1	<i>APPLICATION METHOD</i>	349
4.1.2	<i>TEST ORGANISM</i>	349
4.1.3	<i>OBSERVED EFFECT</i>	349
13.3	Relevance for read-across	349
5	Applicant's Summary and conclusion	349
5.1	Materials and methods	349
5.2	Reliability.....	350
5.3	Assessment of efficacy, data analysis and interpretation	350
5.4	Conclusion	351
5.5	Proposed efficacy specification	351
14	Evaluation by Rapporteur Member State.....	352
	Date	352
	Materials and Methods	352
	Results and discussion	352
	Conclusion	352
	Reliability	352
	Acceptability	352
	Remarks	352
	COMMENTS FROM	352
	Date	352
	Materials and Methods	352
	Results and discussion	352
	Conclusion	352
	Reliability	352
	Acceptability	352
	Remarks	352
1	Reference.....	353
1.1	Reference	353
1.2	Data protection.....	353
1.2.1	<i>DATA OWNER</i>	353
1.2.2	<i>COMPANIES WITH LETTER OF ACCESS</i>	353
1.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	353
1.3	Guideline study.....	353
1.4	Deviations	353
2	Method	353
2.1	Test Substance (Biocidal Product)	353
2.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	353
2.1.2	<i>COMPOSITION OF PRODUCT TESTED</i>	353
2.1.3	<i>PHYSICAL STATE AND NATURE</i>	353
2.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	353
2.1.5	<i>METHOD OF ANALYSIS</i>	353
2.2	Reference substance	353
2.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	354
2.3	Testing procedure.....	354

2.3.1	TEST POPULATION / INOCULUM / TEST ORGANISM	355
2.3.2	TEST SYSTEM	356
2.3.3	APPLICATION OF TS	357
2.3.4	TEST CONDITIONS	357
2.3.5	DURATION OF THE TEST / EXPOSURE TIME	357
2.3.6	NUMBER OF REPLICATES PERFORMED	357
2.3.7	CONTROLS	357
2.4	Examination	357
2.4.1	EFFECT INVESTIGATED	357
2.4.2	METHOD FOR RECORDING / SCORING OF THE EFFECT	357
2.4.3	INTERVALS OF EXAMINATION	357
2.4.4	STATISTICS	357
2.4.5	POST MONITORING OF THE TEST ORGANISM	357
3	Results	357
3.1	Efficacy	358
3.1.1	DOSE/EFFICACY CURVE	358
3.1.2	BEGIN AND DURATION OF EFFECTS	358
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	358
3.2	Effects against organisms or objects to be protected	358
3.3	Other effects	358
3.4	Efficacy of the reference substance	358
3.5	Tabular and/or graphical presentation of the summarised results	359
3.6	Efficacy limiting factors	359
3.6.1	OCCURRENCES OF RESISTANCES	359
3.6.2	OTHER LIMITING FACTORS	359
4	Relevance of the results compared to field conditions	359
4.1	Reasons for laboratory testing	359
14.1	Intended actual scale of biocide application	359
14.2	Relevance compared to field conditions	359
4.1.1	APPLICATION METHOD	360
4.1.2	TEST ORGANISM	360
4.1.3	OBSERVED EFFECT	360
14.3	Relevance for read-across	360
5	Applicant's Summary and conclusion	360
5.1	Materials and methods	360
5.2	Reliability	361
5.3	Assessment of efficacy, data analysis and interpretation	361
5.4	Conclusion	362
5.5	Proposed efficacy specification	362
15	Evaluation by Rapporteur Member State	362
	Date	362
	Materials and Methods	362
	Results and discussion	362
	Conclusion	362
	Reliability	362
	Acceptability	362
	Remarks	362
	COMMENTS FROM	362
	Date	362
	Materials and Methods	363
	Results and discussion	363
	Conclusion	363
	Reliability	363
	Acceptability	363
	Remarks	363

5	Reference.....	364
5.1	Reference	364
5.2	Data protection.....	364
5.2.1	<i>DATA OWNER</i>	364
5.2.2	<i>COMPANIES WITH ACCESS TO DATA</i>	364
5.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	364
5.3	Guideline study.....	364
5.4	Deviations	364
6	Method	364
6.1	Test Substance (Biocidal Product)	364
6.1.1	<i>TRADE NAME/ PROPOSED TRADE NAME</i>	364
6.1.2	<i>COMPOSITION OF PRODUCT TESTED</i>	364
6.1.3	<i>PHYSICAL STATE AND NATURE</i>	364
6.1.4	<i>MONITORING OF ACTIVE SUBSTANCE CONCENTRATION</i>	364
6.1.5	<i>METHOD OF ANALYSIS</i>	364
6.2	Reference substance	364
6.2.1	<i>METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE</i>	364
6.3	Testing procedure.....	364
6.3.1	<i>TEST POPULATION / INOCULUM / TEST ORGANISM</i>	365
6.3.2	<i>TEST SYSTEM</i>	365
6.3.3	<i>APPLICATION OF TS</i>	365
6.3.4	<i>TEST CONDITIONS</i>	365
6.3.5	<i>DURATION OF THE TEST / EXPOSURE TIME</i>	365
6.3.6	<i>NUMBER OF REPLICATES PERFORMED</i>	365
6.3.7	<i>CONTROLS</i>	365
6.4	Examination	365
6.4.1	<i>EFFECT INVESTIGATED</i>	365
6.4.2	<i>METHOD FOR RECORDING / SCORING OF THE EFFECT</i>	365
6.4.3	<i>INTERVALS OF EXAMINATION</i>	366
6.4.4	<i>STATISTICS</i>	366
6.4.5	<i>POST MONITORING OF THE TEST ORGANISM</i>	366
7	Results.....	366
7.1	Efficacy.....	366
7.1.1	<i>DOSE/EFFICACY CURVE</i>	366
7.1.2	<i>BEGIN AND DURATION OF EFFECTS</i>	366
7.1.3	<i>OBSERVED EFFECTS IN THE POST MONITORING PHASE</i>	366
7.2	Effects against organisms or objects to be protected	366
7.3	Other effects	366
7.4	Efficacy of the reference substance	366
7.5	Tabular and/or graphical presentation of the summarised results.....	366
7.6	Efficacy limiting factors.....	366
7.6.1	<i>OCCURRENCES OF RESISTANCES</i>	366
7.6.2	<i>OTHER LIMITING FACTORS</i>	366
8	Relevance of the results compared to field conditions.....	367
8.1	Reasons for laboratory testing	367
8.2	Intended actual scale of biocide application	367
8.3	Relevance compared to field conditions	367
8.3.1	<i>APPLICATION METHOD</i>	367
8.3.2	<i>TEST ORGANISM</i>	367
8.3.3	<i>OBSERVED EFFECT</i>	367
8.4	Relevance for read-across	367
9	Applicant's Summary and conclusion	367
9.1	Materials and methods	367
9.2	Reliability.....	367
9.3	Assessment of efficacy, data analysis and interpretation	367

9.4	Conclusion	367
9.5	Proposed efficacy specification	367
16	Evaluation by Rapporteur Member State.....	368
	Date	368
	Materials and Methods.....	368
	Results and discussion	368
	Conclusion	368
	Reliability.....	368
	Acceptability	368
	Remarks.....	368
17	Comments from ... (specify)	368
	Date	368
	Materials and Methods.....	368
	Results and discussion	368
	Conclusion	368
	Reliability.....	368
	Acceptability	368
	Remarks.....	368
1.1	(mixed) Population / Inoculum (if necessary; include separate table for different samples).....	369
1.2	Test organism (if applicable)	369
	<i>SPECIES.....</i>	<i>369</i>
	<i>STRAIN</i>	<i>369</i>
	<i>SOURCE.....</i>	<i>369</i>
	<i>LABORATORY CULTURE</i>	<i>369</i>
	<i>STAGE OF LIFE CYCLE AND STAGE OF STADIA</i>	<i>369</i>
	<i>MIXED AGE POPULATION.....</i>	<i>369</i>
	<i>OTHER SPECIFICATION.....</i>	<i>369</i>
	<i>NUMBER OF ORGANISMS TESTED.....</i>	<i>369</i>
	<i>METHOD OF CULTIVATION.....</i>	<i>369</i>
	<i>PRETREATMENT OF TEST ORGANISMS BEFORE EXPOSURE</i>	<i>369</i>
	<i>INITIAL DENSITY/NUMBER OF TEST ORGANISMS IN THE TEST SYSTEM.....</i>	<i>369</i>
	<i>CULTURING APPARATUS / TEST CHAMBER.....</i>	<i>370</i>
	<i>NUMBER OF VESSELS / CONCENTRATION.....</i>	<i>370</i>
	<i>TEST CULTURE MEDIA AND/OR CARRIER MATERIAL.....</i>	<i>370</i>
	<i>NUTRIENT SUPPLY</i>	<i>370</i>
	<i>MEASURING EQUIPMENT</i>	<i>370</i>
1.4	Application of test substance	370
1.5	Test conditions.....	371
	<i>SUBSTRATE.....</i>	<i>371</i>
	<i>INCUBATION TEMPERATURE</i>	<i>371</i>
	<i>MOISTURE</i>	<i>371</i>
	<i>AERATION</i>	<i>371</i>
	<i>METHOD OF EXPOSURE.....</i>	<i>371</i>
	<i>AGING OF SAMPLES</i>	<i>371</i>
	<i>OTHER CONDITIONS.....</i>	<i>371</i>
1	Reference.....	372
1.1	Reference	372
1.2	Data protection.....	372
1.2.1	DATA OWNER	372
1.2.2	COMPANIES WITH ACCESS TO DATA	372
1.2.3	CRITERIA FOR DATA PROTECTION	372
1.3	Guideline study.....	372
1.4	Deviations	372

2	Method	372
2.1	Test Substance (Biocidal Product)	372
2.1.1	TRADE NAME/ PROPOSED TRADE NAME	372
2.1.2	COMPOSITION OF PRODUCT TESTED	372
2.1.3	PHYSICAL STATE AND NATURE	372
2.1.4	MONITORING OF ACTIVE SUBSTANCE CONCENTRATION	372
2.1.5	METHOD OF ANALYSIS	372
2.2	Reference substance	372
2.2.1	METHOD OF ANALYSIS FOR REFERENCE SUBSTANCE	372
2.3	Testing procedure	373
2.3.1	TEST POPULATION / INOCULUM / TEST ORGANISM	373
2.3.2	TEST SYSTEM	373
2.3.3	APPLICATION OF TS	373
2.3.4	TEST CONDITIONS	373
2.3.5	DURATION OF THE TEST / EXPOSURE TIME	373
2.3.6	NUMBER OF REPLICATES PERFORMED	373
2.3.7	CONTROLS	373
2.4	Examination	373
2.4.1	EFFECT INVESTIGATED	373
2.4.2	METHOD FOR RECORDING / SCORING OF THE EFFECT	373
2.4.3	INTERVALS OF EXAMINATION	373
2.4.4	STATISTICS	373
2.4.5	POST MONITORING OF THE TEST ORGANISM	373
3	Results	373
3.1	Efficacy	373
3.1.1	DOSE/EFFICACY CURVE	373
3.1.2	BEGIN AND DURATION OF EFFECTS	374
3.1.3	OBSERVED EFFECTS IN THE POST MONITORING PHASE	374
3.2	Effects against organisms or objects to be protected	374
3.3	Other effects	374
3.4	Efficacy of the reference substance	374
3.5	Tabular and/or graphical presentation of the summarised results	374
3.6	Efficacy limiting factors	374
3.6.1	OCCURRENCES OF RESISTANCES	374
3.6.2	OTHER LIMITING FACTORS	374
4	Relevance of the results compared to field conditions	374
4.1	Reasons for laboratory testing	374
4.2	Intended actual scale of biocide application	374
4.3	Relevance compared to field conditions	375
4.3.1	APPLICATION METHOD	375
4.3.2	TEST ORGANISM	375
4.3.3	OBSERVED EFFECT	375
4.4	Relevance for read-across	375
5	Applicant's Summary and conclusion	375
5.1	Materials and methods	375
5.2	Reliability	375
5.3	Assessment of efficacy, data analysis and interpretation	375
5.4	Conclusion	375
5.5	Proposed efficacy specification	375
18	Evaluation by Rapporteur Member State	376
	Date	376
	Materials and Methods	376
	Results and discussion	376
	Conclusion	376
	Reliability	376

Acceptability	376
Remarks	376
19 Comments from ... (specify)	376
Date	376
Materials and Methods	376
Results and discussion	376
Conclusion	376
Reliability	376
Acceptability	376
Remarks	376
10 Reference	377
10.1 Reference	377
10.2 Data protection	377
10.2.1 DATA OWNER	377
10.2.2 COMPANIES WITH ACCESS TO DATA	377
10.2.3 CRITERIA FOR DATA PROTECTION	377
11 Guidelines and Quality Assurance	377
11.1 Guideline study	377
11.2 GLP	377
11.3 Deviations	377
12 MATERIALS AND MethodS	377
12.1 Test material	377
12.1.1 LOT / BATCH NUMBER	377
12.1.2 SPECIFICATION	377
12.2 Test Animals	377
12.2.1 SPECIES	377
12.2.2 STRAIN	377
12.2.3 SOURCE	377
12.2.4 SEX	378
12.2.5 AGE/WEIGHT AT STUDY INITIATION	378
12.2.6 NUMBER OF ANIMALS PER GROUP	378
12.2.7 CONTROL ANIMALS	378
12.3 Administration/ Exposure	378
12.3.1 POSTEXPOSURE PERIOD	378
12.3.2	378
12.3.3 TYPE	378
12.3.4 CONCENTRATION	378
12.3.5 VEHICLE	378
12.3.6 CONCENTRATION IN VEHICLE	378
12.3.7 TOTAL VOLUME APPLIED	378
12.3.8 CONTROLS	378
12.4 Examinations	378
12.5 Method of determination of LD ₅₀	378
12.6 Further remarks	378
13 Results and Discussion	378
13.1 Clinical signs	378
13.2 Pathology	378
13.3 Other	378
13.4 LD ₅₀	379
14 Applicant's Summary and conclusion	379
14.1 Materials and methods	379
14.2 Results and discussion	379
14.3 Conclusion	379
14.3.1 RELIABILITY	379

14.3.2	DEFICIENCIES	380
20	Evaluation by Rapporteur Member State	381
	Date	381
	Materials and Methods	381
	Results and discussion	381
	Conclusion	381
	Reliability	381
	Acceptability	381
	Remarks	381
21	Comments from	381
	Date	381
	Materials and Methods	381
	Results and discussion	381
	Conclusion	381
	Reliability	381
	Acceptability	381
	Remarks	381
15	Reference	382
15.1	Reference	382
15.2	Data protection.....	382
15.2.1	DATA OWNER	382
15.2.2	COMPANIES WITH ACCESS TO DATA	382
15.2.3	CRITERIA FOR DATA PROTECTION	382
16	Guidelines and Quality Assurance.....	382
16.1	Guideline study	382
16.2	GLP	382
16.3	Deviations	382
17	MATERIALS AND MethodS	382
17.1	Test material	382
17.1.1	LOT/ BATCH NUMBER	382
17.1.2	SPECIFICATION	383
17.2	Test Animals.....	383
17.2.1	SPECIES	383
17.2.2	STRAIN	383
17.2.3	SOURCE	383
17.2.4	SEX	383
17.2.5	AGE/WEIGHT AT STUDY INITIATION	383
17.2.6	NUMBER OF ANIMALS PER GROUP	383
17.2.7	CONTROL ANIMALS.....	383
17.3	Administration/ Exposure	383
17.3.1	POSTEXPOSURE PERIOD.....	383
17.3.2	AREA COVERED	383
17.3.3	OCCLUSION	383
17.3.4	VEHICLE	383
17.3.5	CONCENTRATION IN VEHICLE.....	383
17.3.6	TOTAL VOLUME APPLIED.....	383
17.3.7	DURATION OF EXPOSURE	383
17.3.8	REMOVAL OF TEST SUBSTANCE.....	383
17.3.9	CONTROLS.....	384
17.4	Examinations	384
17.5	Method of determination of LD ₅₀	384
17.6	Further remarks.....	384
18	Results and Discussion	384
18.1	Clinical signs	384

18.2	Pathology	384
18.3	Other.....	384
18.4	LD ₅₀	384
19	Applicant's Summary and conclusion.....	384
19.1	Materials and methods	384
19.2	Results and discussion	385
19.3	Conclusion	385
19.3.1	RELIABILITY.....	385
19.3.2	DEFICIENCIES.....	385
22	Evaluation by Rapporteur Member State.....	386
	Date	386
	Materials and Methods	386
	Results and discussion	386
	Conclusion	386
	Reliability.....	386
	Acceptability	386
	Remarks.....	386
23	Comments from	386
	Date	386
	Materials and Methods	386
	Results and discussion	386
	Conclusion	386
	Reliability.....	386
	Acceptability	386
	Remarks.....	386
24	Evaluation by Rapporteur Member State.....	389
25	Comments from	389
26	Evaluation by Rapporteur Member State.....	390
27	Comments from	390
20	Reference	391
20.1	Reference	391
20.2	Data protection.....	391
20.2.1	DATA OWNER	391
20.2.2	COMPANIES WITH ACCESS TO DATA	391
20.2.3	CRITERIA FOR DATA PROTECTION	391
21	Guidelines and Quality Assurance.....	391
21.1	Guideline study.....	391
21.2	GLP	391
21.3	Deviations	391
22	MATERIALS AND MethodS.....	391
22.1	Test material	391
22.1.1	LOT/BATCH NUMBER	391
22.1.2	SPECIFICATION	391
22.2	Test Animals.....	391
22.2.1	SPECIES	391
22.2.2	STRAIN.....	392
22.2.3	SOURCE	392
22.2.4	SEX	392
22.2.5	AGE/WEIGHT AT STUDY INITIATION	392
22.2.6	NUMBER OF ANIMALS PER GROUP.....	392
22.2.7	CONTROL ANIMALS.....	392
22.3	Administration/ Exposure	392

22.3.1	APPLICATION	392
22.3.2	OCCLUSION	392
22.3.3	VEHICLE	392
22.3.4	CONCENTRATION IN VEHICLE.....	392
22.3.5	TOTAL VOLUME APPLIED.....	392
22.3.6	REMOVAL OF TEST SUBSTANCE.....	392
22.3.7	DURATION OF EXPOSURE	392
22.3.8	POSTEXPOSURE PERIOD.....	392
22.3.9	CONTROLS.....	392
22.4	Examinations	392
22.4.1	CLINICAL SIGNS.....	392
22.4.2	DERMAL EXAMINATION.....	392
22.4.3	OTHER EXAMINATIONS.....	393
22.5	Further remarks.....	393
23	Results and Discussion	393
23.1	Average score	393
23.1.1	ERYTHEMA	393
23.1.2	OEDEMA	393
23.2	Reversibility	393
23.3	Other examinations	393
23.4	Overall result	393
24	Applicant's Summary and conclusion.....	393
24.1	Materials and methods.....	393
24.2	Results and discussion	394
24.3	Conclusion	394
24.3.1	RELIABILITY.....	394
24.3.2	DEFICIENCIES.....	394
28	Evaluation by Rapporteur Member State.....	395
	Date	395
	Materials and Methods	395
	Results and discussion	395
	Conclusion	395
	Reliability.....	395
	Acceptability	395
	Remarks	395
29	Comments from	395
	Date	395
	Materials and Methods	395
	Results and discussion	395
	Conclusion	395
	Reliability.....	395
	Acceptability	395
	Remarks	395
25	Reference	397
25.1	Reference	397
25.2	Data protection.....	397
25.2.1	DATA OWNER	397
25.2.2	COMPANIES WITH ACCESS TO DATA	397
25.2.3	CRITERIA FOR DATA PROTECTION	397
26	Guidelines and Quality Assurance.....	397
26.1	Guideline study.....	397
26.2	GLP	397
26.3	Deviations	397

27	MATERIALS AND MethodS	397
27.1	Test material.....	397
27.1.1	LOT/BATCH NUMBER.....	397
27.1.2	SPECIFICATION.....	397
27.2	Test Animals.....	398
27.2.1	SPECIES.....	398
27.2.2	STRAIN.....	398
27.2.3	SOURCE.....	398
27.2.4	SEX.....	398
27.2.5	AGE/WEIGHT AT STUDY INITIATION.....	398
27.2.6	NUMBER OF ANIMALS PER GROUP.....	398
27.2.7	CONTROL ANIMALS.....	398
27.3	Administration/ Exposure.....	398
27.3.1	PREPARATION OF TEST SUBSTANCE.....	398
27.3.2	AMOUNT OF ACTIVE SUBSTANCE INSTILLED.....	398
27.3.3	EXPOSURE PERIOD.....	398
27.3.4	POSTEXPOSURE PERIOD.....	398
27.4	Examinations.....	398
27.4.1	OPHTHALMOSCOPIC EXAMINATION.....	398
27.4.2	OTHER INVESTIGATIONS.....	398
27.5	Further remarks.....	398
28	Results and Discussion	399
28.1	Clinical signs.....	399
28.2	Average score.....	399
28.2.1	CORNEA.....	399
28.2.2	IRIS.....	399
28.2.3	CONJUNCTIVA.....	399
28.3	Reversibility.....	399
28.4	Other.....	399
28.5	Overall result.....	399
29	Applicant's Summary and conclusion	400
29.1	Materials and methods.....	400
29.2	Results and discussion.....	400
29.3	Conclusion.....	400
29.3.1	RELIABILITY.....	400
29.3.2	DEFICIENCIES.....	400
30	Evaluation by Rapporteur Member State	401
	Date.....	401
	Materials and Methods.....	401
	Results and discussion.....	401
	Conclusion.....	401
	Reliability.....	401
	Acceptability.....	401
	Remarks.....	401
31	Comments from	401
	Date.....	401
	Materials and Methods.....	401
	Results and discussion.....	401
	Conclusion.....	401
	Reliability.....	401
	Acceptability.....	401
	Remarks.....	401
32	Evaluation by Rapporteur Member State	404
33	A BRIDGING CASE TO DIFENACOUM DATA IS PROPOSED	406

30	Reference	410
30.1	Reference	410
30.2	Data protection.....	410
30.2.1	<i>DATA OWNER</i>	410
30.2.2	<i>COMPANIES WITH ACCESS TO DATA</i>	410
30.2.3	<i>CRITERIA FOR DATA PROTECTION</i>	410
31	Guidelines and Quality Assurance.....	410
31.1	Guideline study	410
31.2	GLP	410
31.3	Deviations	410
32	MATERIALS AND MethodS.....	410
32.1	Test material	410
32.1.1	<i>LOT/BATCH NUMBER</i>	410
32.1.2	<i>SPECIFICATION</i>	410
32.2	Test Animals.....	411
32.2.1	<i>SPECIES</i>	411
32.2.2	<i>STRAIN</i>	411
32.2.3	<i>SOURCE</i>	411
32.2.4	<i>SEX</i>	411
32.2.5	<i>AGE/WEIGHT AT STUDY INITIATION</i>	411
32.2.6	<i>NUMBER OF ANIMALS PER GROUP</i>	411
32.2.7	<i>CONTROL ANIMALS</i>	411
32.3	Administration/ Exposure	411
32.3.1	<i>PREPARATION OF TEST SITE</i>	411
32.3.2	<i>CONCENTRATION OF TEST SUBSTANCE</i>	412
32.3.3	<i>SPECIFIC ACTIVITY OF TEST SUBSTANCE</i>	412
32.3.4	<i>VOLUME APPLIED</i>	412
32.3.5	<i>SIZE OF TEST SITE</i>	412
32.3.6	<i>EXPOSURE PERIOD</i>	412
32.3.7	<i>SAMPLING TIME</i>	412
32.3.8	<i>SAMPLES</i>	412
33	Results and Discussion	413
33.1	Toxic effects, clinical signs	413
33.2	Dermal irritation.....	413
33.3	Recovery of labelled compound.....	413
33.4	Percutaneous absorption	414
34	Applicant's Summary and conclusion.....	414
34.1	Materials and methods	414
34.2	Results and discussion	414
34.3	Conclusion	415
34.3.1	<i>RELIABILITY</i>	416
34.3.2	<i>DEFICIENCIES</i>	416
34	Evaluation by Rapporteur Member State – FINLAND FOR DIFENACOUM.....	417
	Date	417
	Materials and Methods	417
	Results and discussion	417
	Conclusion	417
	Reliability.....	417
	Acceptability	417
	Remarks	417
35	Comments from ...Ref MS - Ireland	418
	Date	418
	Materials and Methods	418

Results and discussion	418
Conclusion	418
Reliability.....	418
Acceptability	418
Remarks	418
35 Reference	421
35.1 Reference	421
35.2 Data protection.....	421
35.2.1 DATA OWNER	421
35.2.2 COMPANIES WITH ACCESS TO DATA	421
35.2.3 CRITERIA FOR DATA PROTECTION	421
36 Guidelines and Quality Assurance.....	421
36.1 Guideline study.....	421
36.2 GLP	421
36.3 Deviations	421
37 MATERIALS AND MethodS	421
37.1 Test material	421
• LOT/BATCH NUMBER	422
• SPECIFICATION.....	422
37.2 Method of analysis	422
37.3 Exposure	422
37.3.1 REASONS OF EXPOSURE	422
37.3.2 FREQUENCY OF EXPOSURE.....	422
37.3.3 SAMPLING	422
• DESCRIPTION OF EXPOSURE PATTERNS	422
37.3.4 DURATION OF SINGLE EXPOSURE	423
• TEST DESIGN	423
• Calculations	423
• Remarks.....	423
38 Results and Discussion	424
• Securing wax blocks in bait stations	424
• Clean-up and disposal	424
• Applicant's Summary and conclusion	424
• Materials and methods.....	425
• Results and discussion.....	425
38.1 Conclusion	425
38.1.1 RELIABILITY.....	425
38.1.2 DEFICIENCIES	426
35.1.1	426
35.1.2	427
36 Evaluation by Rapporteur Member State.....	427
Date	427
Materials and Methods	427
Results and discussion	427
Conclusion	427
Reliability.....	427
Acceptability	427
Remarks	427
37 Comments from	427
Date	427
Materials and Methods	427
Results and discussion	427

Conclusion	427
Reliability.....	427
Acceptability	427
Remarks	427
Estimation of the Frequency of Dermal Exposure	431
During the Occupational Use of Rodenticides.....	431
39 Introduction.....	432
40 Objective of this report	432
41 Description of data sources.....	432
42 Assessment of representativeness and reliability of used data	433
43 Methods	434
43.1 Selection of relevant data	434
43.2 Statistical procedures	434
44 Results	434
45 Discussion and conclusions.....	437
46 References.....	438
38 Appendix I: Used data.....	439
39 Appendix II: Used questionnaire	440
QUESTIONNAIRE ABOUT RODENTICIDE USE IN EUROPE	440
40 Appendix III: Summary of data from Company 3	443
41 Appendix IV: Summary of rodent control on large sites (company 3).....	444
6.6.1 <i>HUMAN EXPOSURE TOWARDS BIOCIDAL PRODUCT</i>	<i>446</i>
6.6.1.1 <i>PRODUCTION.....</i>	<i>446</i>
6.6.1.2 <i>INTENDED USE(S)</i>	<i>446</i>
6.6.1.3 <i>PROFESSIONAL EXPOSURE.....</i>	<i>447</i>
6.6.1.4 <i>CONSUMER AND SECONDARY EXPOSURE</i>	<i>447</i>
6.6.2 <i>HUMAN EXPOSURE TOWARDS SUBSTANCES OF CONCERN WITHIN THE BIOCIDAL PRODUCT</i>	<i>448</i>
Date	448
Materials and methods.....	448
Conclusion	448
Reliability.....	448
Acceptability	448
Remarks	448
Date	449
Results and discussion	449
Conclusion	449
Reliability.....	449
Acceptability	449
Remarks	449
47 Reference	486
47.1 Reference	486
47.2 Data protection.....	486
47.2.1 <i>CRITERIA FOR DATA PROTECTION</i>	<i>486</i>
48 Guidelines and Quality Assurance.....	486
48.1 Guideline study.....	486
48.2 GLP	486
48.3 Deviations	486
49 Applicant's Summary and conclusion.....	486

49.1	Results and discussion	487
49.1.1	<i>RELIABILITY</i>	487
49.1.2	<i>DEFICIENCIES</i>	487
42	Evaluation by Rapporteur Member State	488
	Date	488
	Materials and Methods	488
	Results and discussion	488
	Conclusion	488
	Reliability	488
	Acceptability	488
	Remarks	488
43	Comments from	488
	Date	488
	Materials and Methods	489
	Results and discussion	489
	Conclusion	489
	Reliability	489
	Acceptability	489
	Remarks	489
50	Reference	490
50.1	Reference	490
50.2	Data protection	490
50.2.1	<i>CRITERIA FOR DATA PROTECTION</i>	490
51	Guidelines and Quality Assurance	490
51.1	Guideline study	490
51.2	GLP	490
51.3	Deviations	490
52	materials and methods	490
52.1	Test material	490
52.1.1	<i>LOT/BATCH NUMBER</i>	491
52.1.2	<i>SPECIFICATION</i>	491
52.2	Test Animals	491
52.2.1	<i>SPECIES</i>	491
52.2.2	<i>STRAIN</i>	491
52.2.3	<i>SOURCE</i>	491
52.2.4	<i>NUMBER OF ANIMALS PER GROUP</i>	491
52.2.5	<i>VOLUME APPLIED</i>	491
53	Applicant's Summary and conclusion	491
53.1	Materials and methods	491
44	491
53.2	Results and discussion	492
53.3	Conclusion	492
53.3.1	<i>RELIABILITY</i>	492
53.3.2	<i>DEFICIENCIES</i>	492
45	Evaluation by Rapporteur Member State	493
	Date	493
	Materials and Methods	493
	Results and discussion	493
	Conclusion	493
	Reliability	493
	Acceptability	493
	Remarks	493

46	Comments from	493
	Date	493
	Materials and Methods	493
	Results and discussion	493
	Conclusion	493
	Reliability.....	493
	Acceptability	493
	Remarks.....	493
54	Reference	494
	54.1 Reference	494
	54.2 Data protection.....	494
	54.2.1 <i>CRITERIA FOR DATA PROTECTION</i>	494
55	Guidelines and Quality Assurance.....	494
	55.1 Guideline study	494
	55.2 GLP	494
	55.3 Deviations	494
56	MATERIALS AND MethodS.....	494
	56.1 Test material	494
	56.1.1 <i>LOT/BATCH NUMBER</i>	494
	56.1.2 <i>SPECIFICATION</i>	494
	56.2 Test Animals.....	494
	56.2.1 <i>SPECIES</i>	494
	56.2.2 <i>STRAIN</i>	494
	56.2.3 <i>SOURCE</i>	494
	56.2.4 <i>SEX</i>	495
	56.2.5 <i>AGE/WEIGHT AT STUDY INITIATION</i>	495
	56.2.6 <i>CONTROL ANIMALS</i>	495
	56.3 Administration/ Exposure	495
57	Applicant's Summary and conclusion.....	495
	57.1 Materials and methods	495
	57.2 Results and discussion	496
	57.3 Conclusion	496
	57.3.1 <i>RELIABILITY</i>	496
	57.3.2 <i>DEFICIENCIES</i>	496
47	Evaluation by Rapporteur Member State.....	497
	Date	497
	Materials and Methods	497
	Results and discussion	497
	Conclusion	497
	Reliability.....	497
	Acceptability	497
	Remarks.....	497
48	Comments from	497
	Date	497
	Materials and Methods	497
	Results and discussion	497
	Conclusion	497
	Reliability.....	497
	Acceptability	497
	Remarks.....	497
58	Reference	499
	58.1 Reference	499

58.2	Data protection.....	499
58.2.1	<i>CRITERIA FOR DATA PROTECTION</i>	499
59	Guidelines and Quality Assurance.....	499
59.1	Guideline study.....	499
59.2	GLP	499
59.3	Deviations	499
60	MATERIALS AND MethodS.....	499
61	Applicant's Summary and conclusion.....	499
61.1	Materials and methods.....	499
61.2	Results and discussion	500
61.3	Conclusion	500
61.3.1	<i>RELIABILITY</i>	500
61.3.2	<i>DEFICIENCIES</i>	500
49	Evaluation by Rapporteur Member State.....	501
	Date.....	501
	Materials and Methods	501
	Results and discussion	501
	Conclusion	501
	Reliability.....	501
	Acceptability	501
	Remarks.....	501
50	Comments from	501
	Date.....	502
	Materials and Methods	502
	Results and discussion	502
	Conclusion	502
	Reliability.....	502
	Acceptability	502
	Remarks.....	502
51	Evaluation by Rapporteur Member State.....	512
	Date.....	512
	Materials and methods.....	512
	Results and discussion	512
	Conclusion	512
	Reliability.....	512
	Acceptability	512
	Remarks.....	512
52	Comments from	512
	Date.....	512
	Results and discussion	512
	Conclusion	512
	Reliability.....	512
	Acceptability	512
	Remarks.....	512
	VI.1 Environmental exposure assessment	521
	Emissions to the environment from the use of brodifacoum in the product	522
	VI.1.1 Fate and distribution of brodifacoum in the environment.....	522
	VI.1.1.1 <i>PEC CALCULATIONS</i>	522
	VI.1.2 PEC in surface water, sewage treatment plant, groundwater and sediment	528
	VI.1.3 PEC in air	528
	VI.1.4 PEC in soil.....	529
	VI.1.5 Summary of calculated PECs.....	530
	VI.1.6 Primary and Secondary Poisoning.....	530

VI.1.7	Non compartment specific exposure relevant to the food chain (secondary poisoning)	538
VI.1.7.2	Calculation of the concentration in fish	544
VI.1.6.3	Calculation of concentration in earthworms	544
Environmental effects assessment		547
	Aquatic compartment	547
	Atmosphere	547
	Terrestrial compartment	547
	<i>NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN (SECONDARY POISONING)</i>	547
Annex 2 - MAC PAR – January 2018		549
1	Conclusion	551
2	Summary of the product assessment	552
2.1	Administrative information	552
2.1.1	<i>IDENTIFIER IN R4BP</i>	552
2.1.2	<i>AUTHORISATION HOLDER</i>	552
2.1.3	<i>MANUFACTURER(S) OF THE PRODUCT</i>	552
2.1.4	<i>MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)</i>	553
2.2	Product composition and formulation	553
2.2.1	<i>QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION</i>	553
2.2.2	<i>INFORMATION ON THE SUBSTANCE(S) OF CONCERN</i>	553
2.2.3	<i>CANDIDATE(S) FOR SUBSTITUTION</i>	554
2.2.4	<i>TYPE OF FORMULATION</i>	554
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008	554
2.4	Use(s) appropriate after major change to the authorisation	555
2.4.1	<i>USE 1 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – HOUSE MICE – GENERAL PUBLIC – INDOOR</i>	556
2.4.2	<i>USE 2 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – RATS – GENERAL PUBLIC – INDOOR</i>	558
2.4.3	<i>USE 3 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – RATS – GENERAL PUBLIC – OUTDOOR AROUND BUILDINGS</i>	560
2.4.4	<i>USE 4 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – HOUSE MICE – PROFESSIONALS – INDOOR</i>	563
2.4.5	<i>USE 5 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – RATS – PROFESSIONALS – INDOOR</i>	566
2.4.6	<i>USE 6 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – HOUSE MICE AND/OR RATS – PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	569
2.4.7	<i>USE 7 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – INDOOR</i>	573
2.4.8	<i>USE 8 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	577
2.4.9	<i>USE 9 APPROPRIATE AFTER MAJOR CHANGE TO THE AUTHORISATION – RATS – TRAINED PROFESSIONALS – SEWERS</i>	581
2.5	General directions for use	584
2.5.1	<i>INSTRUCTIONS FOR USE</i>	584
2.5.2	<i>RISK MITIGATION MEASURES</i>	585
2.5.3	<i>PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT</i>	586
2.5.4	<i>INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING</i>	586
2.5.5	<i>CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE</i>	586
2.5.6	<i>OTHER INFORMATION</i>	587
2.5.7	<i>DOCUMENTATION</i>	587
3	Assessment of the product	588
3.1	Proposed Uses	588
3.1.1	<i>USE 1 – HOUSE MICE – GENERAL PUBLIC – INDOOR</i>	588
3.1.2	<i>USE 2 – RATS – GENERAL PUBLIC – INDOOR</i>	589
3.1.3	<i>USE 3 – RATS – GENERAL PUBLIC – OUTDOOR AROUND BUILDINGS</i>	590

3.1.4	<i>USE 4 – HOUSE MICE – PROFESSIONALS – INDOOR</i>	591
3.1.5	<i>USE 5 – RATS – PROFESSIONALS – INDOOR</i>	592
3.1.6	<i>USE 6 - HOUSE MICE AND/OR RATS – PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i>	594
3.1.7	<i>USE 7 - HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – INDOOR</i>	595
3.1.8	<i>USE 8 - HOUSE MICE AND/OR RATS – TRAINED PROFESSIONALS – OUTDOOR AROUND BUILDINGS</i> <i>597</i>	
3.1.9	<i>USE 9 - RATS – TRAINED PROFESSIONALS – SEWERS</i>	599
3.2	Physical, chemical and technical properties	602
3.3	Physical hazards and respective characteristics	602
3.4	Methods for detection and identification	602
3.5	Efficacy against target organisms.....	602
3.6	Risk assessment for human health	604
3.6.1	<i>ASSESSMENT OF EFFECTS OF THE ACTIVE SUBSTANCE ON HUMAN HEALTH</i>	604
3.6.2	<i>ASSESSMENT OF EFFECTS OF THE PRODUCT ON HUMAN HEALTH</i>	604
3.6.3	<i>EXPOSURE ASSESSMENT</i>	604
3.6.4	<i>RISK CHARACTERISATION FOR HUMAN HEALTH</i>	606
3.7	Risk assessment for animal health.....	608
3.8	Risk assessment for the environment	608
3.9	Assessment of a combination of biocidal products	612
3.10	Comparative assessment	612
4	General Annexes	613
4.1	List of studies for the biocidal product (family)	613
4.2	Output tables from exposure assessment tools	614
4.3	New information on the active substance	614
4.4	Residue behaviour	614
4.5	Summaries of the efficacy studies (B.5.10.1-xx)	615
4.6	Other	617
5	Confidential annex (Access level: “Restricted” to applicant and authority)	618
5.1	Full composition of the product.....	618

1st Renewal PAR – March 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE RENEWAL
OF A NATIONAL AUTHORISATION (NA-RNL)**



Product identifier in R4BP	Vertox 25 Oktablok
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-GR029540-33
Asset No. in R4BP	IE-0016001-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	IE/BPA 70505
Date	14-03-2018 (NA-RNL Renewal)

Table of contents

1	Conclusion	41
2	Summary of the product assessment	45
2.1	Administrative information	45
2.2	Product composition and formulation	46
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008.....	47
2.4	Use(s) appropriate after renewal of the authorisation	49
2.5	General directions for use	77
3	Assessment of the product	80
3.1	Proposed Uses	80
3.2	Physical, chemical and technical properties.....	94
3.3	Physical hazards and respective characteristics	94
3.4	Methods for detection and identification	94
3.5	Efficacy against target organisms	94
3.6	Risk assessment for human health	98
3.7	Risk assessment for animal health.....	101
3.8	Risk assessment for the environment	102
3.9	Assessment of a combination of biocidal products	106
3.10	Comparative assessment	106
4	General Annexes	108
4.1	List of studies for the biocidal product (family)	108
4.2	Output tables from exposure assessment tools	109
4.3	New information on the active substance	109
4.4	Residue behaviour	109
4.5	Summaries of the efficacy studies (B.5.10.1-xx)	110
4.6	Other	112
5	Confidential annex (Access level: "Restricted" to applicant and authority)	113
5.1	Full composition of the product	113

1 Conclusion

The Irish Competent Authority for the authorisation of biocidal products has processed an application for renewal for the biocidal product Vertox 25 Oktablok which contains the active substance Brodifacoum (0.0025 % w/w).

The assessments presented in the Product Assessment Report for the first authorisation (2013) showed acceptable efficacy but unacceptable risks for the environment, if the product is used as a rodenticide (product-type 14) for use in and around buildings, by the general public, professionals and trained professionals, and in sewers by professionals and trained professionals.

A major change evaluation in 2017 (case number BC-YL028939-03) assessed and authorised the reduction in active substance content from 0.005% 0.0025% w/w.

The conditions for granting an authorisation according to Article 19 (1) of Regulation (EU) No 528/2012¹ (BPR) are not fulfilled.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR, as this Article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product.

Detailed information on the uses appropriate at the renewal of authorisation are presented in section 2.4.

General directions for use of the product are summarised in section 2.5.

Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extent. As an outcome of these discussions a set of three standard SPCs (Summary of Product Characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final).

The specific conditions from Commission Implementing Regulation (EU) 2017/1381² for the active substance Brodifacoum were considered for the re-assessment.

¹ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

² Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of Brodifacoum as an active substance for use in biocidal products of product-type 14

The Irish CA concludes that the conditions set out in Article 5(2) b) and c) of the BPR are currently met. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control in Ireland by efficient pest management and as a consequence, to prevent or control any serious danger to human and animal health in which rodents are involved.

Rodent control in Ireland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Ireland. This may not only cause significant negative impacts on human or animal health or the environment, but may also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences in Ireland.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008³. Detailed information on classification and labelling is provided in Section 2.3.

As a consequence of the new harmonised classification, the active substance Brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR. Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Vertox 25 Oktablok has been conducted (for details see Section 3.10).

Comparative assessment

In line with Article 23 (1) BPR a comparative assessment for the product has been conducted (for details see Section 3.10).

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

Approval of the active substance

The active substance Brodifacoum is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

The authorisations of biocidal products containing Brodifacoum are subject to the conditions listed in the Annex to Commission Implementing Regulation (EU) 2017/1381:

Composition and formulation

The ready-to-use product is a wax block bait and contains the active substance Brodifacoum.

No substance of concern has been identified.

Please refer to section 5.1 for detailed information.

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

Efficacy

Effectiveness data has confirmed that Vertox 25 Oktablok is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. An evaluation of the field trials provided demonstrated that the block bait formulation proved to be both palatable to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*).

Vertox 25 Oktablok is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been established previously.

The conclusion of the evaluation is that the product may be authorised.

Risk assessment for human health

The human health risk assessment for this product is based on the active substance.

According to the BPC Opinion the EFSA-Guidance on dermal absorption had been taken into account when reviewing the dermal absorption of the product.

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely.

For risk mitigation measures please refer to section 2.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding the trained professional users health protection, there are no objections against the intended uses if the directions for use are followed (For details see section 2).

Risk assessment for the environment

No new data was provided. The only area where new guidance was relevant was with respect to the groundwater assessment. Following discussion at the CG-18 meeting and subsequent agreement, Tier II PEC groundwater was calculated using the FOCUS models PEARL or PELMO in the instances where Tier I indicated an exceedance of the relevant trigger value.

According to the risk assessment, the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk assessment.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR.

Overall conclusion

The assessment of the biocidal product Vertox 25 Oktablok remains valid. However, the authorisation has to be adapted where necessary taking into account the points mentioned above.

The biocidal product will be authorised according to Article 19 (5) BPR in conjunction with Article 23 (6) BPR.

According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Vertox 25 Oktablok (red)

2.1.2 Authorisation holder

Name and address of the authorisation holder	Name	PelGar International Limited
	Address	18 rue des Remparts d'Ainay 69002 Lyon France Unit 13, Newman Lane Alton Hampshire GU34 2QR UK
Authorisation number	IE/BPA 70505	
Date of the authorisation	14-03-2018	
Expiry date of the authorisation	14-03-2023	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	PelGar International Ltd,
Address of manufacturer	18 rue des Remparts d'Ainay, 69002, Lyon, France
Location of manufacturing sites	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK or

	<p>Promedivet SRL 545500 SOVATA , str. Lunga nr. 46/G jud. Mures, Romania</p> <p>Or</p> <p>Pelgar International Limited, Overly Hill, B5061, Wellington, TF6 5HD, Telford, UK</p>
--	---

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	PelGar International Limited Prazska 54 280 02 Kolin Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl]tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0025

- The product contains a bittering agent and a dye.

- Information on the full composition is provided in the confidential⁴ annex (see section 5).
- According to the information provided, the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: block (RB)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008⁵


Table 2

⁴ Access level: "Restricted" to applicant and authority

⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification	
Hazard classes, Hazard categories	Hazard statements
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
	EUH208: Contains 1,2-benzisothiazolin-3(2H)-one.. May produce an allergic reaction.
	EUH208: Contains 2-octyl-2H-isothiazol-3-one. May produce an allergic reaction. EUH 208: Contains BIT and OIT, may produce an allergic reaction.

Table 3

Labelling		
	Code	Pictogram / Wording
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	EUH208	EUH208: Contains 1,2-benzisothiazolin-3(2H)-one.. May produce an allergic reaction. EUH208: Contains 2-octyl-2H-isothiazol-3-one. May produce an allergic reaction. EUH 208: Contains BIT and OIT, may produce an allergic reaction.
Supplemental label elements		
Precautionary statements	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% w/w Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after renewal of the authorisation

Table 4: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor
8	House mice and/or rats – trained professionals – outdoor around buildings
9	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after renewal of the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 100g Refill packs of multiple blocks (maximum pack sizes 100g): 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in

multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer - Up to 80g
 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 80g
 1 - 5 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. – Up to 100g.
 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 100g.

2.4.1.1 Use-specific instructions for use

- For mice use up to 20g in bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

None

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after renewal of the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 300g Refill packs of multiple blocks (maximum pack sizes 300g): 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box

5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer

1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 200g

1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.

Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.

2.4.2.1 Use-specific instructions for use

- For rats use up to 60g in bait stations.
- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

2.4.2.2 Use-specific risk mitigation measures

None

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after renewal of the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	General Public

Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer-</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p> <p>Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market</p>
-----------------------------------	---

2.4.3.1 Use-specific instructions for use

- For rats use up to 60g in bait stations.
- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped.. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

None

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after renewal of the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles

Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs: 10g – 250 15g – 125 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof mouse bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96</p>

100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.4.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped.
- Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.4.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after renewal of the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g Bait station packs described above are sold for professional use in larger multi-packs: 20g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96</p>

200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96
Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.5.1 Use-specific instructions for use

- For rat infestations use 10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the

risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).

Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.6 Use 6 appropriate after renewal of the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p>

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper- Up to 200g

Bait station packs described above are sold for professional use in larger multi-packs:

10g - 250

20g – 96, 120, 144

30g – 96, 120, 144

40g – 72, 96, 120

50g - 48, 60, 72, 96

60g – 48, 60, 72, 96

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

120g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

240g – 16, 32, 48, 60, 72, 96

1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

400g – 8, 16, 32, 48, 60, 72, 96

Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.6.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations.

- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).
Do not apply this product directly in the burrows.
Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations

Application rate(s) and frequency	<p>Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres</p> <p>Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres</p> <p><i>Pulsed baiting –</i> 10 to 60g for rat, 10m apart (5m apart in areas of high infestation) 5 to 20g for mice, 5m apart (2m apart in high infestation areas)</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer.- Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g Bait station packs described above are sold for professional use in larger multi-packs: 10g - 250 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96</p>

100g - 32, 48, 60, 72, 96
120g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
240g – 16, 32, 48, 60, 72, 96
1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96
Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.7.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations.
- Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the

bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
 - Follow any additional instructions provided by the relevant code of best practice.
 - Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
 - The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
 - The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
 - [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
 - Remove the remaining product at the end of treatment period.
 - Do not use this product for permanent baiting.
 - If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.
- [When available] Follow the specific instructions provided by the applicable code of good practice at national level.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations or in direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	Mice: 5 to 20 g of bait per bait station. High infestation – 5 to 20g bait in bait stations every 2 metres Low infestation – 5 to 20g bait in bait stations every 5 metres

	<p>Rats: 10 to 60 g of bait per bait station. High infestation – 10 to 60g bait in bait stations every 5 metres Low infestation – 10 to 60g bait in bait stations every 10 metres</p> <p>- In burrows: 10-60g of bait per burrow.</p> <p><i>Pulsed baiting –</i> 10 to 60g for rat, 10m apart (5m apart in areas of high infestation) 5 to 20g for mice, 5m apart (2m apart in high infestation areas)</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g Bait station packs described above are sold for professional use in larger multi-packs: 10g - 250 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96</p>

120g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
240g – 16, 32, 48, 60, 72, 96
1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96
Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.8.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations or covered bait points or directly into the burrow.
- Secure 10-60g of blocks in tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been

eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

[When available] Follow the specific instructions provided by the applicable code of good practice at national level.

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).
- Do not use this product in pulsed baiting treatments.

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after renewal of the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole). Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g Bait station packs described above are sold for professional use in larger multi-packs: 20g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96</p>

120g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
240g – 16, 32, 48, 60, 72, 96
1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96
Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

2.4.9.1 Use-specific instructions for use

- In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).
- Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Wear protective chemical resistant gloves during product handling phase (EN374).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Do not open the sachets containing the bait (only for individually wrapped blocks authorised for use by the General Public).
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Professionals and trained professionals: Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

2.5.2 Risk mitigation measures

- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- [For products to be authorised for professionals and trained professionals] Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only"). Do not wash the bait stations with water between applications.
- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only". Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant. Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.

Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

Keep only in original container.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the taskforce for the EU review programme.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice up to 20g in bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 100g Refill packs of multiple blocks (maximum pack sizes 100g): 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer - Up to 80g

	<p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 80g</p> <p>1 - 5 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. – Up to 100g.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 100g.</p>
--	--

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use up to 60g in bait stations. Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.</p> <p>Additional blocks may be included as refills in the outer. - Up to 240g</p>

	<p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>
--	---

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	<p>For rats use up to 60g in bait stations.</p> <p>Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	General Public
Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer-</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.</p> <p>Additional blocks may be included as refills in the outer - Up to 240g</p>

	<p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>
--	--

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.*</p> <p>Minimum pack size of 2.5kg allowed in Ireland*</p> <p>Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in</p>

	<p>a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs: 10g – 250 15g – 125 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof mouse bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market</p>
--	---

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles

Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation). Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg-</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g Bait station packs described above are sold for professional use in larger multi-packs: 20g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96</p>

	400g – 8, 16, 32, 48, 60, 72, 96 Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market
--	---

3.1.6 Use 6 - House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations. Secure 10-60g of blocks in tamper resistant baiting spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg.

Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg

2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g

1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g

1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g

1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Additional blocks may be included as refills in the outer. - Up to 240g

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper- Up to 200g

Bait station packs described above are sold for professional use in larger multi-packs:

10g - 250

20g - 96, 120, 144

30g - 96, 120, 144

40g - 72, 96, 120

50g - 48, 60, 72, 96

60g - 48, 60, 72, 96

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

120g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

240g - 16, 32, 48, 60, 72, 96

1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

400g - 8, 16, 32, 48, 60, 72, 96

Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) - Up to 400g. Multiple units within a pack:

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

	400g – 8, 16, 32, 48, 60, 72, 96
	Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

3.1.7 Use 7 - House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg.

Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg

2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g

1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer.- Up to 120g

1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g

1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Additional blocks may be included as refills in the outer. - Up to 240g

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g

Bait station packs described above are sold for professional use in larger multi-packs:

10g - 250

20g - 96, 120, 144

30g - 96, 120, 144

40g - 72, 96, 120

50g - 48, 60, 72, 96

60g - 48, 60, 72, 96

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

120g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

240g - 16, 32, 48, 60, 72, 96

1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

400g - 8, 16, 32, 48, 60, 72, 96

Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) - Up to 400g. Multiple units within a pack:

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96
Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

3.1.8 Use 8 - House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Trained Professionals

Pack sizes and packaging material

Minimum pack size of 3kg.*

Minimum pack size of 2.5kg allowed in Ireland*

Minimum pack size of 2.5 kg-

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg

Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg

2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g

1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g

1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g

1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Additional blocks may be included as refills in the outer. - Up to 240g

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g

Bait station packs described above are sold for professional use in larger multi-packs:

10g - 250

20g - 96, 120, 144

30g - 96, 120, 144

40g - 72, 96, 120

50g - 48, 60, 72, 96

60g - 48, 60, 72, 96

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

120g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

240g - 16, 32, 48, 60, 72, 96

1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:

80g - 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g - 16, 32, 48, 60, 72, 96

400g - 8, 16, 32, 48, 60, 72, 96

	<p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market</p>
--	---

3.1.9 Use 9 - Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	<p>In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).</p> <p>Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 3kg.* Minimum pack size of 2.5kg allowed in Ireland* Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g 50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer</p>

or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g

Bait station packs described above are sold for professional use in larger multi-packs:

20g – 96, 120, 144

40g – 72, 96, 120

50g - 48, 60, 72, 96

60g – 48, 60, 72, 96

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

120g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

240g – 16, 32, 48, 60, 72, 96

1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

400g – 8, 16, 32, 48, 60, 72, 96

Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:

80g – 32, 48, 60, 72, 96

100g - 32, 48, 60, 72, 96

200g – 16, 32, 48, 60, 72, 96

400g – 8, 16, 32, 48, 60, 72, 96

Additional pack sizes of 1Kg, 1.5Kg and 2Kg have been evaluated and approved but are currently not allowed on the market

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Vertox 25 Oktablok (red) is a ready-to-use, grain based cast block bait formulation for the control of mice and brown rats in a number of proposed use scenarios (section 3.1.1). The product is intended for use by amateurs, professionals and trained professionals for the control of house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*).

For the Major Change evaluation (2017), the applicant provided a comprehensive and valid justification not to repeat the laboratory palatability studies. Their case for extrapolation of the dose from 50ppm to 25ppm (ref: Regulatory Case in support of Vertox 25 Oktablok) took into account the minor changes to the composition of the product and also used worst-case data from palatability choice tests. Minor changes in the preservative and solvents used are not deemed to present any adverse effect the palatability of the product, nor are the inclusion of two additional components in the formulation tested for efficacy which are not present in the current version: 0.25% w/w salt and 0.25% corn starch.

Using the previously evaluated laboratory palatability study data, the likely toxicity of the 25ppm product was predicted. Taking the worst-case data in choice testing, house mouse diet consisted of 36% of bait and rat diet consisted of 35.1% of bait. Using predictions that a rat eats 10% of its bodyweight per day

and a mouse eats 20% of its bodyweight per day (i.e. 1g/kg for a rat and 2 g/kg for a mouse) it was estimated that a brown rat would consume a lethal dose and 0.32 days and a mouse would consume a lethal dose in 0.22 days.

The results of two field trials demonstrated that the 25ppm product is both palatable to, and effective in controlling target populations of brown rats and house mice when applied according to the label advice. The block bait formulation proved to be both attractive to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*) in the trials and provided complete (100%) control of the infestations treated based upon census baiting and tracking data.

Potential for the development for resistance owing to the reduction in active content in the product:

The applicant claims that that a 25ppm Brodifacoum bait presentation would suffer no lack in control in regards to resistance for the following reasons.

- Out of all the gene loci so far identified which have been shown to confer resistance to the Second and First Generation Anticoagulants (SGAR/FGAR), none have shown a practical resistance to Brodifacoum.
- The average lethal dose for Brodifacoum at 25ppm is around 3grams for a 250gram rat. Even if a resistance loci were to occur which showed a x10 resistance to Brodifacoum (considered to be the threshold of practical resistance in SGAR's where resistance has already been identified) this would translate to a consumption of an average lethal dose of 30 grams. This level of bait would easily be consumed over a 2-3 day period even with food competition being a factor.
- At present the maximum identified tolerance to Brodifacoum is a resistance factor of 1.8 in rats showing the Y139C gene variant.
- Therefore if proper integrated pest management is observed there is no reason that a rat or a mouse population would be repeatedly exposed to chronic partial dosing, meaning there should be little if not any population bias towards animals which are showing any partial resistances.

The applicant's defence of the reduced active substance not being a factor in the development of resistance are regarded as robust by the IE CA and the points outlined above are discussed in greater detail in the Rodenticide Resistance Action Committee resistance guidelines (RRAC guidelines on Anticoagulant Rodenticide Resistance Management, September 2015)

No efficacy data using the wax block formulation was provided for the black rat (*Rattus rattus*), therefore only claims relating to control of the brown rat (*Rattus norvegicus*) and house mice (*Mus musculus*) are authorised. References to UK specialist agencies on the proposed product label should be amended in line to reflect Irish local/national waste disposal regulations.

The label reference to permanent baiting must be removed in accordance with the BPC opinion. The use of pulse baiting techniques is authorised for trained professional users only.

Data previously evaluated demonstrated that Vertox 25 Oktablok is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and

effectiveness even under adverse environmental conditions has been demonstrated. These findings remain valid for the 25ppm product.

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.

The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.

For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.

For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982⁶; Lund, 1984⁷; Pelz et al. 1995⁸). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988⁹). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products

⁶ Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.

⁷ LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.

⁸ Pelz H-J, Ha'nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus*. *Pestic Sci* 43, 61–67

⁹ Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), *Current advances in vitamin K research*, Elsevier, N.Y., 381–388.

are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b¹⁰).

Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone. It is important to understand that all known resistance mutations, in both rats and mice, are capable of effective control with applications of the most potent second-generation anticoagulants (brodifacoum, difethialone and flocoumafen) and that no practical resistance to any of these active substances is presently known.

So, resistance to second generation anticoagulant rodenticides should not be underestimated.

An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program "impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators").

The document CropLife International (RRAC 2016) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.

The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

¹⁰ Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (*Rattus norvegicus*). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

3.6 Risk assessment for human health

Similarly to the previous evaluation, a dermal absorption value of 0.047% was used for brodifacoum for the wax block product. The dermal absorption value for brodifacoum was obtained by way of read across from studies on a wax block product containing brodifacoum.

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:

A read across from brodifacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance (EFSA Journal 2012; 10(4):2665).

Re-assessment of the relevant data:

The product has been evaluated using the reduced active ingredient concentration and new dermal absorption.

3.6.3 Exposure assessment

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products. The dermal absorption value used previously for brodifacoum of 0.047% was used for brodifacoum by way of read across for the wax block product.

Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE.

The AELs considered in the risk characterization for *Brodifacoum* were:

AEL_{acute} of 0.000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)

<p>AEL_{medium term} of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day</p> <p>AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day</p> <p>For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 8 Kg based on HEEG opinion endorsed at TM II 2013.</p>	
<p>Biocidal Exposure Risk assessment for Vertox 25 Oktablok Brodifacoum rodenticide (25 ppm) using read across values for dermal absorption obtained from brodifacoum of 0.047% (block).</p>	
Professional user	
	Block
Without PPE	19.9% of AEL (0.001 µg/kg bw/day)
With PPE	1.9% of AEL (0.0001 µg/kg bw/day)
Non-trained professional user (farmer)	
	Block
Without PPE	0.896% of AEL (0.00006 µg/kg bw/day)
With PPE	0.0896% of AEL (0.000001 µg/kg bw/day)
Exposure to children (Infant)	
	Block
Oral exposure -treated with repellent	947% of AEL (0.00003125 mg/kg bw/day)
Oral exposure - without repellent	473484% of AEL (0.015625 mg/kg bw/day)

Derived values indicated safe usage scenarios for professional users handling the brodifacoum block product, both with and without PPE. Derived values for professional users handling the block product without PPE were 0.001 µg/kg bw/day (19.9% AEL). Derived values for professional users handling the block product with PPE were 0.0001 µg/kg bw/day (1.9% AEL).

Derived values indicated safe usage for non-trained professional users handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.00006 µg/kg bw/day (0.896% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.000006 µg/kg bw/day (0.0896% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.00006 µg/kg bw/day (0.896% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the infant found transient mouthing of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mouthing of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated safe usage scenarios for professional users handling the brodifacoum block product, both with and without PPE. Derived values for professional users handling the block product without PPE were 0.001 µg/kg bw/day (19.9% AEL). Derived values for professional users handling the block product with PPE were 0.0001 µg/kg bw/day (1.9% AEL).

Derived values indicated safe usage for non-trained professional users (farmer) handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.00006 µg/kg bw/day (0.896% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.000006 µg/kg bw/day (0.0896% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.00006 µg/kg bw/day (0.896% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the renewal. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The previous change in active substance concentration from 0.005% to 0.0025% resulted in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides

As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:

- *Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.*
- *Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.*

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

As the major change led to a lower PEC_{gw}, a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0025% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios $PEC/PNEC$ are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the $PNEC$ for birds and mammals. The $PNEC$ values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	8.64	6.22	0.00013	66462	47846
Chaffinch	7.5	5.4	0.00013	57692	41538
Wood pigeon	2.71	1.95	0.00013	20846	15000
Pheasant	2.69	1.94	0.00013	20692	14923
Dog	1.5	1.08	0.000222	6757	4865
Pig	0.188	0.135	0.000222	847	608
Pig, young	0.6	0.432	0.000222	2703	1946

The ratios $PEC/PNEC$ are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral}/PNEC_{ratio}$ after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral}/PNEC_{ratio}$ are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The $EC_{oral}/PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days	EC_{oral} after 5 days	$PNEC_{oral}$	Ratio $EC_{oral}/PNEC_{oral}$
---------	--------------------------	--------------------------	---------------	-------------------------------

	(mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw) ^a	(mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw) ^a	(mg/kg b.w./d)	
Tree sparrow	15.31	11.02	0.00013	84836
Chaffinch	13.3	9.58	0.00013	73662
Wood pigeon	4.8	3.46	0.00013	26585
Pheasant	4.77	3.43	0.00013	26418
Dog	2.66	1.92	0.000222	8627
Pig	0.333	0.240	0.000222	1080
Pig, young	1.06	0.76	0.000222	3438

^a calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term PEC_{oral}/PNEC_{oral} ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The PEC_{oral}/PNEC_{oral} values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated (ETE_{oral predators}) and compared to the PNEC_{oral}

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE _{oral predators} (mg a.s./kg/d)	PNEC _{oral} (mg a.s./kg/d)	Ratio ETE _{oral predators} / PNEC _{oral}
Barn owl	Day 5 before the last meal	0.549	0.00013	4224
	Day 5 after the last meal	0.895		6885
	Day 14 after the last meal	1.02		7892

Species	Exposure	ETE _{oral} predators (mg a.s./kg/d)	PNEC _{oral} (mg a.s./kg/d)	Ratio ETE _{oral} predators / PNEC _{oral}
Kestrel	Day 5 before the last meal	0.83	0.00013	6415
	Day 5 after the last meal	1.35		10456
	Day 14 after the last meal	1.55		11896
Little owl	Day 5 before the last meal	0.62	0.00013	4820
	Day 5 after the last meal	1.02		7856
	Day 14 after the last meal	1.17		9005
Tawny owl	Day 5 before the last meal	0.50	0.00013	3883
	Day 5 after the last meal	0.82		6329
	Day 14 after the last meal	0.94		7255
Fox	Day 5 before the last meal	0.20	0.000222	910
	Day 5 after the last meal	0.32		1484
	Day 14 after the last meal	0.37		1701
Polecat	Day 5 before the last meal	0.42	0.000222	1895
	Day 5 after the last meal	0.68		3089
	Day 14 after the last meal	0.78		3541
Stoat	Day 5 before the last meal	0.60	0.000222	2710
	Day 5 after the last meal	0.98		4418
	Day 14 after the last meal	1.12		5064
Weasel	Day 5 before the last meal	0.86	0.000222	3911
	Day 5 after the last meal	1.41		6375
	Day 14 after the last meal	1.62		7307

All ratios ETE_{oral} predators / PNEC_{oral} are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk assessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The Irish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Brodificaoum. The active substance Brodificaoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).

Therefore, in line with Article 23 (1) BPR, a comparative assessment for this product has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of the BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

- (a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
- (b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
- (c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
- (d) Are these alternatives sufficiently effective?;
- (e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532¹¹. In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Irish CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

Conclusion

¹¹ Commission Implementing Decision (EU) 2017/532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the Irish CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The Irish CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view do not provide sufficient alternatives to anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

DRAFT

4 General Annexes

4.1 List of studies for the biocidal product (family)

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
██████████	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Wax Block against the house mouse (<i>Mus musculus</i>)	unpublished	PEL-BCM25WBB0615-Mm01-0216	██████████ ██████████	29/2/2016	Non-GLP	Y
██████████	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Wax Block against the brown rat (<i>Rattus norvegicus</i>)	unpublished	PEL-BCM25WBB1015-Rn01-0416	██████████ ██████████	13/4/2016	Non-GLP	Y

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

DRAFT

4.5 Summaries of the efficacy studies (B.5.10.1-xx)¹²

Function and field of use envisaged	Test substance	Test organism(s)	Test method, test system/concentrations applied/ exposure time	Test results; effects	Reference																												
Vertox 25 Oktablok (PT14)	A wax block bait containing 25 ppm Brodifacoum	Brown Rat (<i>Rattus norvegicus</i>) Wild population located on a poultry farm in ██████████, UK (resistance status unknown)	Field trial conducted on a poultry farm. Activity noted from rat prints, faeces, rat runs and rats seen running around water tanks and into drainage pipes. Five locations used for; pre-treatment census, treated bait and post-treatment census points. A pre-treatment census using untreated whole grain and sand trays employed for 4 days. One day lag period. 25ppm Wax block Bait was placed into commercially available tamper proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.	<table border="1"> <thead> <tr> <th>Bait consumption</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> </thead> <tbody> <tr> <td>Total bait consumption (g)</td> <td>509</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily bait consumption (g)</td> <td>94</td> <td>0</td> <td>100</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <th>Activity over sand patches</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> <tr> <td>Total activity score</td> <td>7</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily activity score</td> <td>3</td> <td>0</td> <td>100</td> </tr> </tbody> </table> <p>Extended baiting period was observed and explained as being due to some of the population exhibiting a</p>	Bait consumption	Pre-treatment census	Post-treatment census	% control	Total bait consumption (g)	509	0	100	Maximum daily bait consumption (g)	94	0	100					Activity over sand patches	Pre-treatment census	Post-treatment census	% control	Total activity score	7	0	100	Maximum daily activity score	3	0	100	██████████ (2016)
Bait consumption	Pre-treatment census	Post-treatment census	% control																														
Total bait consumption (g)	509	0	100																														
Maximum daily bait consumption (g)	94	0	100																														
Activity over sand patches	Pre-treatment census	Post-treatment census	% control																														
Total activity score	7	0	100																														
Maximum daily activity score	3	0	100																														

¹² If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

			<p>The trial was ended after 26 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</p>	<p>neophobic response to the bait placement, this may have been compounded by movement of farm material on site at the beginning of the trial. 942g of treated bait was consumed during the 26 day baiting phase. No evidence was found during the trial that the use of 25ppm Brodifacoum Wax block Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. Complete (100%) control of <i>Rattus norvegicus</i> achieved based on census baiting and tracking.</p>																													
Vertex 25 Oktablok (PT14)	A wax block bait containing 25 ppm Brodifacoum	<p>House mouse (<i>Mus musculus</i>)</p> <p>Wild population located on a poultry farm in [REDACTED] UK (resistance status unknown)</p>	<p>A pre-treatment census using untreated whole grain and sand trays was employed to measure rodent populations both quantitatively and qualitatively for a period of 4 days prior to commencement of the test.</p> <p>The pre-treatment census showed a population of rodents primarily established inside a grain silo. Droppings established these rodents to be mice.</p> <p>A lag period of three days between the census data and the trial was observed.</p> <p>The trial was then undertaken using the product as per the proposed label instructions.</p> <p>25ppm Wax Block Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt</p>	<table border="1"> <thead> <tr> <th>Bait consumption</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> </thead> <tbody> <tr> <td>Total bait consumption (g)</td> <td>53</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily bait consumption (g)</td> <td>16</td> <td>0</td> <td>100</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <th>Activity over sand patches</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> <tr> <td>Total activity score</td> <td>10</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily activity score</td> <td>4</td> <td>0</td> <td>100</td> </tr> </tbody> </table> <p>30g of treated bait was consumed during the 6 day baiting phase.</p>	Bait consumption	Pre-treatment census	Post-treatment census	% control	Total bait consumption (g)	53	0	100	Maximum daily bait consumption (g)	16	0	100					Activity over sand patches	Pre-treatment census	Post-treatment census	% control	Total activity score	10	0	100	Maximum daily activity score	4	0	100	[REDACTED] (2016)
Bait consumption	Pre-treatment census	Post-treatment census	% control																														
Total bait consumption (g)	53	0	100																														
Maximum daily bait consumption (g)	16	0	100																														
Activity over sand patches	Pre-treatment census	Post-treatment census	% control																														
Total activity score	10	0	100																														
Maximum daily activity score	4	0	100																														

			<p>were either topped up or swapped with fresh bait.</p> <p>The trial was ended after 6 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</p>	<p>No evidence was found during the trial that the use of 25ppm Brodifacoum Wax block Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. Complete (100%) control of <i>Mus musculus</i> achieved based on census baiting and tracking.</p>	
--	--	--	---	---	--

4.6 Other

None

[Redacted]

[Redacted]

[Redacted]

Annex 1 - Initial PAR – July 2013



Product Assessment Report

Vertox[®] Oktablok (Red, Blue)

Active substance: **Brodifacoun**
Product-type: **PT 14: Rodenticides**
Type of application: **Authorisation**
Authorisation No: **IE/BPA 70232 (Professional)**
IE/BPA 70232-001 (Red)
IE/BPA 70232-002 (Blue)
IE/BPA 70233 (Non-professional)
IE/BPA 70233-001 (Red)
IE/BPA 70233-002 (Blue)
Date: **18 July 2013**

Version 1.1

Biocidal Product Assessment Report (PAR) related to
Product Authorisation under Directive 98/8/EC.



Pesticide Registration and Control Division
Department of Agriculture, Food and the Marine
Backweston Campus
Young's Cross
Celbridge
Co. Kildare
Ireland

CONTENTS

1.	General information about the product application	116
1.1.	Applicant/ Authorization Holder	116
1.2.	Marketing/Distributing Company (where applicable)	116
1.3.	General Information on the Biocidal Product	116
1.4.	Information on active substance(s)	117
1.5.	Information on the intended use(s) of the biocidal product	118
1.6.	Documentation	120
	<i>DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION</i>	120
	<i>ACCESS TO DOCUMENTATION</i>	120
2	Classification, labelling and packaging	121
2.1.	Harmonised classification of the active substance	121
2.2.	Harmonised classification and labelling of the biocidal product	122
2.3.	Packaging	125
3.0.	Summary of the product assessment	136
3.1.	Physico/chemical properties and analytical methods	136
3.1.1.	Identity related issues	136
3.1.2.	<i>PHYSICO-CHEMICAL PROPERTIES</i>	137
3.1.3.	Physical, Chemical and Technical Properties of the Biocidal Product	138
3.1.4.	<i>ANALYTICAL METHODS</i>	147
3.1.5.	<i>ANALYTICAL METHOD FOR THE RELEVANT IMPURITIES, ISOMERS AND CO-FORMULANTS IN THE BIOCIDAL PRODUCT</i>	148
3.2.	Efficacy of the Biocidal Product	149
3.2.1.	<i>FUNCTION/FIELD OF USE</i>	149
3.2.2	<i>ORGANISMS TO BE CONTROLLED</i>	149
3.2.3	<i>DOSE/MODE OF ACTION</i>	149
3.2.4	<i>EFFECTS ON THE TARGET ORGANISMS (EFFICACY)</i>	149
3.2.5	<i>KNOWN LIMITATIONS (E.G. RESISTANCE)</i>	151
3.2.6	<i>HUMANENESS</i>	154
3.3.	Biocidal Product Risk Assessment (Human Health and the Environment)	155
3.3.1	<i>DESCRIPTION OF THE INTENDED USE(S)</i>	155
3.3.2	<i>HAZARD ASSESSMENT FOR HUMAN HEALTH</i>	155
3.3.3	<i>EXPOSURE ASSESSMENT FOR HUMAN HEALTH</i>	163
3.3.4.	<i>RISK CHARACTERISATION FOR HUMAN HEALTH</i>	171
3.3.5.	<i>EFFECT AND EXPOSURE ASSESSMENT FOR THE ENVIRONMENT</i>	174
3.3.6.	<i>EXPOSURE ASSESSMENT FOR THE ENVIRONMENT</i>	182
3.3.7.	<i>RISK CHARACTERISATION FOR THE ENVIRONMENT</i>	192
	<i>NON COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN</i>	194
3.4.	Measures to protect man, animals and the environment	202
3.4.1	<i>METHODS AND PRECAUTIONS CONCERNING HANDLING, USE, STORAGE, TRANSPORT OR FIRE</i>	202
3.4.2	<i>SPECIFIC PRECAUTIONS AND TREATMENT IN CASE OF AN ACCIDENT</i>	203
3.4.3	<i>PROCEDURES FOR CLEANING APPLICATION EQUIPMENT</i>	205
3.4.4	<i>IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE</i>	206
3.4.5	<i>PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING</i>	206
3.4.6	<i>POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING ACCIDENTAL RELEASE</i>	206
3.4.7	<i>UNDESIRABLE OR UNINTENDED SIDE-EFFECTS</i>	206
3.4.8	<i>POISON CONTROL MEASURES</i>	206
4.	Proposal for Decision	208

1. General information about the product application

This application for product authorisation is for:

Trade name:	Vertox® Oktablok
Authorisation No.:	IE/BPA 70232 (Professional and Trained Professional) IE/BPA 70233 (General public / Non-professional)
	Please refer to the Frame Formulation document attached to this PAR: Products with the suffix -001 contain the red colour dye. Products with the suffix -002 contain the blue colour dye.

Vertox Oktablok trade names in other Member States (based on R4BP data):

Trade name	Member State
Brodifacoum Wax Block	Greece
CARAT Mus og Rattemiddel	Norway
Country Rat & Mouse Killer Brodifacoum Block Bait	UK
Rotan Brodifacoum Blokke	Norway
Ratex Wax Block	Spain
Vertox – Momeala Blocuri de ceara	Romania
Vertox Oktablok	Bulgaria + Cyprus
Vertox Wax Block Bait	UK
Vertox Wax Blocks	Czech Republic
Vertox Weatherproof Block	Ireland

1.1. Applicant/ Authorization Holder

Company Name:	PelGar International Ltd,
Address:	Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK
Tel:	+44 1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.2. Marketing/Distributing Company (where applicable)

Company Name:	N/A
Address:	N/A
Tel:	N/A
E-mail:	N/A
Contact:	N/A

1.3. General Information on the Biocidal Product

Trade name:	Vertox® Oktablok
Manufacturer's development code number(s):	N/A
Active substance content:	0.005% w/w Brodifacoum
Main group:	MG03 Pest Control
Product type:	PT14 (Rodenticides)
Product Specification:	See Confidential Annex
Site of product formulation:	See Confidential Annex
Frame formulation (yes/no):	Yes (see additional Frame Formulation document)
Formulation type:	BB Block Bait RB Ready-to-use bait
Ready to use product (yes/no):	Yes
Chemical/micro-organism:	Chemical Substance
Contain or consist of GMOs¹³ (yes/no):	N/A
Is the product already notified/authorised (Directive 98/8/EC) (yes/no); If yes: product name:	Vertox Wax Blocks (Professional) PCS 95567
Is the biocidal product equivalent to the product assessed for the purpose of Annex I inclusion to 98/8/EC (yes/no):	No.

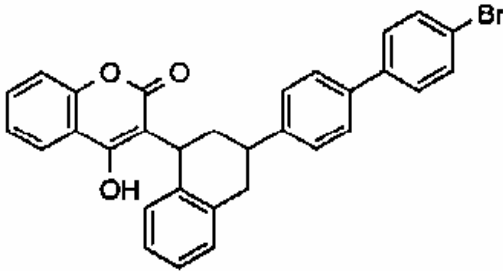
Manufacturer of Formulated Product	
Company Name:	PelGar International Ltd,
Address:	Unit 13, Newman Lane Industrial Estate, Newman Lane, Alton Hampshire GU34 2QR, UK
Tel:	+44 1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.4. Information on active substance(s)¹⁴

Active substance chemical name:	Brodifacoum
IUPAC name:	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
CAS No:	56073-10-0
EC No:	259-980-5

¹³ A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

¹⁴ Please insert additional columns as necessary

Purity (minimum, g/kg or g/l):	950 g/kg
Molecular formula:	C ₃₁ H ₂₃ BrO ₃
Structural Formula:	
Manufacturing site:	See Confidential Annex
Specification of pure active substance:	See Confidential Annex
Is a new active substance data package (source) supplied (yes/no):	No
If yes, Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	N/A
If no, does the applicant have a LoA to the active substance data packaged used to support Annex I inclusion (yes/no):	Yes (Pelgar International Ltd.)

Manufacturer of active substance(s)	
Company Name:	Pelgar International Ltd.
Address:	Unit 13 Newman Lane Industrial Estate Alton. Hants. GU34 2 QR UK
Tel:	+44 (0)1420 80744
E-mail:	anne@pelgar.co.uk
Contact:	Ms Anne Withall

1.5. Information on the intended use(s) of the biocidal product

Main Group:	MG03 (Pest control)
Product-type:	PT14 (Rodenticide)
Intended use:	Brodifacoum wax block bait to control rodents indoors, outdoors around buildings and in sewers for the protection of public health, stored products and materials.
Target organisms:	(I.1) Rodents (I.1.1) Murids (I.1.1.1) Brown rats (<i>Rattus Norvegicus</i>) (I.1.1.3) House mouse (<i>Mus musculus</i> and <i>Mus domesticus</i>)
Development stage:	(II.1) Juveniles (II.2) Adults
Function:	Rodenticide
Mode of action:	Anticoagulant

	<p>III.2 long-term action III.2.1 anticoagulant III.2.1.1 ingestion toxin III.2.1.1.1 ingestion by eating</p>
Application aim:	<p>VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)</p>
Category of users:	<p>V.1 Non Professional/General public V.2 Professional V.3 Trained/specialised professional</p>
Area of use (indoors/outdoors):	<p>IV.1 Indoors (warehouses, houses, outbuildings) IV.2 Outdoors (in and around buildings), IV.3 Sewers (IE/BPA 70232 only)</p>
Application method:	<p>VI.2 Covered applications VI.2.1 In bait stations VI.2.2 Other coverings</p>
Directions for use including minimum and maximum application rates, typical size of application area:	<p>IE/BPA 70232, IE/BPA 70233 Indoors and outdoors (in and around buildings) Rats (Adult and Juvenile): Secure 10-60g of bait in covered, tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).</p> <p>Mice (Adult and Juvenile): Secure 5-20g of bait, in covered, tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).</p> <p>In sewers (IE/BPA 70232 only) Rats (Adult and Juvenile): Secure 20-200g of blocks per station to available structures to ensure the block is not washed away. Regularly check bait consumption and replace consumed or spoilt bait until</p>

	consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no):	No

1.6. Documentation

Data submitted in relation to product application

A full new product dossier was submitted by Pelgar International Ltd. in support of the product Vertox® Oktablok containing brodifacoum.

Relevant access to active substance data was obtained, see below under section 1.6.2. In addition, confirmatory data on the active substance was submitted and assessed by Germany. The Irish CA for Biocides agreed with the conclusion drawn on this data on Brodifacoum.

Please see the attached reference list in Annex IV.

Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the Pelgar/Activa taskforce for the EU review programme.

Pelgar International Ltd. is a member of the RDDG and has a letter of access to a study owned by the RDDG consortium, the study is 'Validation of analytical methodology to determine rodenticides in food matrices'. This study was carried out by Central Science Laboratory (CSL) in York, UK. Study number PGD-180.






2 Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

2.1. Harmonised classification of the active substance

Brodifacoum is not currently classified in Annex I of Council Directive 67/548/EEC or according to Annex VI of Regulation (EC) no 1907/2006 (REACH). The following classification and labelling is proposed on the basis of available data resulting from the review programme for brodifacoum and is provided in the table below according to Directive 67/548/EEC/Regulation (EC) 1272/2008. Additionally, the extrapolation of these proposals using the BG RCI converter tool (<http://www.gischem.de/ghs/konverter>) is also provided in the table below in accordance with Regulation (EC) 1272/2008.

Classification of the active substance, brodifacoum, according to Directive 67/548/EEC and CLP Regulation (EC) 1272/2008:

Symbol(s):	 	Pictogram(s):	  
Indication(s) of danger:	T+ Very Toxic N Dangerous for the Environment	Signal word(s):	Danger
Risk phrases:	R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed. R43: May cause sensitisation by skin contact R48/23/24/25: Toxic: Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61: May cause harm to the unborn child. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	Hazard statements:	H300: Fatal if swallowed. H310: Fatal in contact with skin. H317: May cause an allergic skin reaction H330: Fatal if inhaled. H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure through inhalation. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Safety phrases:	S20/21: When eating do not eat, drink or smoke S35: The material and its container must be disposed of in a safe way S36/37: Wear suitable protective clothing and gloves S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheet.	Precautionary statements:	P101: If medical advice is needed, have product container or label at hand. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves and clothing P281: Use personal protective equipment as required. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

			<p>P308 + P313: IF exposed or concerned: Get medical advice/attention. P314: Get medical advice/attention if you feel unwell. P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations.</p>
--	--	--	--

Specific concentration limits for brodifacoum are proved below in accordance with Directive 67/548/EEC:

Specific concentration limits:	$C \geq 2.5\%$	T+, N; R26/27/28-48/23/24/25-43-61-50/53
	$1\% \leq C < 2.5\%$	T+, N; R26/27/28-48/23/24/25-43-61-51/53
	$0.5\% \leq C < 1\%$	T+, N; R26/27/28-48/23/24/25-61-51/53
	$0.25\% \leq C < 0.5\%$	T+, N; R26/27/28-48/23/24/25-51/53
	$0.025\% \leq C < 0.25\%$	T ; R23/24/25-48/20/21/22-52/53
	$0.0025\% \leq C < 0.025\%$	Xn; R20/21/22

Additionally, brodifacoum does not exhibit hazardous physical-chemical properties. Brodifacoum is thermally stable at 52°C. It is not classified as highly flammable and does not undergo self ignition below its melting point. It is not considered to be explosive or to have oxidising properties. There is no record that it has reacted with any storage container during many years of industrial production. It is concluded therefore, that there are no hazards associated with its physico-chemical properties under normal conditions of use.

2.2. Harmonised classification and labelling of the biocidal product

The current classification and labelling, based on the biocidal product evaluation for Vertox® Oktablok, is provided in the tables below according to Directive 99/45/EC and Regulation (EC) 1272/2008, Annex VI, Part 3.

Classification and Labelling of the biocidal product according to Directive 99/45/EC:

Symbol(s):	N/A
Indication(s) of danger:	N/A
Risk phrases:	N/A
Safety phrases:	<p>S1+S2: Keep locked up and out of reach of children S13: Keep away from food, drink and animal feeding stuffs. S20 + S21: When using do not eat, drink or smoke. S24: Avoid contact with skin S35: This material and its container must be disposed of in a safe way. S37: Wear suitable gloves (Professional Only) S46: If swallowed, seek medical advice immediately and show this container or label. S49: Keep only in the original container</p>

	S61: Avoid release to the environment. Refer to special instructions/safety data sheet
--	--

Classification and Labelling of the biocidal product according to the CLP Regulation (EC) 1272/2008:

Pictogram(s):	N/A
Signal word(s):	N/A
Hazard statements:	N/A
Precautionary statements	<p>P102: Keep out of reach of children.</p> <p>P103: Read label before use.</p> <p>P220: Keep/Store away from food, drink and animal feedingstuffs.</p> <p>P262: Do not get on skin</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P273: Avoid release to the environment</p> <p>P280: Wear protective gloves (Professionals only)</p> <p>P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician.</p> <p>P404+405: Store locked up in a closed container.</p> <p>P501: Dispose of contents/container in accordance with national regulations.</p>

Physical-chemical properties:

Not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view.

Toxicology:

There is no toxicology classification for the product under the Directive 99/45.

There is no toxicology classification for the product under the CLP Regulation 1272/2008.

Environment:

There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

Other:

Further, the content of the label should be updated to comply with the labelling requirements established (for biocidal products) where the labelling requirements in Article 20(3) of Directive 98/8/EC has been implemented. The safety data sheet should comply with the requirements in Regulation (EC) 1907/2006.

Additional Labelling Requirements:

Addition safety Information:	<p>To avoid risks to human health and the environment, comply with the instructions for use.</p> <p>Harmful to wildlife</p> <p>Use bait containers clearly marked "poison" at all surface baiting points.</p> <p>Remove all remains of bait, dead rodents during and after treatment and dispose of safely.</p> <p>Apply only in positions inaccessible to children and pets.</p>
Special labelling provisions for Ireland:	<p>Use Biocides Safely and Sustainably (IE/BPA 70232) Not For Amateur Sale</p> <p>It is illegal to use this product for uses or in a manner other than that prescribed on this label.</p>
If a separate leaflet is attached to or supplied with the product, add the following information to the front label:	<p>Read attached instructions before use</p>

2.3. Packaging

The packaging details for the biocidal product, Vertox® Oktablok, as presented by the applicant, are outlined below for amateur and professional users.

Nomenclature: PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride, AL = Aluminium

Amateur product packaging:

On the basis of the packaging details presented, it is considered appropriate to limit aspects of the packaging for amateur users as a risk mitigation measure. Packaging restrictions are to be limited to pre-baited bait stations and refill packs with a **maximum pack-size of 500g**. Additionally, the block bait should be supplied to the amateur market in sachets/wrapped in order to reduce exposure risks to amateur operators during application to bait stations. This is an Irish RMM, loose blocks can be MR in OMS.

The applicant applied for pack sizes greater than 500g for amateur products, these are detailed below with a strikethrough (i.e. ~~strikethrough~~). The Irish RMM allows a maximum pack size of 500g and therefore only pack sizes up to 500g were authorised for amateur users in Ireland. Pack sizes >500g mentioned below can be authorised in OMS.

Amateur Product Packaging:

Product packaging: Tub

Container description:	Tub or pail							
Pack size(s):	500g	1kg	1.5kg	100g	150g	200g	250g	300g
Baits per pack:	100x5g	200x5g	300x5g	20x5g	30x5g	40x5g	50x5g	60x5g
	50x10g	100x10g	150x10g	10x10	15x10g	20x10g	25x10g	30x10g
	25x20g	50x20g	75x20g	g	7x20g	10x20g	12x20g	15x20g
	17x28g	35x28g	53x28g	5x20g	5x28g	7x28g	8x28g	10x28g
	10x50g	20x50g	30x50g	3x28g	3x50g	4x50g	5x50g	6x50g
				2x50g				
Packaging materials:	PE or PP tub or pail							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							

Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Product packaging: Cardboard Box

Container description:	lined cardboard outers or bags in cardboard box							
Pack size(s):	500g	4kg	1.5kg	100g	150g	200g	250g	300g
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	200x5g 400x10g 50x20g 35x28g 20x50g	300x5g 150x10g 75x20g 53x28g 30x50g	20x5g 10x10 g 5x20g 3x28g 2x50g	30x5g 15x10g 7x20g 5x28g 3x50g	40x5g 20x10g 10x20g 7x28g 4x50g	50x5g 25x10g 12x20g 8x28g 5x50g	60x5g 30x10g 15x20g 10x28g 6x50g
Packaging materials:	PE lined cardboard outers or PE bags in cardboard box							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 years							
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.							

Product packaging: Cardboard Outer

Container description:	pouches with or without cardboard outer							
Pack size(s):	500g	4kg	1.5kg	100g	150g	200g	250g	300g
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	200x5g 400x10g 50x20g 35x28g 20x50g	300x5g 150x10g 75x20g 53x28g 30x50g	20x5g 10x10 g 5x20g 3x28g 2x50g	30x5g 15x10g 7x20g 5x28g 3x50g	40x5g 20x10g 10x20g 7x28g 4x50g	50x5g 25x10g 12x20g 8x28g 5x50g	60x5g 30x10g 15x20g 10x28g 6x50g
Packaging materials:	paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer							
Inner Packaging:	Blocks are wrapped in PP or PE for amateur use							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 years							
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.							

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station		
Pack size(s):	10g (x 1, 2 or 4)	15g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	2 x 5g	3 x 5g	4 x 5g
Multiples of pack	1, 2 or 4	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station		

Outer packaging	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 years		
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.		

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	10g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	1 x 10g	2 x 10g
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	20g (x 1, 2 or 4)
Baits per pack:	1 x 20g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	40g (x 1, 2 or 4)	60g (x 1, 2 or 4)
Baits per pack:	2 x 20g	3 x 20g
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Amateur product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	50g (x 1, 2 or 4)
Baits per pack:	1 x 50g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Professional Product Packaging:**Product packaging: Tub**

Container description:	Tub or pail						
User Category	Prof	Prof	Prof	Prof	Prof	Prof	Prof
Pack size(s):	500g	1kg	1.5kg	2.5kg	4kg	5kg	6kg
Baits per pack:	100x5g 50x10g 25x20g 17x28g 10x50g	200x5g 100x10g 50x20g 35x28g 20x50g	300x5g 150x10g 75x20g 53x28g 30x50g	500x5g 250x10g 125x20g 89x28g 50x50g	800x5g 400x10g 200x20g 142x28g 80x50g	1000x5g 500x10g 250x20g 178x28g 100x50g	1200x5g 60x10g 30x20g 214x28g 120x50g
Packaging materials:	PE or PP tub or pail						
Ready-to-use (yes/no)	Yes						
Shelf-life:	2 years						
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.						

Product packaging: Double-walled or fibreboard carton

Container description:	Double-walled or fibreboard carton		
Pack size(s):	10kg	20kg	12kg
Baits per pack:	2000x5g 1000x10g 500x20g 257x28g 200x50g	4000x5g 2000x10g 1000x20g 714x28g 400x50g	2400x5g 1200x10g 600x20g 428x28g 240x50g
Packaging materials:	Cardboard or fibreboard	Cardboard or fibreboard	Fibreboard carton (moulded styrene)
Inner Packaging materials:	Unlined, PP or PE bag	Unlined, PP or PE bag	N/A
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 years		

Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.
-------------------------------	---

Product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station		
Pack size(s):	10g (x 1, 2 or 4)	15g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	2 x 5g	3 x 5g	4 x 5g
Multiples of pack	1, 2 or 4	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station		
Outer packaging	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes		
Shelf-life:	2 years		
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.		

Professional product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	10g (x 1, 2 or 4)	20g (x 1, 2 or 4)
Baits per pack:	1 x 10g	2 x 10g
Multiples of pack	1, 2 or 4	1, 2 or 4
Packaging materials:	HDPE or PP bait station	

Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Professional product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	20g (x 1, 2 or 4)	
Baits per pack:	1 x 20g	
Multiples of pack	1, 2 or 4	
Packaging materials:	HDPE or PP bait station	
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Professional product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station	
Pack size(s):	40g (x 1, 2 or 4)	60g (x 1, 2 or 4)
Baits per pack:	2 x 20g	3 x 20g
Multiples of pack	1, 2 or 4	1, 2 or 4

Packaging materials:	HDPE or PP bait station	
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Professional product packaging: Single or Multi-use tamper-proof bait station

Container description:	Single or Multi-use tamper-proof HDPE or PP bait station
Pack size(s):	50g (x 1, 2 or 4)
Baits per pack:	1 x 50g
Multiples of pack	1, 2 or 4
Packaging materials:	HDPE or PP bait station
Outer packaging	Packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper
Ready-to-use (yes/no)	Yes
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Pack size:

Amateur Packs: IE/BPA 70233 – Maximum pack size of 500g
 Tub or Pail containing 5g, 10g, 20g, 28g and 50g blocks: PE or PP 500g
 Tamper-proof bait stations containing 5g, 10g, 20g or 50g blocks: HDPE or PP 10g, 15g, 20g, 40g, 50g or 60g

Professional Packs: IE/BPA 70232

Tub or Pail containing 5g, 10g, 20g, 28g and 50g blocks: PE or PP
 500g, 1kg, 1.5kg, 2.5kg, 4kg, 5kg, or 6kg
 Double-walled or fibreboard carton containing 5g, 10g, 20g, 28g
 and 50g blocks either unlined or in a PP or PE bag: 10kg, 20kg
 Double-walled or fibreboard carton containing (moulded styrene)
 5g, 10g, 20g, 28g and 50g blocks: 12kg
 Tamper-proof bait stations containing 5g, 10g, 20g or 50g blocks:
 HDPE or PP 10g, 15g, 20g, 40g, 50g or 60g

Container materials¹⁵:

Tub or pail – PP or PE
 Tamper-proof bait station – HDPE, PP
 Carton – Double-walled or fibreboard carton

Safety features:

Covered bait stations (tamper resistant)
 Wrapped bait for amateur users

¹⁵ PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride

3.0. Summary of the product assessment

3.1. Physico/chemical properties and analytical methods

Active substance (taken from the Activa/PelGar Brodifacoum and Difenacoum Task Force CAR):

Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C. Brodifacoum is non-volatile, with a Henry's Law Constant value of 2.35E-18 Pa.m³.mol⁻¹. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4-hydroxycoumarin group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log P_{ow} was found to be 4.92 at pH 7 and 20°C. As expected, Log P_{ow} decreased with higher temperature and pH. Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

Biocidal product:

The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (20°C). The test item is a ready-to-use block bait and is not intended to be added or mixed with any other product.

3.1.1. Identity related issues

An equivalence check was carried out by Italy that showed that the PelGar source of Brodifacoum active substance was equivalent to the source of Brodifacoum active substance listed in Annex I of 98/8/EC (see Annex I: Confidential Information and Data).

Composition of the biocidal product Vertox Oktablok

Component	% w/w	g/kg	Chemical name	CAS no	Function
Brodifacoum	0.005	0.05	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	56073-10-0	Active substance
Co-formulants	See Confidential Data and Information (Annex I)				

Note: The biocidal product Vertox Oktablok is not the same as the representative biocidal product accompanying the Annex I inclusion. See confidential information and data for details of the composition of Vertox Oktablok.

3.1.2. Physico-chemical properties

PelGar International Limited is a member of the Activa/PelGar Difenacoum and Brodifacoum Task Force and as such has access to the complete Annex I listing documentation submitted by this group. In this case, since PelGar are data owners, a Letter of Access is not required.

3.1.3. *Physical, Chemical and Technical Properties of the Biocidal Product*

Summary of the Physical and Chemical Properties of the Biocidal Product Vertox Oktablok

Section	Study	Method	Results	Comment	Reference
1.1	Appearance	Observation (appearance). Odour (nasal inhalation)	Colour: Dark red Physical state: Opaque waxy octagonal block (~35 x 35 x 15 mm) containing light brown grains and a small hole on top. Odour: Strong sweet smell.	Carried out to GLP. Carried out at 20°C ± 0.5°C. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17 th July 2007.
1.2.1	Explosive properties	Justification	"Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity. On the basis of the above, a derogation to perform this study is requested."	The RefMS accepts the applicants justification for the non-submission of data. Vertox Oktablok is not explosive.	
1.2.2	Oxidising properties	Justification	Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested.	The RefMS accepts the applicants justification for the non-submission of data. Vertox Oktablok is not oxidising.	
1.3.1	Flash point			Not required. The test item is not a liquid.	

Section	Study	Method	Results	Comment	Reference
1.3.2	Flammability	EEC method A 10.	Preliminary screening test: The pile ignited with an orange flame and propagated 33 mm in 4 minutes 12 seconds. The result of the preliminary screening test obviated the need to perform the main test.	Carried out to GLP. The test material has been determined to be not highly flammable as it did not propagate combustion over the 200 mm of the preliminary screening test. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17 th July 2007.
1.3.3	Auto-flammability	EEC method A 16.	The test material was determined to have a relative self-ignition temperature of 237°C.	Carried out to GLP. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17 th July 2007.
1.4.1	Free acidity/ Alkalinity	Justification	Product is a large solid wax block composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested.	The RefMS accepts the applicants' justification for the non-submission of data.	
1.4.2	pH (1 %)			Not required. See 1.4.1 above.	
1.5.1	Viscosity	Justification	The product is a solid block at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	The RefMS accepts the applicants' justification for the non-submission of data. Not required for Vertox Oktablok (solid wax block bait) as the	

Section	Study	Method	Results	Comment	Reference									
				product is not mixed with water.										
1.5.2	Surface tension	Justification	The product is a solid block at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	The RefMS accepts the applicants' justification for the non-submission of data. Not required for Vertox Oktablok (solid wax block bait) as the product is not mixed with water.										
1.6	Relative density	EEC method A 3.	1.17 at 20°C ± 0.5°C.	Carried out to GLP. Carried out using a gas comparison pycnometer. The results are acceptable.	"Brodifacoum wax block: Determination of physico-chemical properties". SPL Project number: 2254/0037. Fox, J.M. and Mullee, D.M. 17 th July 2007.									
1.7.1a	Storage stability – Accelerated storage (storage at 54°C for 2 weeks)	CIPAC MT 46	<p>Aspect:</p> <p>T₀ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{14 days} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>The appearance of the samples was satisfactory and there was no indication of loss of product integrity.</p> <p>Content of active substance:</p> <table border="1"> <thead> <tr> <th></th> <th>Conc. (mg/kg)</th> <th>Deviation from T₀</th> </tr> </thead> <tbody> <tr> <td>T₀</td> <td>50</td> <td>-</td> </tr> <tr> <td>T_{14 days}</td> <td>51</td> <td>+2.0%</td> </tr> </tbody> </table>		Conc. (mg/kg)	Deviation from T ₀	T ₀	50	-	T _{14 days}	51	+2.0%	Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray. The test item is stable after storage at 54°C for 2 weeks. The results are acceptable.	"Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum". Study reference code: 96021261. Thomas, K.T. 16 th July 1999.
	Conc. (mg/kg)	Deviation from T ₀												
T ₀	50	-												
T _{14 days}	51	+2.0%												

Section	Study	Method	Results	Comment	Reference															
1.7.1b	Storage stability (storage at 40°C)		<p>Aspect:</p> <p>T₀ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{6 months} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{1 year} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{2 years} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>The appearance of the samples was satisfactory and there was no indication of loss of product integrity.</p> <p>Content of active substance:</p> <table border="1"> <thead> <tr> <th></th> <th>Conc. (mg/kg)</th> <th>Deviation from T₀</th> </tr> </thead> <tbody> <tr> <td>T₀</td> <td>52</td> <td>-</td> </tr> <tr> <td>T_{6 months}</td> <td>53</td> <td>+1.9%</td> </tr> <tr> <td>T_{1 yr}</td> <td>52</td> <td>None</td> </tr> <tr> <td>T_{2 yrs}</td> <td>52</td> <td>None</td> </tr> </tbody> </table>		Conc. (mg/kg)	Deviation from T ₀	T ₀	52	-	T _{6 months}	53	+1.9%	T _{1 yr}	52	None	T _{2 yrs}	52	None	<p>Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray.</p> <p>The test item is stable after storage at 40°C for 2 years.</p> <p>The results are acceptable.</p>	<p>“Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum”. Study reference code: 96021261. Thomas, K.T. 16th July 1999.</p>
	Conc. (mg/kg)	Deviation from T ₀																		
T ₀	52	-																		
T _{6 months}	53	+1.9%																		
T _{1 yr}	52	None																		
T _{2 yrs}	52	None																		
1.7.2	Shelf life – Ambient temperatures (storage at 25°C)		<p>Aspect:</p> <p>T₀ = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{6 months} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{1 year} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{2 years} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p> <p>T_{3 years} = Red block measuring ~ 35 mm square and 13 mm in depth with a hole through the centre.</p>	<p>Carried out to GLP. The test item was stored in a PE (polyethylene) casting tray.</p> <p>The test item is stable after storage at ambient temperatures for 3 years at 25°C.</p> <p>The results are acceptable.</p>	<p>“Storage stability and Physical-Chemical Characteristics of a 0.005% w/w Wax Block formulation of Brodifacoum”. Study reference code: 96021261. Thomas, K.T. 16th July 1999.</p>															

Section	Study	Method	Results	Comment	Reference															
			<p>The appearance of the samples was satisfactory and there was no indication of loss of product integrity.</p> <p>Content of active substance:</p> <table border="1"> <thead> <tr> <th></th> <th>Conc. (mg/kg)</th> <th>Deviation from T₀</th> </tr> </thead> <tbody> <tr> <td>T₀</td> <td>53</td> <td>-</td> </tr> <tr> <td>T_{1 yr}</td> <td>53</td> <td>None</td> </tr> <tr> <td>T_{2 yrs}</td> <td>51</td> <td>-3.8%</td> </tr> <tr> <td>T_{3 yrs}</td> <td>52</td> <td>-1.9%</td> </tr> </tbody> </table> <p>Vertox Oktablok: is a solid material, which does not allow active substance (AS) to migrate because the wax (paraffin) does not dissolve AS. Further, during the manufacturing process of the Oktablok, cereal grain and flour is firstly impregnated with brodifacoum concentrate in propylene glycol where there is a good affinity to grain and flour, formed from polyhydroxy- material (polysaccharides - cellulose and starch), that enables the propylene glycol solution to penetrate inside the grains. Signs of this are that the grains are coloured whereas the paraffin remains colourless (the dyestuff is also a large organic molecule). The paraffin may be coloured under macroscopic observation, but this is caused by small particles released from the grain being mechanically suspended into the paraffin outer layer.</p> <p>So, the paraffin forms a further insulation layer between the AS and the surrounding environment. The wax is inert and will not react with any type of packaging.</p>		Conc. (mg/kg)	Deviation from T ₀	T ₀	53	-	T _{1 yr}	53	None	T _{2 yrs}	51	-3.8%	T _{3 yrs}	52	-1.9%		
	Conc. (mg/kg)	Deviation from T ₀																		
T ₀	53	-																		
T _{1 yr}	53	None																		
T _{2 yrs}	51	-3.8%																		
T _{3 yrs}	52	-1.9%																		
1.7.3	Packaging stability	Justification	From the packing materials used by PelGar the following materials may come into contact with the baits/AS: paper (cellulose), Polyethylene (PE) and Polypropylene (PP).	The RefMS accepts the applicant's justification.																

Section	Study	Method	Results	Comment	Reference
			<p>Paper (cellulose)/‘tea-bags’: cellulose is a polysaccharide and chemically the same as starch or cellulose in grain, flour, i.e. has the same degree of chemical inertness. Cellulose could potentially adsorb some AS, but in case of sachets of pasta this is not possible because brodifacoum cannot migrate through the lard due to its physico-chemical properties as explained above. Additionally, once the cellulose is impregnated with lard it will lose its ability to adsorb brodifacoum.</p> <p>PE and PP: both materials are hydrocarbons similar to paraffins with long hydrocarbon chains, which are inert and will not react with the AS under normal conditions. PE and PP do not contain any reactive substituents and because they are non polar substances, will not adsorb any AS.</p> <p>All the baits are solid, non-free flowing materials. Point contact with the packing material will therefore be further reduced limiting interaction.</p> <p>As a further observation both PE and PP are used for the packing of strong acids, strong bases, strong oxidizing chemical and strongly reducing agents (hydrides), hydrofluoric acid etc and are stable. Given the stability of these far more reactive chemicals in these packaging materials, it is clear that the inert rodenticide baits will be stable when stored in these materials.</p> <p>In conclusion, the rodenticide baits are all extremely stable, solid materials and will not react with the inert packaging used for PelGar’s products. Given the nature of the products, it should be possible to support all the proposed packs using the storage data package available across the full range of PelGar products.</p>		

Section	Study	Method	Results	Comment	Reference
1.8.1	Wettability	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	
1.8.2	Persistent foaming	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	
1.8.3.1	Suspensibility			Not required for block baits. The product is a solid.	
1.8.3.2	Dispersibility			Not required for block baits. The product is a solid.	
1.8.4	Wet/dry sieving test			Not required for block baits. The product is a solid.	
1.8.5	Particle size distribution in suspension	Only for powders and granules.	The product is a solid wax block bait. It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested.	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	

Section	Study	Method	Results	Comment	Reference
1.8.6	Water content			Not required for block baits. The product is a solid.	
1.8.7	Emulsion stability		Only for ECs and ready for use emulsions.	Not required for block baits. The product is a solid.	
1.8.8	Flowability, pourability and dustability	Justification	Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty. On the basis of the above, a derogation to perform this study is requested	The RefMS accepts the applicants' justification for the non-submission of data. Not required for block baits. The product is a solid.	
1.9	Physical compatibility			Not required. The block bait is a ready to use bait that is not intended to be mixed with any other product.	

Conclusion:

The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical and chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (20°C). The test item is a ready-to-use block bait and is not intended to be added or mixed with any other product.

Data requirements:

None.

The block bait is considered compatible with the following packaging:

Polyethylene (PE) or polypropylene (PP) tubs or pails, double-walled or fibreboard carton, plastic or wire-tied polyethylene bag within a double-walled or fibreboard carton, fibreboard carton of 'uni-trays' (moulded styrene tray with pop-out blocks) and Blocks within HDPE or PP bait stations.

Proposed shelf life for the block bait:

3 years (based on ambient storage stability data).

	<table border="1"> <tr> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> </tr> <tr> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> </tr> <tr> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> <td>[REDACTED]</td> </tr> </table> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]												
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]												
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]												
[REDACTED]	[REDACTED]															
[REDACTED]	[REDACTED]															
[REDACTED]	[REDACTED]															

Conclusion:

The method of analysis is acceptable for the determination of Brodifacoum in waxed baits.

Data requirements:

None.

3.1.5. Analytical method for the relevant impurities, isomers and co-formulants in the biocidal product

Not applicable.

3.2. Efficacy of the Biocidal Product

3.2.1. Function/Field of use

PT14: Rodenticide

3.2.2 Organisms to be controlled

VERTOX® OKTABLOK® (containing 50 mg/kg brodifacoum) is a ready-to-use (RB) block bait (BB) which is proposed for the control of the brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and the house mouse mice (*Mus domesticus*, *Mus musculus*). The product is intended for use in domestic, industrial and commercial buildings, including in and around farm buildings and sewers. PelGar International Limited has claimed amateur and professional use of VERTOX® OKTABLOK® in and around buildings.

For rats, each bait point may contain a maximum of 60 g bait; a mouse point may contain a maximum of 20 g bait. Bait points are placed typically every 5-10m (rats) or 2-5 m (mice) depending on the level of infestation. The sewer use is intended solely for professionals and a maximum of 200g of bait per station is proposed.

3.2.3 Dose/Mode of action

Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K₁ epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidoting therapy (vitamin K₁).

3.2.4 Effects on the target organisms (efficacy)

Comprehensive data on the palatability and effectiveness of brodifacoum was assessed as part of the annex I inclusion process and the CAR confirmed that the baits are both palatable and effective in controlling the target pests. Additional data from trials using the block formulation were provided in the form of laboratory (including studies on bait subjected to sewer like conditions) and field studies to verify the proposed label claims.

Laboratory palatability and efficacy studies:

One laboratory palatability and efficacy (choice) test conducted on mice with bait aged for two years.

One laboratory palatability and efficacy (choice) test conducted on rats with fresh bait.

One laboratory palatability and efficacy (choice) test conducted on mice with fresh bait.

One laboratory palatability and efficacy (choice) test conducted on rats with bait aged for two years.

One laboratory study on determination of mould growth under simulated sewer conditions (28 day exposure).

Field efficacy studies:

Two field studies conducted on mice.

Two field studies conducted on rats.

Simulated use and palatability study:

One simulated use (choice) study on rats using anticoagulant-free bait stored in simulated sewer conditions.

PelGar International Limited provided the study reports from four laboratory choice studies conducted using VERTOX® OKTABLOK®. The experiments were all choice studies conducted according to OEPP/EPPO (1982) and US EPA (1982) guidance. Two studies were conducted on the house mouse, one with fresh bait and one with two year aged bait. Two additional studies were done on the brown rat, one of which used aged bait. The results from the studies are summarised in **Table 1**. The results demonstrated that VERTOX® OKTABLOK® is palatable to the house mouse and the brown rat according to the criteria given in TNsG on Product Evaluation as the bait intake was greater than 20% of the total food consumption in all the studies. The two years storage time in the ambient conditions was found not to adversely affect the palatability of the product. As all test animals (mice & brown rats) died within 8-10 days after the start of the experiments the results from the laboratory testing scheme confirm that product is both palatable to and effective against the target organisms.

Results from four field studies using VERTOX® OKTABLOK® were provided. The field trial programme achieved effectiveness figures of 99.4 to 99.7% (total census bait take) and 95.2% to 97.5% (maximum track score or total track score) for rats (*Rattus norvegicus*) and 100% control (total census bait take and maximum track score) for mice (*Mus musculus*).

Results on the performance of bait kept in simulated sewer conditions were also provided, albeit on a difenacoum based, wax block bait (ROBAN® Wax Blocks) which the applicant claims is of similar wax block formulation. No mould growth was detected during the 28 d study.

In addition, the performance of a so-called “blank” wax block bait which was stored under simulated sewage conditions (active substance removed and replaced with propylene glycol) was assessed. There was no detrimental effect on palatability of bait left in ‘sewer’ like conditions for periods up to and including 5 days. The report’s conclusions indicated that the ‘sewer’ bait was more palatable than the normal bait.

No efficacy data using the wax block formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat may be used on the label.

Table 1. : Experimental data on the effectiveness of VERTOX® OKTABLOK® containing 50 mg/kg brodifacoum against the intended target organisms

Test organism	Test system/ Test conditions	Test results: effects, mode of action, resistance	Reference
House mouse (<i>Mus musculus</i>)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 36% of the total food consumption. The mean consumption of the test product and the reference meal were 3.3 g and 5.9 g, respectively. 100% mortality 9-10 d after the start of exposure.	B5.10.2(1)
House mouse (<i>Mus musculus</i>)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 38.1% of the total food consumption. The mean consumption of the test product and the reference meal were 3.7 g and 6.0 g, respectively. 100% mortality 8-9 d after the start of exposure.	B5.10.2(2)
Brown rat (<i>Rattus norvegicus</i>)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 37% of the total food consumption. The mean consumption of the test product and the reference meal were 36.7 g and 62.3 g, respectively. 100% mortality 8-10 d after the start of exposure.	B5.10.2(3)
Brown rat (<i>Rattus norvegicus</i>)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 35.1% of the total food consumption. The mean consumption of the test product and the reference meal were 34.2 g and 63.1 g, respectively. 100% mortality 9-10 d after the start of exposure.	B5.10.2(4)
House mouse	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(5)

Test organism	Test system/ Test conditions	Test results: effects, mode of action, resistance	Reference
(<i>Mus musculus</i>)			
House mouse (<i>Mus musculus</i>)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(6)
Brown rat (<i>Rattus norvegicus</i>)	Field trial	Efficacy based on total census bait take = 99.7% Efficacy based on total track score = 97.5%. No resistance noted. No other limiting factors noted.	B5.10.2(7)
Brown rat (<i>Rattus norvegicus</i>)	Field trial	Efficacy based on total census bait take = 99.4% Efficacy based on maximum track score = 95.2%	B5.10.2(8)
Not applicable	Determination of mould growth under simulated sewage inspection chamber conditions/ 28 d exposure	No mould growth was detected on the surface or inside the wax blocks by visual inspection.	B5.10.2(9)
Brown rat (<i>Rattus norvegicus</i>)	Palatability – blank wax block bait (minus AS concentrate)	No detrimental effect on palatability following storage of wax block bait in sewer conditions for 5 days. The sewer-treated bait comprised 66.8% of the total bait consumed.	B5.10.2 (10)

3.2.5 Known limitations (e.g. resistance)

The following resistance management strategy was proposed by the applicant:

Management of resistance

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance. The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants Brodifacoum, Flocoumafen and Difethialone and the non-anticoagulants Calciferol and Bromethalin, all appear to have a role in resistance management. A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical. A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance.

Prevention of Resistance

The following are considered the most feasible to limit the development of resistance to anticoagulants: Maximise the use of non-chemical control techniques.

Preferential use of rodenticides and formulations to which resistance rarely develops.

Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.

Further information on resistance is also provided in the Annex Document IIIB, Section 5.11. An extensive literature review was conducted by Pelgar International Limited which concluded that commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials are likely to be fully effective for the control of resistant rodents in the EU.

In addition, the IE CA recommends the following in relation to resistance management:

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003).

Resistance management strategies

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use.

To this extent the applicant suggests the following measures to aid in the prevention of resistance:

- Maximum use of non-chemical control techniques.
- Preferential use of rodenticides and formulations to which resistance rarely develops.
- Ensure the complete eradication of the target population whenever a rodenticide is used.
- Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.
- Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.

It is recommended that the label states that any instances of resistance are referred to the manufacturer of the a.s.

In order to prevent the development and spreading of resistance, some resistance management strategies measures such as those from the Codes of Good Practices in rodent control are recommended:

- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the infestation level.

- A complete elimination of rodents in the infested area should be achieved.
- The use instruction of products should contain guidance on resistance management for rodenticides.
- The authorisation holder shall report any observed resistance incident to the Competent Authorities or other appointed bodies involved in resistance management.

The proposed labels contain detailed instructions for use.

- The population size of the target rodent should be evaluated before a control campaign.
- The number of baits and the timing of the control campaign must be in proportion to the infestation level.
- Baits must be placed in a safe manner inaccessible to children and non-target species and not be applied to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product.
- Bait consumption should be regularly checked and consumed or spoilt bait replaced until consumption has stopped. The remaining baits and material must be removed and disposed of safely at the end of the treatment according to local/national wastes disposal regulation.
- Water must not be contaminated with the product or its container.
- The rodents' bodies all along the treatment must be disposed of according to local/national regulation.

In addition to the above applicant and label recommendations the RMS advocates the adoption of the following advice to avoid the development of resistance in susceptible rodent populations.

Details of treatment should be recorded.

- Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).
- Inspected baiting points weekly and replace old bait where necessary.
- Do not routinely use anticoagulant rodenticides as permanent baits. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas. (The RMS view is that routine use of anticoagulant baits should not be recommended in above described situations.) .
- Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting programme or apply alternative control techniques to eliminate the residual infestation (acute or sub-acute rodenticides, gassing or trapping).

Treatment of rodent infestations containing resistant individuals

- Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.
- Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.
- In both cases it is essential that complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.
- Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).

Application of area or block rodent control to eliminate resistance

- Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties.
- Where there are indications that resistance may be more extensive than a single infestation, apply area or block control rodent programmes.
- The area under such management should extend at least to the boundaries of the area known resistance and ideally beyond.
- These programmes must be effectively coordinated and should encompass the procedures identified above.

3.2.6 Humaneness

The use of brodifacoum as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. It is recognised that such substances do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 5.1 of Directive 98/8/EC 'to avoid unnecessary pain and suffering of vertebrates', as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

Conclusion:

Although the studies provided on simulated sewer conditions are non-standard they are considered adequate to support the proposed label claim on the basis of the fact that no negative effects on the palatability of the product were observed it may be concluded that the product is suitable for use in sewers.

The IE CA considers that the palatability and efficacy data provided is adequate to support the recommendation for the use of the product against rats and mice, even when stored for up to two years.

Issues identified:

The treatment frequency is 2-4 applications per year, 3-6 months apart, when re-infestation occurs.

This treatment frequency recommendation should be included on the draft label.

There are no indications as to application rate or recommendations relating to the use of bait in sewers on the draft professional product label. This must be addressed.

There is no indication on the draft label on how long the bait can be stored while still remaining effective.

No efficacy data using the wax block formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat may be used on the label.

3.3. Biocidal Product Risk Assessment (Human Health and the Environment)

3.3.1 Description of the intended use(s)

The product Wax Block is a rodenticide. It is a ready-to-use wax block bait which contains 50 ppm (0.005% w/w) brodifacoum (56073-10-0) used by professional and amateur users. The wax block bait is used in and around buildings and in sewer systems. The target organisms to be controlled are Brown rat, Roof rat or House rat, House mouse and Field mouse.

3.3.2 Hazard Assessment for Human Health

No new exposure studies have been submitted for evaluation. Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. Non-target organisms are most at risk from secondary poisoning, i.e. consumption of rodent carcasses by predators such as raptors.

3.3.2.1 Toxicology of the active substance

Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Like all anticoagulant rodenticides, brodifacoum is structurally similar to vitamin K. Blood forms a clot at the site of injury by virtue of a complicated 'clotting cascade', involving numerous clotting factors. The clotting factors are made in the liver as inactive precursors, converted to active form and allowed to circulate in the bloodstream. Vitamin K is employed in the liver in the activation process, and is used in a continuous cyclic process involving several enzymes. The anticoagulant rodenticides block these enzymes, preventing regeneration of the vitamin K and preventing activation of the clotting factors.

Brodifacoum requires labelling with the symbol T+ and the risk phrases R 28 'Very toxic if swallowed'; R27 'Very toxic in contact with the skin' and R26 'Very toxic by inhalation'. Brodifacoum is not classified as a skin irritant or eye irritant.

Repeated dosing studies show effects on blood coagulation and death at low doses ($\mu\text{g}/\text{kg}$ bw/day), and therefore labelling with R48/23/24/25 is warranted.

Under the GHS scheme Acute tox. 1, H310, Acute tox. 2 H300 and STOT RE 1 H372.

The Commission Working Group of Specialised Experts on Reproductive Toxicity has unanimously recommended that all AVK rodenticides should collectively be regarded as human teratogens due to the structural similarity to and the same mode of action as the known developmental toxicant warfarin (meeting in Ispra, 19-20 September 2006). Therefore based on read across data from warfarin, brodifacoum is considered to be a possible developmental toxicant and requires the classification as Reprotoxic with the labelling R61, may cause harm to the unborn child.

An almost complete oral absorption can be considered, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. *Brodifacoum* is widely distributed and bioaccumulates mainly in the liver with lower concentrations in the kidney. Hepatic bioaccumulation of *Brodifacoum* is a non-linear vs dose and time. The elimination kinetic from the liver was biphasic, with an half-life in the range of 282-350 days. The excretion after oral administration is very slow (11 – 14% in 10 days), occurring via the urine and the bile, both as polar metabolites (glucuronide) and parent compound. The metabolism of *Brodifacoum* is limited and the toxicologically relevant chemical species is the parent compound.

As long as dermal absorption is concerned, on the basis of the available study and reading across from data on other 2nd generation anticoagulant rodenticides, two different values could be used for risk characterisation depending on the type of formulation, that is 3% (pellets and grains) or 0.047% (wax block bait).

Brodifacoum is very toxic after oral administration and also via the dermal and inhalation routes. Death was the result of internal haemorrhage. Classification with T+; R26/27/28; 'Very toxic by inhalation, in contact with skin and if swallowed' is warranted. *Brodifacoum* does not fulfil the EU criteria for classification as a skin or eye irritant. Although showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

Summary of Brodifacoum subchronic, chronic, mutagenic and reproductive toxicity.

Repeated oral exposure to resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The NOEL for subchronic oral toxicity is in the range 0.04 -0.001 mg/kg/day (the lowest values identified with sensitive end-points, such as increases in both the kaolin-cephalin time and the prothrombin time). Based on results from the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum*, it is justified to assume serious damages associated to prolonged exposure through dermal and inhalation routes also. Therefore, classification with T; R48/23/24/25 "Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed" is warranted.

Genotoxicity and Carcinogenicity

Brodifacoum displayed no mutagenic activity in a standard range of genotoxicity tests. No long-term carcinogenicity study was submitted. In fact, chronic toxicity studies were not considered to be technically feasible due to the specific action of the active substance on the test/target species. However, the anticoagulant action is apparently the only pharmacological action of *Brodifacoum*. The active substance has no structural alerts for carcinogenicity and no concern about possible non-

genotoxic carcinogenic potential can be derived from the toxicological studies. Therefore the justifications for non-submission of carcinogenicity data was considered acceptable.

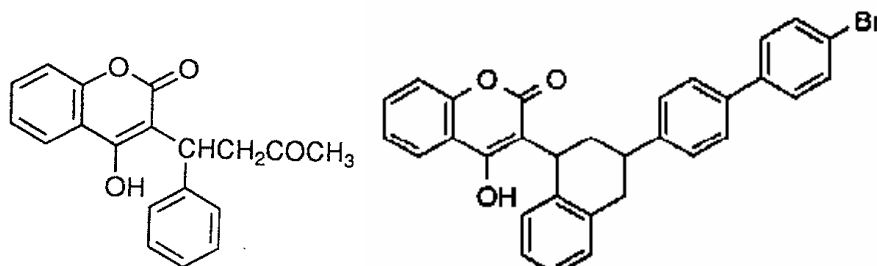
Conclusion on Reproductive toxicity

Reproductive and developmental toxicity studies on Brodifacoum did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw. In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*. None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum*.

Medical data

Routine monitoring of workers (industrial users) producing Brodifacoum and formulating products has been carried out for the last forty years. Between June 1981 and September 1982, three poisoning incidents occurred with successful recovery. With the exception of these incidents, routine monitoring has shown no clinical effects in any workers. During this time there has been no evidence of allergenicity, sensitisation or any other abnormal effects induced by repeated and continual exposure to these anticoagulant rodenticides.

The molecules both have significant structural similarity to vitamin K. This structural similarity is responsible for the ability to interfere with i.e. block the enzymes used to regenerate vitamin K. The major differences in the active substances lie in their 'tails', which have varying degree of lipophilicity. There is long term experience with warfarin, widely used in anti-clotting therapy in humans for over forty years, with no association with increased incidence of cancer. The absence of adverse effects in millions of humans following four decades of long term warfarin therapy is considered sufficient evidence that warfarin is not carcinogenic. The structural similarity of brodifacoum to warfarin (see below), together with the negative results in the guideline mutagenicity tests, indicates that brodifacoum is not carcinogenic.



Warfarin

Brodifacoum

TMIII09 agreed to derive AEL_{medium term} consistently with what decided for the other AVK rodenticides. Therefore, AEL_{medium term} was calculated from the NOAEL of 0.002 mg/kg bw/day (developmental oral toxicity study in rabbit) divided by an Assessment Factor of 300 (10 for interspecies x 10 for intraspecies x 3 additional factor for severity of effects). The AEL_{medium term} results to be of 6.7×10^{-6} mg/kg bw/day.

Conclusions:

The following AELs should be considered in the risk characterization for *Brodifacoum*:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- AEL_{medium term} of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)

None.

3.3.2.2 Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

Summary of acute toxicity data for the biocidal product Ruby Block

Parameter	Test material	Species	Result	Classification	Ref.		
Acute Oral Toxicity	Brodifacoum wax block bait. Batch: 61309601	Rat, female, Sprague-Dawley,	LD ₅₀ > 2000 mg/kg bw	none.	██████████ (2007a). study number: 2254/0021		
					Acceptable (Y/N): Yes	Method: OECD 420 (2001)	GLP (Y/N): Yes
					Comments: No mortality occurred during the study at 2000mg/kg. There were no clinical signs observed. 2g of wax block was powdered and mixed with arachis oil BP before use.		
Acute Dermal Toxicity	Brodifacoum wax block bait. Batch: 61309601	Rat, male & female, Sprague-Dawley,	LD ₅₀ > 2000 mg/kg bw	none.	██████████ (2007b). study number: 2254/0022		
					Acceptable (Y/N): Yes	Method: OECD 402 (1987)	GLP (Y/N): Yes
					Comments: No mortality occurred during the study at 2000mg/kg. No cutaneous reactions or systemic clinical signs related to the administration of the test item were observed.		
Acute Inhalation Toxicity	none	none	none	none	none		
	Acceptable (Y/N):		Method:		GLP (Y/N):		
	Comments: Inhalation exposure is not appropriate for wax block formulation. Active substance has very low volatility and is only present at 0.005% (w/w) in the solid, wax product. Company justification accepted.						

Parameter	Test material	Species	Result	Classification	Ref.																																																																																																
Information on mixture of biocidal products	none	none	none	none	none																																																																																																
	Acceptable (Y/N): Yes		Method:		GLP (Y/N):																																																																																																
	Not applicable since following the proposed uses of BLOCK BAIT and the label claims, the rodenticide BLOCK BAIT is not intended to be used in a mix with other biocidal products. Company justification accepted.																																																																																																				
Acute Skin Irritation	Brodifacoum wax block bait. Batch: 61309601	Rabbit, male, NZW, 3 in total	No irritation	none	(2007c). study number: 2254/0023																																																																																																
	Acceptable (Y/N): Yes		Method: OECD 404 (2002)		GLP (Y/N): Yes																																																																																																
	Comments: The test item was applied at a dose of 0.5 g mixed with water , on an undamaged skin area of one flank of each animal for 4 hours. Scores of 1 for oedema and erythema in one animal at 24 hours had reversed at 48 and 72 hours. No classification required.																																																																																																				
Acute Eye Irritation	Brodifacoum wax block bait. Batch: 61309601	Rabbit, male, NZW, 3 in total	Slight irritation	none	(2007d). study number: 2254/0024																																																																																																
	Acceptable (Y/N): Yes		Method: OECD 405 (2002)		GLP (Y/N): Yes																																																																																																
	Comments: The test item was reduced to a fine powder. The test item was applied at a dose of 0.1 g instilled into the conjunctival sac of one eye in each animal.																																																																																																				
		<table border="1"> <thead> <tr> <th rowspan="3">Time/Animal</th> <th colspan="3">Cornea</th> <th colspan="3">Iris</th> <th colspan="6">Conjunctivae</th> </tr> <tr> <th colspan="3"></th> <th colspan="3"></th> <th colspan="3">Redness</th> <th colspan="3">Chemosis</th> </tr> <tr> <th>1</th> <th>2</th> <th>3</th> <th>1</th> <th>2</th> <th>3</th> <th>1</th> <th>2</th> <th>3</th> <th>1</th> <th>2</th> <th>3</th> </tr> </thead> <tbody> <tr> <td>24 hours</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>2</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>48 hours</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>72 hours</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> </tr> <tr> <td>Mean individual scores 24, 48 and 72 h</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> <td>0.6</td> <td>0.6</td> <td>0.3</td> <td>0.0</td> <td>0.0</td> <td>0.0</td> </tr> </tbody> </table>											Time/Animal	Cornea			Iris			Conjunctivae												Redness			Chemosis			1	2	3	1	2	3	1	2	3	1	2	3	24 hours	0	0	0	0	0	0	1	2	1	0	0	0	48 hours	0	0	0	0	0	0	1	0	0	0	0	0	72 hours	0	0	0	0	0	0	0	0	0	0	0	0	Mean individual scores 24, 48 and 72 h	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.3	0.0	0.0	0.0
Time/Animal	Cornea			Iris			Conjunctivae																																																																																														
							Redness			Chemosis																																																																																											
	1	2	3	1	2	3	1	2	3	1	2	3																																																																																									
24 hours	0	0	0	0	0	0	1	2	1	0	0	0																																																																																									
48 hours	0	0	0	0	0	0	1	0	0	0	0	0																																																																																									
72 hours	0	0	0	0	0	0	0	0	0	0	0	0																																																																																									
Mean individual scores 24, 48 and 72 h	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.3	0.0	0.0	0.0																																																																																									
Skin Sensitisation	none	none	none	none	none																																																																																																
	Acceptable (Y/N):		Method:		GLP (Y/N): Yes																																																																																																
	Comments: A skin sensitisation study is not available for the product so active substance data has been used to derive a classification. Brodifacoum showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer (CAR IT). However, based on the generic concentration limits for mixtures at a Brodifacoum concentration of 0.005% w/w classification is not required by Directive 1999/45/EC or Regulation (EC) No 1272/2008.																																																																																																				

Conclusion:

According to the results of the toxicological studies, Brodifacoum Block bait does not classify with respect to Directive 1999/45/EC or Regulation (EC) No 1272/2008. However, safety phrases and precautionary statements are proposed by the Rapporteur.

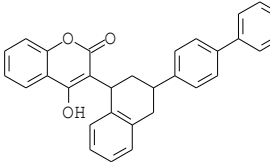
Data requirements: (List if applicable)

None.

3.3.2.3 Toxicology of the co-formulants (substances of concern)

The biocidal product contains no other substances in quantities that would be of toxicological concern. The majority of these components are food grade materials and are not classified.

Block Bait

Trade name	IUPAC Name	CAS-No.	EC-No.	Molecular formula	Structural formula	Classification according to Directive 67/548/EEC
Brodifacoum (in technical concentrate)	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxychromen-4-one	56073-10-0	259-980-5	C ₃₁ H ₂₃ BrO ₃		0.25% technical concentrate is classified
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]



3.3.3 Exposure Assessment for Human Health

The most relevant route of exposure to the active substance is the dermal route. For exposure assessment only active substance from wax blocks has been modelled. The block product typically takes the form of a solid waxy block with a strong sweet smell containing 0.005% w/w Brodifacoum.

In the final CAR for brodifacoum dermal absorption values were derived from read across from data on Difenacoum. The values chosen were 0.047% for wax formulations and 3% for grain/pellet formulations. These values were deemed appropriate in the absence of product specific data.

The active substance has a low vapour pressure, therefore the potential for evaporation is low, and hence the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. In the case of wax blocks, inhalation exposure is irrelevant. Inhalation exposure from handling grain bait during loading/application and cleaning is also proposed as negligible. The only relevant inhalation exposure is assumed to be that from the decanting of loose grain, pellets and granules due to the potential release of airborne dusts.

Any potential oral exposure will be indirect exposure via possible release to the environment. Other possible exposure scenarios include dermal contact with dead animals and accidental ingestion of poison baits by children.

Key Endpoints for Exposure Assessment

The following AELs should be considered in the risk characterization for *Brodifacoum*:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- AEL_{medium term} of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)

None.

3.3.3.1. Exposure to professional users

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
Main group 03; PT 14	Professional uses	
	Rodenticide used in and around buildings	0.005% w/w
	Use in sewerage (only against rats)	
	Non-professional uses	
Rodenticide used in and around buildings	0.005% w/w	

There are two groups of humans which may be potentially exposed to the rodenticide baits : those who handle, apply and dispose of the product or other residues such as carcasses or faeces (direct exposure) and those who may be incidentally exposed while the product is in use (incidental exposure).

3.3.3.2. Method of application

Block bait is made of paraffinic blocks to which the active substance has been added. These Brodifacoum baits are used indoors and outdoors to kill mice and rats: they are placed at the appropriate places in bait stations or covered under a curved tile, a wooden board or in a piece of tube; the animals eat some of the product and die.

Baits must be deposited in a way to minimize the risk for non-target animals and for children. Where possible, baits are secured so that they cannot be dragged away by the rodents. Preferably bait stations will be used where the bait can't be hidden, fixed or locked up.

The common strategy is to explore the site, locate runs, burrows, droppings or signs of damage and place the bait boxes at entry points into buildings and around areas where rats are known to feed. For the mice control, as mice are sporadic feeders, many bait points are placed throughout the areas where mice are known to feed.

In sewers, the bait is eaten *in situ* by target rodents. The brown rat is the only mammal able to live in sewers.

For house and field mice control, the recommended dose is 20 to 30 g of bait every 2 to 5 meters.

For rat control, the recommended dose is 60 to 100 g of bait every 5 to 10 meters.

In sewers, place 200 to 300 g every 30-50m (never more than 300 g at each manhole).

There are three phases for the human exposure:

- Application phase: application of rodenticides by professionals and non-professionals.

In and around domestic, industrial and commercial buildings, the product is applied manually, at measured amounts in bait boxes or covered. Professional users are assumed to wear protective gloves when handling the product unlike amateur users.

In sewerage, the bait is applied only by professionals, typically hanged to a wire tied up to the wall a few centimetres above the bottom of manholes.

Bait points are controlled regularly. Any bait eaten or damaged has to be replaced. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. During the bait inspections, also a search in the zone will be done for dead rodents.

- Use phase: Post-application, *i.e.* from the use of rodenticide products and from contact with the product (*e.g.* residential exposure including indoor air contamination, contact with the product during use). The use phase is the period when the biocidal product is waiting to be consumed by the target

organism. This means that no primary exposure of humans is intended and should not take place (please refer to point 3.2.4 Secondary exposure).

- Disposal phase: Disposal (including handling of surplus formulated product, burning/incineration, dumping, empty containers, dead rodents (carcasses) disposal).

When no further bait take is observed, bait stations must not be left in place. All bait stations must be removed from the site, cleaned up and the bait and bait remainders must be disposed of in accordance with local requirements.

For sewer systems no specific removal disposal is instructed.

3.3.3.3. Human exposure assessment

5.1.1.1.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use ¹⁾	Professional use ²⁾	General public ³⁾	via the environment ⁴⁾
Inhalation ⁵⁾	Not appropriate	Yes	Yes	No
Dermal ⁶⁾	Not appropriate	Yes	Yes	No
Oral	Not appropriate	No	Yes	No

¹⁾ Industrial use (manufacture of active substance and formulation of products) is not covered by BPD. Workers in formulation manufacture are not exposed to levels of a.s. that would affect blood clotting.

²⁾ Includes non-trained professionals.

³⁾ Indirect exposure due to transient mouthing by infants is included in the scenarios for the general public.

⁴⁾ According to the TNsG, indirect exposure *via* the environment is considered to be of minor importance as the release of rodenticides to the environment is limited.

⁵⁾ The skin is the main exposure route with a small proportion of inhalation exposure to dust when grain-based baits are mechanically handled by professionals. The active substance is of low volatility and it is incorporated at very low concentrations into a solid, non-volatile matrix. Therefore inhalation exposure is considered as negligible.

⁶⁾ Except for the grain block bait which is always packed in individual sachets for both professionals and general public and for grain bait only for the amateurs, dermal contact with the product is a realistic scenario.

The magnitude of human exposure to block bait can be assessed by applying standard exposure models of TNsG¹⁶ for human exposure (2007) or the Harmonised approach for the assessment of rodenticides (anticoagulants) endorsed at TM II 2011 for professionals and amateurs users. Moreover, CONSEXPO 4.1 model can be used to assess the exposure to the biocidal product used by non-professionals.

The following basic primary exposure pathways have to be considered for a risk assessment in order to sum up the exposure of humans to Brodifacoum. The main exposure path is direct skin contact during the use of the biocidal product.

Ingestion is a secondary pathway or an accidental primary exposure during the use of the biocidal product.

Inhalation is considered as negligible.

According to the various pathways, the following absorptions will be applied in the assessment:

- Inhalatory uptake fraction: 1 (default value of 100%);
Inhalation rate: 1.25 m³/h (default value)
- Dermal uptake: 0.047% for wax formulations and 3 % for and grain/pellet.
- Oral uptake fraction 100%

¹⁶ Human exposure to Biocidal products-Technical Notes for Guidance, June 2007

3.3.3.4. Professional exposure

For professional use, the operator is trained in the correct use of the bait, *i.e.* placement, number of bait points/boxes required based on the infestation rate area, the amount of bait or number of bait place packs per bait point/box and safe handling procedures.

The use of PPE - disposable gloves and a dust mask may be employed when decanting bait and disposable gloves may be employed when loading bait boxes and disposing of remaining bait and carcasses. However, when the bait is contained within a bait box there will be no exposure of the operator to the product.

PPE (coverall, boots and gloves) is required as standard when the bait is used in sewage systems.

Exposure calculations – professionals

The CEFIC/EBPF Rodenticides Data Development Group conducted an operator exposure study using flocoumafen (which may be considered a suitable surrogate for all other second generation anti-coagulants) to determine exposure during simulated use of rodenticide baits (*Chambers 2004*, unpublished, confidential). This study examined exposure to wax blocks (20g wax block baits, 5 blocks/bait box) and grain bait. Guidance is also taken from a confidential paper entitled “Harmonised Approach for Rodenticides” by the German Competent Authority, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA).

The daily exposure frequency and its division between different tasks are based on a survey organised by CEFIC (and based on a questionnaire answered by selected pest control companies in several EU countries), and on an agreement between Member States on the common approach for exposure assessment and ECB guidelines. Based on an *in vitro* study of formulated active (bait:saline incorporated brodifacoum 0.00255 w/w) and a representative wax block formulation (0.005 % w/w) a worst case value of 0.36% was obtained that was used for this risk assessment (Bromadiolone LOEP).

The Chambers study determined exposure from the application phase from the following scenario: 5 operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks. Three trials were conducted with 1, 5 and 10 times securing of these wax blocks. Since the results of 1, 5 and 10 securing are similar all trials were included in the calculation of the 75th percentile by the RMS. The proposed value of **28mg (of wax bait) per manipulation** is valid for loading of one bait box with 100g of wax blocks (a single manipulation constitutes the placement of a single bait station). Since the recommended amount for rat control is up to 200g bait per bait point, this exposure value is multiplied by a factor of 2 because only 100g was used in the Chambers Study. The proposed value of **56mg (of wax bait) per manipulation** is valid for loading of one bait box with 200g of wax blocks.

For professional operators the potential total daily dermal exposure (assuming the previously agreed number of 60 manipulations from TM III/10 is applied) from the application-phase is **3360mg** wax block product (i.e. 56mg x 60 bait sites).

The Chambers study determined exposure from the disposal or post-application phase from the following scenario: 5 operators emptied a loaded bait station by sliding the wax block off the mounting pegs into a 10 L plastic bucket. This is done 1, 5 and 10 times. The proposed value of **5.75 mg per manipulation (determined by the RMS, Difenacoum CAR 2009)** is valid for cleaning of one bait box. For the resulting potential dermal exposure of post-application-phase the agreed number of 15 manipulations (TM III/10) should be taken into account. For the post-application phase the potential total daily dermal exposure is **86 mg** wax block product (i.e. 5.75mg x 15 disposal manipulations). The size of one bait block is ignored and the figure is valid for different sized blocks (e.g. 10g, 100 g).

The calculation of PCO (pest control operator) and amateur dermal exposure in placing and clean-up of rodenticidal wax blocks, taking into account measured values (75th percentiles), defaults according to ECB guidelines and the common agreement on daily exposure frequencies (TM III/10) is presented in the following table.

Pest Control Operator, No PPE:

Amount of exposure to product (75 th percentile) during securing of 10 20g wax blocks (200g). Value is for placement of 1 bait station.	56.0 mg
Amount of Brodifacoum on fingers/hands (0.005% in wax block, 20 x 10g blocks sewer maximum application)	112 mg × (0.005 / 100) = 5.6×10 ⁻³ mg
Systemic dose per application at 1 bait station: (dermal absorption 0.047%, bw 60kg)	(5.6×10 ⁻³ mg) × (0.047 / 100) / 60kg = 4.39×10 ⁻⁸ mg/kg
Amount of exposure to product (75 th percentile) during clean-up and disposal per bait station	5.75 mg
Systemic dose (Brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg) per clean-up of one bait station.	2.25×10 ⁻⁹ mg/kg
Assuming 'reasonable worst case' scenario of 60 bait sites and 15 clean-ups, systemic dose per day	((4.39×10 ⁻⁸ mg/kg × 60) + (2.25×10 ⁻⁹ mg/kg × 15)) = 2.6×10⁻⁶ mg/kg/day 0.0026 µg/kg/day
<u>Expressed as a % of the AEL:</u> AEL _{medium term} of 6.7 x 10 ⁻⁶ mg/kg bw/day (0.0067 µg/kg/d)	39% of the AEL

Pest Control Operator, With PPE (gloves)

Default 10-fold reduction of exposure.	2.6×10⁻⁷ mg/kg/day 0.00026 µg/kg/day
<u>Expressed as a % of the AEL:</u> AEL _{medium term} of 6.7 x 10 ⁻⁶ mg/kg bw/day (0.0067 µg/kg/d)	3.9% of the AEL

Non-Trained Professional (e.g. farmer), No PPE:

Systemic dose resulting from application of product to five bait sites plus five bait sites cleaned per day, no PPE (brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg).	((2.19×10 ⁻⁸ mg/kg × 5) + (2.25×10 ⁻⁹ mg/kg × 5)) = 1.2×10⁻⁷ mg/kg/day 0.0001 µg/kg/day
<u>Expressed as a % of the AEL:</u> AEL _{medium term} of 6.7 x 10 ⁻⁶ mg/kg bw/day (0.0067 µg/kg/d)	1.5%

Non-Trained Professional (e.g. farmer), With PPE (gloves):

Default 10-fold reduction of exposure.	1.2×10⁻⁸ mg/kg/day 0.00001 µg/kg/day
<u>Expressed as a % of the AEL:</u> AEL _{medium term} of 6.7 x 10 ⁻⁶ mg/kg bw/day (0.0067 µg/kg/d)	0.15%

3.3.3.5. Exposure to non-professional users

Bait boxes for use by the general public may be supplied as sealed units or as lockable, tamper-proof units that may be refilled by the user. Bait may be used in covered/protected bait points, rather than bait boxes, where appropriate.

Calculations for non-professional exposure are presented below; the first scenario assumes no exposure during application phase while the second scenario assumes that the bait boxes would have to be loaded by the user. As for the non-trained professionals, it is assumed that a non-professional user places ten bait blocks per site (200g) on five bait sites and cleans five bait sites per day.

Product type	Exposure scenario	PPE	Inhalation uptake	Dermal uptake
14	Non-professional (amateur)	None	Not relevant	1.12×10^{-8} mg/kg/day ¹⁾
14	Non-professional (amateur)	None	Not relevant	1.2×10^{-7} mg/kg/day ²⁾

1) scenario 1, 2) scenario 2.

Scenario 1: No dermal contact during placing of baits due to sealed bait boxes. Potential exposure is only during clean-up. Default exposure value for cleanup is 5.75mg product per bait site, bromadiolone present at a concentration of 0.005% (w/w), 60kg body mass, 0.047% dermal absorption value. The value is calculated from the cleanup exposure per bait station of $(2.25 \times 10^{-8}$ mg/kg) \times 5).

Scenario 2: Assuming that conventional bait boxes are loaded then the exposure is equal to that of the non-trained professional (e.g. farmer) with no PPE. As a worst case scenario, scenario 2 can be taken forward to risk assessment.

3.3.3.6. Exposure to children/workers/general public

Bait points should be covered or protected in such a way to prevent access to the bait. However, the ingestion of wax block bait by infants has been assessed as a potential secondary exposure route associated with the use of Brodifacoum in rodenticide products. Secondary exposure is anticipated to be acute in nature. Two different scenarios of secondary exposure are available, the 'handling of dead rodents' scenario and the 'transient mouthing of poison bait' scenario. The former is excluded from the risk assessment due to unrealistic assumptions. The estimated exposure for the 'transient mouthing of poison bait' scenario is either 2.5×10^{-2} mg/kg or 5.0×10^{-5} mg/kg, depending on the default assumptions. This results in Margin of Exposure (MOE) values of 0.01 or 6.6, respectively. It shows that infants are at significant risk for secondary exposure, i.e. there is no safe use for children.

For the 'transient mouthing of poison bait' scenario, either 5g (User Guidance) or 10 mg (TNsG, with bittering agent) of the product is assumed to be swallowed by an infant per poisoning event.

Oral exposure infant. TNsG Assumptions: Transient mouthing of poison bait (10mg) treated with repellent: $(10\text{mg} \times 0.00005) / 10\text{kg bw}$

Transient mouthing infant. User Guidance Assumptions: Transient mouthing of poison bait (5000mg) without repellent; $(5000\text{mg} \times 0.00005) / 10\text{kg bw}$

	Total dose (mg/kg b.w./day)	% AELacute (0.0033 µg/kg b.w.)
Oral exposure infant	0.00005	1515%
Transient mouthing infant	0.025	757575%

The RMS considered that in connection with transient mouthing of poison baits, infants are also exposed via the dermal route while handling the bait. This however is assumed to play a minor role relative to the amount that could be ingested. It is therefore not included in the overall exposure scenario.

3.3.3.7. Exposure to consumers from residues in food

Not applicable.

3.3.3.8. Overall Summary

The exposure data based on measurements in simulated use conditions are acceptable and should be used in risk assessment. The models assume that inhalation exposure is of minor importance compared with dermal exposure. The calculations have been made with the assumptions of rat control, and there are no separate calculations to assess exposure in mice control in which smaller bait sizes are used.

3.3.4. Risk Characterisation for Human Health

3.3.4.1. Professional users

The exposure assessment for professional pest control operators (PCOs) under reasonable worst case assumptions (60 loadings and 15 clean-ups/day), as presented above, yielded a potential dermal exposure leading to a systemic dose 0.0026µg/kg/day for an unprotected operator during bait handling operations. Comparison to calculated NOAEL for MOE shows that the use of rodenticide baits containing 0.005% brodifacoum results in a margin of exposure of 257.

Since pest control operators wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting margin of exposure (MOE = 2570) indicates that the use of rodenticide baits containing 0.005% brodifacoum does not cause a risk for PCOs if gloves are worn.

Likewise, the exposure assessment for non-trained professionals (e. g., farmers) under reasonable worst case assumptions (five loadings and five clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 1.2×10^{-7} mg/kg/day for an unprotected person. Even without PPE, the resulting margin of exposure (MOE = 6700) indicates that use of rodenticide baits containing 0.005 % brodifacoum is not a risk at the stated exposure frequency. A refined assessment was, nevertheless, conducted since wearing of protective gloves is recommended in the instructions for use. The resulting margin of exposure (MOE = 67000) indicates a high level of protection for non-trained professional users when gloves are worn.

The result of the risk assessment concerning use of brodifacoum in bait Blocks indicates that the acceptable exposure level is not exceeded for trained professionals (PCOs) without PPE (gloves). In addition, the risk is at an acceptable level without gloves for non-trained professionals. However, use of protective gloves is recommended in all cases for hygiene reasons. Exposure during manufacture of the active substance and formulation of products is beyond the scope of BPD and therefore has not been addressed in this document.

3.3.4.2. Non-professional users

Blocks are supplied either in pre-sealed units or as loose blocks for use in covered/protected bait points or refillable bait boxes. An exposure assessment has been performed taking into account potential exposure both from application and post-application tasks as a worst-case scenario. In the calculations, amateurs were assumed to load five bait points and clean five bait points per day without PPE. The estimated daily systemic dose, 1.2×10^{-7} mg/kg/day, results in an MOE value of 6700 showing that there is also little risk to amateurs.

3.3.4.3. Children/Workers/general public

As a potential secondary exposure route, associated with the use of brodifacoum in rodenticide products, ingestion of wax block bait by infants has been assessed. Secondary exposure is anticipated to be acute in nature. The estimated exposure for the scenario, 2.5×10^{-2} mg/kg/day or 5.0×10^{-5} mg/kg/day, depending on the default assumptions, results in MOE values of 0.01 or 6.6, respectively indicating that infants are at risk of poisoning. This should be addressed by ensuring all bromodialone products targeted for amateur use are provided in sealed packs and tamper resistant bait boxes with a bittering agent. The potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic.

3.3.4.4. Consumers from residues in food

Not applicable, product is not used to treat food stuffs.

3.3.4.5. Overall Summary

The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value ($0.0033 \mu\text{g}/\text{kg}/\text{day}$), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

Workplace operation	PPE	Exposure path	Dose ($\mu\text{g}/\text{kg}/\text{day}$)	MOE	%AEL
<i>Trained Professional:</i> Placing of wax block baits and clean-up	None	Dermal, hands	0.0026	257	39
<i>Trained Professional:</i> Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00026	2570	3.9
<i>Non-Trained Professional:</i> Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
<i>Non-Trained Professional:</i> Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00001	6700	1.5
<i>Amateur:</i> Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
<i>Secondary Exposure Transient Mouthing of bait by infants</i>	--	Oral	5.0×10^{-5} (TNsG)	6.6	--
			2.5×10^{-2} (User Guidance)	0.35	--

3.3.5. Effect and Exposure Assessment for the Environment

An overview of the EU review of environmental fate and behaviour and ecotoxicology for the active substance is presented below in conjunction with the exposure assessment and environmental effects for the biocidal product.

Environmental fate and behaviour of the active substance

5.1.1.1.2 Degradation

Biodegradation

Brodifacoum is not readily or inherently biodegradable.

The overall conclusion on biodegradation is that Brodifacoum is not readily or inherently biodegradable.

Abiotic Degradation

Brodifacoum is stable to hydrolysis ($t_{1/2} > 1$ year). It is however predicted to undergo rapid indirect photolysis with OH radicals and ozone ($t_{1/2} =$ approximately 2 hours) and undergoes rapid direct photodegradation ($t_{1/2} = 0.217$ days). There are no predicted effects on the atmosphere.

The overall conclusion on abiotic degradation is that Brodifacoum is hydrolytically stable to hydrolysis ($t_{1/2} > 1$ year).

Distribution

Brodifacoum is a large aromatic organic compound of low volatility with two polar groups, which can potentially ionise at environmental pH. The active substance has a Log Pow (4.92), and is of low solubility in water (5.8×10^{-5} g/l at pH 7 and 20°C).

The DT50 value of 157 days (The Pesticide Manual 13th ed) and the Koc of 50000 (The Pesticide Manual 13th ed) indicate that Brodifacoum would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

On the basis of its low volatility (vapour pressure of 2.6×10^{-22} Pa at 20°C) the exposure to the atmosphere is highly unlikely.

The overall conclusion on distribution is as follows: Brodifacoum is persistent (DT50 157 days) and immobile in soil (Koc > 9155 l/kg). Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Mobility in soil

The Koc value (50000 The Pesticide Manual 13th Edition) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater (PEC < 0.1 µg/l).

The overall conclusion on mobility in soil is as follows Brodifacoum is immobile in soil (Koc > 9155 l/kg). Brodifacoum is not expected to contaminate groundwater.

5.1.1.1.3 Accumulation


Based on a measured Log Kow = 4.92 it is considered that Brodifacoum has a potential for bioaccumulation. The BCF_{fish} (3034) was calculated using the equation 74 of TGD (part II); the BCF_{earthworm} (999) was calculated according to the equation 82d of TGD

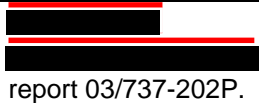
The overall conclusion on bioaccumulation potential is as follows: No reliable bioaccumulation study is available. The measured log Kow = 4.92 (retrieved from CAR B) indicates that Brodifacoum can be potentially bioaccumulative and provides a calculated BCF_{fish} = 3034. The experimental Kow confirms the adequacy of using, in CAR A, the calculated log Kow of 6.12 (rather than 8.5) and indicates that this value still overestimated the actual lipophilicity and, consequently, the BCF values estimated herein. The measured log Kow = 4.92 and a BCF_{fish} = 3034 and BCF_{earthworm} = 999, are considered therefore more reliable endpoints to be used in risk assessment.

3.3.5.2 Environmental effects (hazard) of the active substance (ecotoxicology)

Table 3.3.5.2-1 Summary of the eco-toxicological data for the active substance Brodifacoum

Parameter	Test material	Species	Result	Classification	Ref.		
Short term toxicity testing on fish	ECO120140	Oncorhynchus mykiss	96-hour LC50 = 0.042 mg/L	Yes - R50/R53	██████████ March 2003. ██████████ ██████████ ██████████ report ENV5803/120140 (2003)		
					Acceptability (Y/N): Yes	Method: OECD 203	GLP (Y/N): Yes
					Comments: None		
					Acceptability (Y/N): Yes	Method: OECD 202	GLP (Y/N): Yes
Comments: Recorded under semi-static conditions.							
Toxicity to aquatic invertebrates	ECO120140	Daphnia magna	48 hour - EC50 = 0.25mg/l	Yes - R51 /R53	W J Craig - March 2003. Chemex Environmental International Ltd report - ENV5802/120140		
					Acceptability (Y/N): Yes	Method: OECD 202	GLP (Y/N): Yes
					Comments: Recorded under semi-static conditions.		

Growth inhibition study on algae	ECO120140	Selenastrum capricornutum (Pseudokirkneriella subcapitata)	72h ErC50 = 0.04 mg/l	Yes - R50 /R53	W J Craig - March 2003. Chemex Environmental International Ltd. Report - ENV5801/120140
	Acceptability (Y/N): Yes		Method: OECD 201		GLP (Y/N): Yes
	Comments: None				
Inhibition of microbial activity	7909101	3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage	EC10 was set > water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C	No acute toxicity	Staniland, J. (2004) Chemex Environmental International Ltd. Ref: ENV7009/120140
	Acceptability (Y/N): Yes		Method: OECD 209		GLP (Y/N): Yes
	Comments: Although the results of the study (EC50 >1003mg/l) are not reliable, the study can be used to derive the NOECmicroorganisms on the basis of the brodifacoum water solubility (EC50 > 0.058 mg/l).				
Studies on sediment dwelling organisms	-	No experimental data available for sediment dwelling organisms.	-	-	-
	Acceptability (Y/N): -		Method: -		GLP (Y/N): -
	Comments: The risk for the sediment compartment will be covered by the risk for the aquatic compartment.				
Growth inhibition of aquatic plants	-	No study submitted	-	-	-
	Acceptability (Y/N): -		Method: -		GLP (Y/N): -
	Comments: The evaluation concluded that there is no need for a study as there is no evidence that brodifacoum would be toxic to aquatic plants to a greater extent than to other aquatic organisms.				
Toxicity to earthworms	Chemex reference: ECO120140	14-day LC50	> 994 mg/kg dw	No acute or chronic toxicity	Staniland, J (2005) Environmental International Ltd. Ref:ENV7010/120140
	Acceptability (Y/N): Yes		Method: Static test conditions according to SOP E260 based on OECD 207.		GLP (Y/N): Yes
	Comments: 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt.				
Toxicity to birds	Difenacoum	LD50 (Japanese quail)	19 mg/kg bw	Acute toxicity	 Study code: 04/903-115FU
	Acceptability (Y/N): Yes		Method: OPPTS 850.2100		GLP (Y/N): Yes

	Comments: An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d.				
Toxicity to mammals	04359	Two-generation fertility study (rat, parent females)	NOAEL (0.001mg/kg bw/day)	Yes	 report 03/737-202P.
	Acceptability (Y/N): Yes		Method: OECD 416		GLP (Y/N): Yes
	Comments: Although a two-generation study is not normally required for anticoagulant rodenticides, the study is relevant for the establishment of an overall NOAEL for anticoagulant effects in rodents.				

5.1.1.1.4 Effects on Aquatic Organisms including the determination of PNECs:

Toxicity data are available for aquatic organisms exposed in an acute test. In a test performed under semi-static conditions, the 96-hour LC50 was 0.042mg/L for *Oncorhynchus mykiss*, based on measured concentrations. *Daphnia magna* was less sensitive than fish, with a 48-hour EC50 of 250 µg/L recorded under semi-static conditions. The endpoint was based on immobilisation and on measured concentrations of Brodifacoum in the test media. In a 72-hour algal growth inhibition test with *Selenastrum capricornutum* (*Pseudokirkneriella subcapitata*) the ErC50 was 40 µg/l. The NOEC was 10µg/l with respect to specific growth rate. Results are based on measured concentrations. The outcome is that Brodifacoum is considered very toxic to aquatic organisms. The PNEC is derived from the algae 72h ErC50 = 0.04 mg/l (or fish 72h LC50 = 0.042 mg/l), and the application of an assessment factor of 1000. Therefore the **PNEC = 0.00004 mg/l**.

No experimental data are available for sediment dwelling organisms. A PNEC_{sediment} (0.043 mg/kg ww) was derived through the Equilibrium Partitioning Method described in the TGD. However, due to the absence of measured data for the determination of a PEC_{sed}, according to TGD a quantitative risk characterization cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

Based on the result of a 3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage, no effects of Brodifacoum on aerobic biological sewage treatment processes are expected. As the test was carried out at nominal concentration much higher than the water solubility of Brodifacoum, the EC10 was set as greater than the water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C. According to TGD, PNEC is derived applying an AF=10 to the NOEC from the respiration inhibition test. Therefore, the **PNEC_{micro-organisms} > 0.0058 mg/l**.

No degradation or transformation products of Brodifacoum in water were detected. Toxicity of metabolites is not of concern.

PNEC_{aquatic organisms} = 0.00004 mg/l

PNECsediment organisms = 0.00004 mg/l
PNECmicro-organisms = > 0.0058 mg/l

Conclusion on hazard to the aquatic organisms:

PNEC	Task Force
PNECaquatic organisms	0.00004 mg/l
PNECsediment organisms	0.00004 mg/l
PNECmicro-organisms	> 0.0058 mg/l

The Brodifacoum a.s. results in the classification of toxic to aquatic organisms.

5.1.1.1.5 Effects on the Atmosphere including the determination of PNECs

Brodifacoum has a low vapour pressure (1×10^{-6} Pa) and a Henry's Law constant of 2.18×10^{-3} Pa.m³mol⁻¹ (pH 7). Release to air via water is expected to be negligible. This is also supported by calculations using the TGD on risk assessment for percent release to air from a sewage treatment plant where a default of 0 is given (i.e., no release to air). The manufacture of the active substance is in a closed system. There are no releases to air of Brodifacoum from manufacturing, formulating, use or disposal phases.

5.1.1.1.6 Effects on Terrestrial Organisms including the determination of PNECs:

The effect of Brodifacoum on earthworms was assessed in an acute toxicity test in which *E. fetida* in artificial soil was exposed to concentrations of Brodifacoum up to 994 mg/kg dw. The 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt. The PNEC for terrestrial organisms is derived from the LC50 with an AF of 1000 used. Therefore, **the PNECsoil ≥ 0.88 mg/kg wwt soil.**

Conclusion on hazard to terrestrial organisms:

PNEC	Task Force
PNECsoil	> 0.88 mg/kg wwt

Earthworms were not affected after acute exposure to Brodifacoum at concentration closed to 1 g/kg dw. It is concluded that Brodifacoum is of low toxicity to earthworms. **The PNECsoil ≥ 0.88 mg/kg wwt soil.**

Effects on Birds including the determination of PNECs:

Brodifacoum is moderately toxic to birds upon acute oral exposure with a LD50 value of 19 mg/kg bw in the Japanese quail.

No studies are available on the avian short term dietary toxicity.

A 6 weeks reproduction test on the Japanese quail exposure to Brodifacoum in drinking water was submitted but it was judged not adequate for risk assessment purposes. Therefore, acknowledging the decision taken at the Biocides TMIII09, the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants. An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d. According to the TGD, an assessment factor of 30 is applied to derive the PNEC. Therefore the **PNEC_{coral-birds} = 0.012 mg Brodifacoum/kg diet/30 = 0.0004 mg Brodifacoum/kg diet**. In relation to dose the **PNEC_{coral-birds} = 0.0012 mg Brodifacoum/kg bw/d/30 = 0.00004 mg Brodifacoum /kg bw/d**.

Conclusion on hazard to birds:

PNEC	PNEC _{coral bird diet}	PNEC _{coral bird}
Task Force	0.0004 mg/kg	0.00004 mg/kg bw/d

Effects on Mammals including the determination of PNECs:

The lowest mammalian NOAEL (0.001mg/kg bw/day) comes from a two-generation fertility study with rats and refers to parent females. This endpoint was converted, according to TGD, to NOEC mammal, food = 0.02 mg/kg food. As the exposure lasted 90 days as a minimum, for PNEC derivation an AF oral of 90 is applied (table 23 of TGD). Therefore, the **PNEC_{coral-mammals} = 0.02/90 = 2.22E-04 mg/kg food**, corresponding to **PNEC_{coral-mammals} = 0.001 mg/kg bw day/90 = 1.1 E-05 mg/kg bw**.

Conclusion on hazard to mammals:

PNEC	Task Force
PNEC _{coral mammals food}	2.22E-04 mg/kg
PNEC _{coral mammals}	1.1 E-05 mg/kg bw

Brodifacoum is very toxic to mammals.

Metabolites

No significant amounts of metabolites are expected to be formed in soil. In rats, no toxicologically relevant metabolites have been identified which could be introduced in soil via urine or faeces.

3.3.5.3. Environmental effects (hazard) of the biocidal product

The example products in the EU-review program for approval of the active substance for inclusion in Annex I of Directive 98/8/EC were pellet bait and wax block mixtures (formulations) containing Brodifacoum.

The aquatic, terrestrial, avian and mammalian toxicity data used for the assessment of the Annex I representative biocidal product was based on data determined in the Brodifacoum active substance studies. This included the following studies.

7.8.7.1 (1)	[REDACTED]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10 th Vertebrate Pest Conference (1982). Published	N	Public Domain
7.8.7.1 (2)	[REDACTED]	-	Effects of New Rodenticides on Owls, [REDACTED] [REDACTED] [REDACTED] Published	N	Public Domain
7.8.7.1 (3)	[REDACTED]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain
7.8.7.1 (4)	[REDACTED]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, [REDACTED] [REDACTED] [REDACTED] Published	N	Public Domain

There were no additional ecotoxicology studies provided for authorisation of the biocidal product in this process.

3.3.5.4. Environmental effects (hazard) of the co-formulants (substances of concern)

Please refer to Annex I of the consolidated Annexes I-IV which contains the confidential information on the co-formulants that are used in this product along with the active substance.

None of the co-formulants that carry an environmental classification are present at a sufficient concentration to trigger the classification of the product.

Product Classification & Labelling:

There is no requirement for classification and labelling with regard to the co-formulants used in the product.

There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

3.3.6. Exposure Assessment for the Environment

The environmental exposure was assessed during the EU active substance review process and the current intended uses are similar.

The rodenticide product is used by professional and amateur users. The product is intended for indoors use, in and around buildings and for use in sewers for professional users only.

It is always used in the same manner for all these purposes. Bait points are placed throughout the infested areas with 20g per bait point for mice and 20 to 60 g per bait point for rats. Application sites are located 2-5 m apart for mice and 5-10 m apart for rats. A shorter distance is used in severe infestations. The number of baits and the distances should be adapted to the infestation level. Bait points are inspected frequently and replenished when bait has been eaten.

Bait points are placed securely to help prevent access to non-target animals. For amateur use, the label prescribes to use tamper resistant bait stations for rat control. Baits for amateur mouse control have to be placed into/at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the wax blocks must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Based on the environmental fate and behaviour of Brodifacoum, as outlined in the detailed calculations provided in Annex VI of this Product Authorisation Report, the environmental exposure assessment was conducted.

3.3.6.1. Aquatic compartment

Exposure to the aquatic compartment can occur following use of the product in sewers which flow into a local STP. Based on worst case ESD assumptions the maximum predicted environmental concentration (PEC) of the active substance for microorganisms in the STP is 1.93×10^{-5} mg/L. The corresponding amount in surface water is 1.77×10^{-6} mg/L. The maximum permissible concentration by directive 80/778/EEC (amended by 98/83/EC) of 0.1 µg/L is not exceeded in surface waters. Full details of the calculations are contained in Annex VI.

3.3.6.2. Atmospheric compartment

Brodifacoum has a vapour pressure of less than 10^{-6} Pa at 20°C and a Henry's Law constant of less than 2.18×10^{-3} Pa.m³.mol⁻¹ at pH 7. In the Assessment Report for brodifacoum it has been concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

3.3.6.3. Terrestrial compartment

Exposure of soil to the active substance occurs via direct (spillages) and disperse release (deposition by urine and faeces) after the use of the product in and around buildings. Exposure of agricultural soil via spreading of sludge from an STP is also considered in the risk assessment following use of the product in sewers.

Using ESD worst-case assumptions of the typical usage patterns and release mechanisms, the maximum concentration in agricultural soil (averaged over 30 d) after 10 years of sludge application from STP is 4.86×10^{-4} mg/kg wwt. When the applicant's dosage rates are used as inputs the figure for agricultural soil is 3.24×10^{-4} mg/kg wwt. The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator removed this as no exposure assessment on the brodifacoum metabolites was included.

The highest concentration of Brodifacoum in soil following use in and around buildings is 0.047 mg/kg wwt under ESD realistic worst case conditions (see table below). For a normal use pattern the ESD recommends a total of 2.6 replenishments (as opposed to 5 for the worst case). This usage pattern leads to an estimated soil concentration of 0.006 mg/kg wwt.

Sewers	In and around buildings
Amount of product used in control operation for each bait point:	

30 kg (ESD), 20 kg (applicant). Number of emission days: 7 (ESD) Fraction of active ingredient released: 0.9 No. of replenishments: 5	Amount of product used in control operation for each bait point: 0.25 kg (ESD), 0.06 kg (applicant). Realistic worst-case: 21 day campaign Bait stations: 10 No. of replenishments: 5 (2.6 realistic) Bait stations are 5 m apart. Fraction released due to spillage: 0.01 Fraction ingested: 0.99 Spillage area: 0.09 m ² (0.1 m around station) Frequented area: 550 m ² (10 m around building)
--	---

3.3.6.4. Groundwater

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

3.3.6.5. Primary & Secondary Poisoning Exposure Assessment

Non-target vertebrates may be exposed to rodenticides primarily through consumption of bait and secondarily from consumption of poisoned rodents. Small pellets and whole grain baits are highly attractive to birds.

In Sewers:

Primary Poisoning:

For rodenticide applications in sewer systems, there is no primary poisoning hazard to non-target mammals or birds because this is no habitat for them (cf. ESD PT 14).

Secondary Poisoning:

The secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In that case the situation is similar to the one described below for rat control in and around buildings. However, according to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.

Calculation of the Concentration in Fish:

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{\text{oral, predator}}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP).

The $PEC_{\text{oral, predator}}$ (mg/kg wet fish) is calculated from the annual average PEC for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (cf. TGD, 2003). The following table summarises the $PEC_{\text{oral, fish}}$ for the scenario 'sewage system'.

Predicted concentration in fish

		Tier 1 ^a	Tier 2 ^b
Input			
PEC_{water}	Annual average local PEC in surface water (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{\text{oral, fish}}$	Predicted environmental concentration in fish (mg/kg wet fish)	3.19×10^{-1}	2.13×10^{-1}

^a Product specific application data and default value for release

^b Product specific application data and refined metabolism

Calculation of concentration in earthworms:

Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1 ^a	Tier 2 ^b
Input			
$C_{\text{soil sewer system}}$	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
$C_{\text{soil building}}$	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050

BCF _{earthworm}	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
C _{porewater sewer system}	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
C _{porewater building}	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F _{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
CONV _{soil}	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
PEC _{oral, earthworm sewer}	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326

In and around buildings:**Primary Poisoning:**

Regarding the possible primary hazard to non-target animals this is assessed for birds and mammals.

Acute:

In the first tier scenario, PEC_{oral} is the concentration of the rodenticide in the food of a non-target organism. The PEC_{oral} is **50 mg/kg** (Brodifacoum present at 0.005% w/w in the product) and is used in the quantitative risk assessment for the acute and long-term situation.

In the second tier (refined) risk assessment the daily uptake (ETE) for birds and mammals is considered. This risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor.

Table-1 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	Body weight (g)	Daily food intake (FIR) (g/d) ^a	Conc. of a.i. after single meal (mg/kg bw/d) (ETE)	Expected conc. after elimination ^b (mg/kg bw/d) (EC)
Tree sparrow	22	7.6	17.27	12.43
Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456 ^d	2.28	1.64
Pig	80 000	600 ^e	0.375	0.270
Pig, young	25 000	600 ^e	1.20	0.864

Long-term:

In the first tier scenario, the risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor.

Expected concentration of Brodifacoum in the animal after one meal followed by a 24-hour elimination period

Species	Estimated daily uptake of a compound (ETE) (mg/kg b.w./d)		Fraction of daily uptake eliminated (number between 0 and 1) (EI)	Expected concentration of active substance in the animal (EC) (mg/kg b.w./d)	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

In the second tier scenario for primary poisoning long-term exposure according to the guidance agreed at the 23rd Biocides CA meeting, EC₅ values are used for quantitative risk assessment of primary poisoning in the long-term situation.

EC_{oral} for different relevant species

Days	EC _{oral} (mg/kg b.w./d)
------	-----------------------------------

Species	Tree sparrow	Chaffinch	Wood pigeon	Pheasant	Dog	Pig	Young pig
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Secondary Poisoning:

Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Predators among mammals and birds may occur inside buildings or they may hunt in the immediate vicinity of buildings, e.g. parks and gardens. Scavengers may also search for food close to buildings.

Tier 1 exposure assessment:

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been set to a default value of 5-days, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation). Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted. The assessment also takes into account the concentration in resistant rodents.

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	0.5	1.0
A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00

Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 <u>after</u> the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

Tier 2 Exposure Assessment:

The refined tier 2 considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

Species		Body weight (*) (g)	Daily mean food intake* (g)	Normal susceptible rodents caught on day 5, before their last meal.		Normal susceptible rodents caught on day 5 just after their last meal		Resistant rodents caught on day 14 just after their last meal	
				Amount a.s. consumed by the non-target animal** (mg)	Concentration in non-target animal (mg a.s./kg b.w.)	Amount a.s. consumed by the non-target animal*** (mg)	Concentration in non-target animal (mg a.s./kg b.w.)	Amount a.s. consumed by the non-target animals**** (mg)	Concentration in non-target animal (mg a.s./kg b.w.)
Barn Owl	Tyto alba	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	Falco tinnuncul.	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	Athene noctua	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	Strix aluco	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89
Fox	Vulpes vulpes	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76

Polecat	Mustela putorius	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58
Stoat	Mustela erminea	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	Mustela nivalis	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Calculation of concentration in earthworms:

Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1 ^a	Tier 2 ^b
Input			
C _{soil sewer system}	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70 x 10 ⁻⁵	3.70 x 10 ⁻⁵
C _{soil building}	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
BCF _{earthworm}	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
C _{porewater sewer system}	Concentration in porewater (mg/L) divided by 2	5.35 x 10 ⁻⁷	2.29 x 10 ⁻⁷
C _{porewater building}	Concentration in porewater (mg/L) divided by 2	3.48 x 10 ⁻⁵	3.10 x 10 ⁻⁵
F _{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
CONV _{soil}	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
PEC _{oral, earthworm building}	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

3.3.6.6. Overall Summary of exposure assessment

The biocidal product is a ready-to-use bait containing 0.005% Brodifacoum as the active substance. Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It is used against rat at the maximal rate of 60 g of product equivalent to 3 mg a.s. per baiting post and against mouse at 20 g product equivalent to 1 mg a.s. by baiting post. This formulation is intended for indoor and outdoor uses.

PECs were calculated in accordance with the ESD for PT14. These calculations are outlined in the previous sections. Based on environmental fate and behaviour of Brodifacoum the following PEC values were determined:

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC soil (mg/kg wwt)	0.047	0.006		
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}		
PEC microorganisms (mg/l)			1.93×10^{-5}	1.27×10^{-5}
PEC surface water (mg/l)			1.77×10^{-6}	1.18×10^{-6}
PEC agricultural soil (mg/kg wwt)			4.86×10^{-4}	3.24×10^{-4}
PEC groundwater (ag) (mg/l)			4.66×10^{-7}	3.11×10^{-7}

No new data related to the environment fate and behaviour or the ecotoxicology of the active substance or the biocidal product has been submitted by the applicant. There were three studies submitted related to secondary poisoning to dogs and foxes and the hazard/risk to barn owls which are considered only supplementary data and not considered further in the risk assessment.

PNECs were calculated based on the studies submitted for the EU approval of the active substance. PECS for assessment of primary and secondary poisoning were determined based on the ESD for PT14 and the TGD (2003).

3.3.7. Risk Characterisation for the Environment

Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals.

Product containing brodifacoum are placed at secured bait points. To maximise exposure of the target rodents and minimise unintended exposure of other non-target vertebrates, the products are placed where they are most likely to be encountered by the target organisms (e.g. on habitual rat-runs).

The type of secured bait point suitable for a given situation is determined on a case-by-case basis, taking into account such factors as shielding from sunlight and moisture necessary to maintain bait integrity and the level of security required to prevent access to and/or interference by non-target animals etc.

The risks posed by products containing 50 mg Brodifacoum/kg are characterised for the following scenarios:

1. **Sewers**
2. **In and around buildings (houses, animal houses, commercial and industrial sites)**

3.3.7.1. Aquatic compartment

A contamination of surface water with Brodifacoum from the placing of product in and around buildings is highly unlikely. A lack of exposure to surface water is also stated in the EUBEES 2 emission scenario document. Contamination of surface waters is however expected to arise following use of bait blocks in sewers.

The most sensitive organism in the aquatic tests was alga with a nominal 72 hr ErC50 of 0.04 mg/L. This **PNEC_{water}** of 0.04/1000 AF= **0.00004 mg/L**.

The test with micro-organisms in inhibition of microbial activity showed that concentrations that it is not likely that Brodifacoum will have a negative impact on the microbial processes in a sewage treatment plant at solubility limits. This gives a **PNEC_{STP}** of = **0.0058 mg/L**.

As no specific data are available, the toxicity of Brodifacoum to sediment-dwelling organisms is covered by the risk to aquatic compartment. The application of an additional factor of 10, as done in CAR A, is considered not necessary as an experimental log Kow = 4.92 (i.e. lower than 5) is available. **Therefore, the PNEC_{sediment organisms} = 0.00004 mg/l.**

The risk characterisation for the aquatic compartment is presented in the following table applying the relevant PEC values as indicated in the table in the overall summary of the exposure assessment in the previous section.

Aquatic PEC/PNEC ratios using the realistic and worst case scenario

Exposed compartment	Endpoint	PNEC mg/L	PEC Worst case	PEC Realistic	Risk quotient PEC/PNEC
Surface water	Algae	0.00004	1.77E-06	1.18E-06	0.044
Sediment	Based on aquatic data and equilibrium partitioning method	4.348E-02	1.92E-03	1.28E-03	0.044
STP	Inhibition of microbial activity	0.0058	1.93E-05	1.27E-05	0.003

The PEC/PNEC risk quotient in all compartments are below the trigger value of 1 indicating Brodifacoum following the recommended use of the product does not cause an unacceptable risk to aquatic organisms.

Brodifacoum is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes. Accordingly, the degradation of Brodifacoum in sediment is also anticipated to be low. However, it has limited exposure to the aquatic compartment and this is confirmed by the PEC calculations. The PEC/PNEC ratio is below the level that leads to an unacceptable risk, thus the risk for unacceptable accumulation in sediment can be regarded as low.

For an indication of the risk in relation to surface water and groundwater/porewater used for drinking refer to the section on the aquatic compartment and groundwater in the exposure assessment.

Since the potential for metabolites formation is negligible, risk characterisation is not required.

Summary: No risk is identified

3.3.7.2. Atmospheric compartment

There are no releases of brodifacoum to air from manufacturing, formulating, use or disposal phases. Based on this and the physical and chemical properties of brodifacoum, the compound is not expected to contribute to global warming, ozone depletions in the stratosphere, or acidification.

Summary: No risk is identified

3.3.7.3. Terrestrial compartment

Contamination of soil following the use of product in sewers is highly unlikely during application and use. However, soil may contain low concentrations of Brodifacoum from the spreading of sludge on land derived from waste water treatment works receiving water after the baiting of sewer systems.

Exposure of the terrestrial compartment (soil) will also occur when product is deployed outdoors. Exposure is assumed to arise through a combination of transfer (direct release) and deposition via urine and faeces (disperse release) onto soil.

As there is only one test result available with soil dwelling organisms the risk assessment is performed on the basis of this result using AF and on the basis of the equilibrium partition method. For the EPM the PNEC is calculated from the aquatic toxicity data **PNECaquatic= 0.00004 mg/kg**.

Aquatic PEC/PNEC ratios using the realistic worst case scenario

Exposed compartment	Endpoint	PNEC	PEC Worst case	Risk quotient PEC/PNEC Worst case
Sewer application of sewage sludge	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.86E-04	1. 0.011 2. 0.00055
In and around buildings	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.68E-02	1. 1.07 2. 0.053

The PEC/PNEC ratio was greater than 1 when used **in and around buildings** when applying the EPM indicating for this calculation method that Brodifacoum, following recommended use of the product, causes an unacceptable risk to organisms in this terrestrial compartment. However, this PNEC value based in and around buildings PEC **represents only a screening value** of contamination and is superseded by the PNEC value determined from the 14-day earthworm toxicity study.

Summary: No risk is identified

Non compartment specific effects relevant to the food chain

3.3.7.4. Primary poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (cf. ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, several non-target species are assessed for primary poisoning risk assessments.

Acute exposure:

Non-target mammals and birds are unlikely to enter sewers and feed on product in sewage systems. Therefore, there will be no significant exposure following the use of product in sewers. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. In conclusion, the risks to non-target mammals and birds following the use of bait blocks containing Brodifacoum in sewers are considered to be very low.

Following applications in and around buildings, the empirical risk assumes direct or indirect consumption of the deployed baits. For primary poisoning the initial PEC_{oral} values assume that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the product.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The PEC_{oral} is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

Tier I risk assessment: PEC_{oral}/PNEC_{oral} ratio for birds and mammals exposed to Brodifacoum

	PEC _{oral} (concentration in food, mg/kg)	PNEC _{oral} (concentration in food, mg/kg)	PEC / PNEC
Acute			
Bird	50	19	2.63
Mammal	50	-	-
Long-term			
Bird	50	0.0004	125000
Mammal	50	0.000011	4545454

The ratios PEC/PNEC are above 1 indicating a potential risk.

Therefore, a refined tier 2 assessment is set out below, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 acute risk assessment: PEC_{oral}/PNEC_{oral} for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		PNEC _{oral} (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2

Tree sparrow	17.27	12.09	0.0004	43175	30225
Chaffinch	15.00	10.50	0.0004	37500	26250
Wood pigeon	5.42	3.79	0.0004	13550	9475
Pheasant	5.39	3.77	0.0004	13475	9425
Dog	2.28	1.596	0.000011	207272	159600
Pig	0.375	0.2625	0.000011	34090	26250
Pig, young	1.20	0.864	0.000011	109090	78545

In Tier 2, Step 1 (worst case) AV, PT and PD are all set to 1, whilst in the realistic worst case (Step 2) these AV and PT are refined to 0.9 and 0.8, respectively.

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-term exposure:

In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 1-day elimination of Brodifacoum

Species	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.0004	30225	21775
Chaffinch	10.5	7.56	0.0004	26250	18900
Wood pigeon	3.79	2.73	0.0004	9475	6825
Pheasant	3.77	2.72	0.0004	9425	6800
Dog	1.596	1.149	1.1E-05	145091	104455
Pig	0.2625	0.189	1.1E-05	23864	17182
Pig, young	0.864	0.6048	1.1E-05	78545	54982

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC_5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC _{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw) ^a	EC _{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw) ^a	PNEC _{oral} (mg/kg b.w./d)	Ratio EC _{oral} /PNEC _{oral}
Tree sparrow	30.7	22	0.0004	55260
Chaffinch	26.6	19	0.0004	47880
Wood pigeon	9.61	7	0.0004	17298
Pheasant	9.56	7	0.0004	17208
Dog	4.05	3	0.000011	265091
Pig	0.666	0.480	0.000011	43593
Pig, young	2.13	2	0.000011	139418

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Summary: Risk is identified

Overall, for primary poisoning all acute and long-term PEC_{oral}/PNEC_{oral} ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

3.3.7.5. Secondary poisoning

It is unlikely that target rodents that have ingested bait blocks containing Brodifacoum will leave the sewer system and be exposed, in significant numbers, to predators or scavengers. Therefore, the secondary poisoning risks from the use of bait blocks in sewers are considered to be very low.

For the first tier assessment of secondary poisoning in and around buildings the maximum residue levels in target rodents that arise on day-5 after the last meal (ETE_{oral, predator}) are compared to the PNEC values for concentration in food. The first tier assessment also assumes the following three levels of Brodifacoum bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide and that the non-target animals consume 50% of their daily intake on poisoned rodents.

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	PNEC _{oral} (mg a.s./kg b.w.)	ETE _{oral, predator} (mg a.s./kg b.w.)			PEC _{oral} /PNEC _{oral} – day 5		
		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	-				-	-	-
Long-term							
Birds	0.0004	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000011				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	PNEC _{oral} (mg a.s./kg b.w.)	ETE _{oral, predator} (mg a.s./kg b.w.)	PEC _{oral} /PNEC _{oral} – day 14
----------------	--	--	--

PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.31	5.79	11.58	0.121	0.30	0.60
Mammals	-				-	-	
Long-term							
Birds	0.0004	1.15	2.31	5.79	287	5775	14475
Mammals	0.000011				104545	231000	526363

According to the tier 1 assessment the risk for secondary poisoning of non-target predator birds and mammals during long-term exposure via rodents poisoned with Brodifacoum is very high as indicated by the trigger value of 1 being exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE _{oral} predators (mg a.s./kg/d)	PNEC _{oral} (mg a.s./kg/d)	Ratio ETE _{oral} predators / PNEC _{oral}
Barn owl	Day 5 before the last meal	1.10	0.0004	2750
	Day 5 after the last meal	1.72		4300
	Day 14 after the last meal	2.06		5150
Kestrel	Day 5 before the last meal	1.68	0.0004	4200
	Day 5 after the last meal	2.62		6550
	Day 14 after the last meal	3.13		7825
Little owl	Day 5 before the last meal	1.26	0.0004	3150
	Day 5 after the last meal	1.97		4925
	Day 14 after the last meal	2.35		5875
Tawny owl	Day 5 before the last meal	1.01	0.0004	2525
	Day 5 after the last meal	1.58		3950
	Day 14 after the last meal	1.89		4725
Fox	Day 5 before the last meal	0.41	0.000011	41000
	Day 5 after the last meal	0.63		63000
	Day 14 after the last meal	0.76		76000
Polecat	Day 5 before the last meal	0.85	0.000011	77272
	Day 5 after the last meal	1.32		132000
	Day 14 after the last meal	1.58		143636
Stoat	Day 5 before the last meal	1.21	0.000011	121000
	Day 5 after the last meal	1.89		189000
	Day 14 after the last meal	2.26		226000
Weasel	Day 5 before the last meal	1.74	0.000011	174000
	Day 5 after the last meal	2.72		272000
	Day 14 after the last meal	3.25		325000

Summary: Risk is identified

The ratios PEC/PNEC are all above 1 indicating a potential risk even after refinement.

3.3.7.6. Secondary poisoning via the aquatic food chain

Only one of the proposed use scenarios, namely use in sewers, will lead to exposure of surface water.

Scenario	PEC _{oral,fish} (mg/kg wet fish)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1 ^a	Tier 2 ^b		Tier 1 ^a	Tier 2 ^b
Application in sewer system	3.19 * 10 ⁻¹	2.13 * 10 ⁻¹	Birds: 4.0 x 10 ⁻⁴	797.5	532.5
			Mammals: 2.22 x 10 ⁻⁴	1396	968

From this result it is concluded that there is a risk of secondary poisoning to birds and mammals that eat fish. However, due to the low water solubility and high adsorption tendency of brodifacoum to organic matter, it is expected that the substance would preferably partition into sediments.

Summary: Risk is identified but is likely to have been overestimated

Overall, it is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded although it is likely to have been overestimated.

3.3.7.7. Secondary poisoning via the terrestrial food chain

Emissions of brodifacoum to soil take place in two scenarios. In the scenario **in and around buildings** the uptake to soil proceeds directly (when considering outdoor applications as proposed in the ESD PT 14), whereas in the scenario for the **sewer** it occurs indirectly via sewage sludge.

However, the TGD gives advice to take the 180 days averaged PEC_{local} for soil with respect to sewage sludge when calculating the PEC in earthworms. Hence, the mode of application given in the TGD is in fact not applicable for direct intake of substances.

In the product dossier PEC_{oral,earthworm} for the direct soil intake has been calculated. The applicant advises that these figures be interpreted with care as concentrations in earthworm due to direct soil intake are not dealt with in the TGD. Soil concentrations used for the calculation represent a brodifacoum intake within a soil mixing depth of just 10 cm. Degradation has not been considered. Soil concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm to origin from the contaminated area.

Table-2: Secondary poisoning risk to earthworm-eating birds and mammals

Scenario	PEC _{oral,earthworm} (mg/kg wet earthworm)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1 ^a	Tier 2 ^b		Tier 1 ^a	Tier 2 ^b
Birds					
Sewer system	0.00763	0.00326	4.0×10^{-4}	19	8.15
In and around buildings	0.495	0.441		1237	1102
Mammals					
Sewer system	0.00763	0.00326	2.22×10^{-4}	34	14.81
In and around buildings	0.495	0.441		2229	2004

^a Product specific application data and default value for release (90% direct +indirect release)

^b Product specific application data and refined metabolism

Summary: Risk is identified but is likely to have been overestimated

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

3.3.7.8. Overall Summary

Based on toxicity data Brodifacoum presents a hazard to birds and non-target mammals. Non-target vertebrate animals may be exposed to the product containing Brodifacoum, either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain Brodifacoum residues (secondary poisoning). Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals. There are many uncertainties associated with quantification of the risk associated with the use of Brodifacoum products. Overall, because of the toxic nature of rodenticides and the over-riding public health requirement it is more appropriate to develop and validate risk management measures than to refine the risk assessment procedures further. It is noted that the product contains a bittering agent and this may deter some non-target animals. It is also noted that the attractiveness of the product may be impacted by the use of dye.

5.1.1.1.7 Primary poisoning:

Overall, all acute and long-term PECoral/PNECoral ratios are above the trigger value of 1 indicating acute and long-term unacceptable risks. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals.

5.1.1.1.8 Secondary poisoning:

Via ingestion of target rodents by non-target vertebrates

All ratios of PECoral/PNECoral are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals. Studies are submitted in the product dossier that indicate that the realistic risk for secondary poisoning is significantly lower than that using the PEC/PNEC approach. These studies are only considered as supplementary information.

Via the aquatic food chain

Only one of the proposed four use scenarios, namely use in sewers, will lead to exposure of surface water. It is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded it potentially is overestimated.

Via the terrestrial food chain

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

5.1.1.1.9 Conclusion for primary and secondary poisoning:

Due to the risk assessment results for primary and secondary poisoning and the uncertainty associated with quantification of this risk, risk mitigation measures must be taken into account to lead to an acceptable use of the rodenticide product.

5.1.1.1.10 The following risk mitigation measures are proposed to mitigate the primary and secondary poisoning risk to non-target mammals and lead to an acceptable use of this rodenticide:

- Use of an integrated management strategy and precautionary systems
- Unless under the supervision of a pest control operator use or other competent person do not use anticoagulants as permanent baits
- There should be proper and secure placing of baits so as to minimise the risk of consumption by other animals or children. Where possible secure baits so they cannot be dragged away.
- Users should select tamper-resistant bait boxes, secured bait boxes, covered applications or burrow baiting (placing of bait in appropriate containers or under a curved tile or in a piece of tube) to minimize exposure of non-target animals
- Monitor and replenish bait stations as appropriate
- Frequent visits to bait stations to ensure that any bait that is split or dragged out of bait stations is removed

- Unconsumed baits must be collected after termination of the control campaign and dispose of them in accordance with local requirements
- Remove dead and moribund rodents at frequent intervals, at least as often as baits are checked or replenished during a baiting campaign
- Baits should be deployed in accordance with the product labelling
- Baits should be deployed in accordance with other approved guidance on good practice.
- Restrict the use of the product to treatment campaigns of limited duration
- To minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides, long-term deployment of baits as a preventative control measure is not recommended
- The resistance status of the population should be taken into account when considering the choice of rodenticide to be used.
- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary and secondary poisoning by the anticoagulant as well as indicating the first measure to be taken in case of poisoning must be made available alongside the baits

3.4. Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 is provided below.

3.4.1 Methods and precautions concerning handling, use, storage, transport or fire

Methods and precautions concerning handling and use:

- Always read the label before use and follow the instructions provided.
- Do not decant product into unlabelled containers.
- Product must be handled in a safe manner.
- Avoid all unnecessary exposure, in particular avoid ingestion.
- A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
- Baits must be securely deposited in baiting stations or other coverings so as to minimise the risk of consumption by companion animals, other non-target animals and children. Where possible, secure baits so that they cannot be dragged away.
- PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- For use in sewers where there is no risk to children, companion animals and non-target species blocks should be secured to available structures by wire to ensure the block is not washed away.
- Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- It is illegal to use this product for the intentional poisoning of non-target, beneficial and protected animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.
- For professional users the use of appropriate personal protective equipment (PPE) is advised.

Methods and precautions concerning storage:

- Store in a cool, dry, well-ventilated secure (lockable) place
- Store locked up in the original container
- Store original container tightly closed
- Keep/store out of reach of children and companion animals
- Keep/store away from food, drink and animal feedstuffs and products which may have an odour.

Methods and precautions concerning transport:

Hazard classification for transport: TOXIC, MARINE POLLUTANT

UN-No Coumarin derivative pesticide, solid, toxic, n.o.s (BRODIFACOUM)

Class 6.1 Hazard ID 66

Proper Shipping name Coumarin derivative pesticide, solid, toxic (contains brodifacoum)

UN-No 3027 Packing Group 1

Class 6.1

Methods and precautions concerning fire:**Suitable Extinguishing Media:**

Keep fire exposed containers cool by spraying with water if exposed to fire. Fight surrounding fire with foam, water fog, or dry powder.

Extinguishing media which must not be used for safety reasons:

DO NOT USE WATER JETS

Specific hazards:

This product is not flammable but is combustible. Avoid run-off into water courses. Self-contained breathing apparatus should be worn by fire-fighting personnel.

Special protective equipment for fire-fighters:

In the event of fire, wear self contained breathing apparatus, a chemical protection suit, suitable gloves and boots.

Residues:

Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.

3.4.2 Specific precautions and treatment in case of an accident**Personal precautions**

Wear suitable protective clothing, gloves and eye/face protection, if applicable and where appropriate.

- Respiratory Protection: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.
- Hand protection: Wear gloves for professional products.
- Skin protection: No special clothing/skin protection equipment is recommended under normal conditions of use.
- Eye protection: Not required.

- Ingestion: When using this product, do not eat, drink or smoke

Personal treatment

- General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible and report the authorisation number).
- Skin contact: Obtain medical advice immediately. Remove contaminated clothing. After contact with skin, wash immediately with plenty of water, followed by soap and water in order to minimise skin contact.
- Contaminated clothing should be washed and dried before re-use.
- Eye contact: Obtain medical advice immediately. Rinse eyes immediately with copious amounts of water.
- Inhalation: Unlikely to present an inhalation hazard unless excessive dust is present. Remove person to fresh air. Obtain medical advice immediately.
- Ingestion: Do not induce vomiting. If swallowed, obtain medical advice immediately. Wash out mouth with water.

ADVICE FOR DOCTORS:

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre; include information on the product authorisation number, product trade name and active substance. In Ireland, this is the National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166)

Environmental precautions

- Prevent accidental exposure of the product to the environment.
- Keep un-used bait locked-up and in secure storage containers
- Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms.

Environmental treatment

- Clean up accidental spillages promptly by sweeping or vacuum.
- If the product gets into water or soil, it should be removed mechanically. In the event of a significant accidental release, inform the appropriate authority.
- Transfer to a suitably labelled container and dispose of to a certified waste disposal operator for incineration and licensed waste disposal site.
- Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.
- For further instructions, see section 3.4.6 below.

3.4.3 Procedures for cleaning application equipment

No application equipment is required, therefore, no specific cleaning for equipment is required

If necessary, following use, bait boxes should be washed with detergent and water. The bait box should be washed out 3 times (triple rinsed).

3.4.4 Identity of relevant combustion products in cases of fire

This product contains

3.4.5 Procedures for waste management of the biocidal product and its packaging

The best means of disposal of any product is through proper use according to the label. For the product incinerate under controlled conditions. For the pack, do not dispose of the pack in domestic refuse. Empty completely, puncture or crush and dispose of safely to Local Authority and National requirements. Dispose of packaging, remains of unused product and dead rodents to a certified waste disposal operator for incineration and licensed waste disposal site.

3.4.6 Possibility of destruction or decontamination following accidental release

Air:

Brodifacoum has a low vapour pressure, therefore the potential for evaporation is low. The vapour pressure is 5×10^{-5} Pa. As a rodenticide, this material is not intentionally aerosolised. Therefore, destruction in air is not a concern.

Water (including drinking water):

Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.

Soil:

Direct and/or intentional release to soil is not anticipated for the use of the product as a rodenticide. In the event of a significant accidental release, inform the appropriate authority.

3.4.7 Undesirable or unintended side-effects

Toxic to mammalian and avian species, including domesticated animals, wildlife and humans. Therefore the risk to these non-target species should be considered when using bait.

3.4.8 Poison control measures

The wax blocks are dyed (e.g. red or blue) to make them unattractive to wildlife, and birds in particular. In addition, in case of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

The product contains a human taste deterrent (adversive agent – Bitrex).

To report human poisoning incidents call the relevant national poison information centre. Include information on the product authorisation number, product trade name and active substance. Where possible provide a copy of the label or safety data sheet (SDS).

In Ireland to report a poisoning incident, call: 01 (8092566 / 8379964) The Poisons Information Centre of Ireland, Beaumont Hospital, Beaumont Road, Dublin 9.

ADVICE FOR DOCTORS:

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre (include information on the product authorisation number, product trade name and active substance)

4. Proposal for Decision

The assessment presented in this report has shown that the ready-to-use product, Vertox Oktablok, formulated by Pelgar International Limited with the active substance Brodifacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) for the control of rodents (rats and mice).

Physical-Chemical Properties:

Vertox Oktablok has been shown not to present a physical-chemical hazard to end users and does not classify as highly flammable, oxidising or explosive. The block bait is stable when stored at ambient temperatures (20°C) for three years, therefore a shelf life of three years is proposed, however as there is only efficacy studies for two years only a shelf life of two years can be given. A suitable method of analysis for the determination of Brodifacoum in the block bait was provided.

The source of active substance used in the biocidal product Vertox Oktablok is the same source of active substance that is listed in Annex I of 98/8/EC. Syngenta initially supported the source, then the task force (Pelgar International Ltd and Activa) also supported the source, Italy carried out an equivalence check on the Task force source of Brodifacoum and found it to be equivalent to the Syngenta source. The RefMS accepted Italy's assessment.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). All the dyes are non-toxic at the concentrations proposed in the final product and will have no impact on the physical & chemical profiles of the product, the only effect being the change of colour. The Vertox Oktablok (blue) bait does not classify from a physical & chemical point of view. The change in colour is acceptable.

Efficacy:

Effectiveness data has confirmed that Vertox Oktablok is effective in the proposed areas for use, at the recommended dose rate. *Rattus rattus*, one of the target organisms was removed from the recommended list of target organisms. There was no efficacy data provided using wax block formulation for the black rat (*Rattus rattus*). The block bait formulation proved to be both highly palatable and effective against brown rats and mice in the trials. Vertox Oktablok is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been demonstrated.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The change in colour of the formulation Vertox Oktablok from red to blue has no impact on the efficacy of the formulation and is for marketing purposes only. Rats and mice are nocturnal animals and therefore have relatively poor colour vision. In their normal period of activity (at night), they have monochromatic vision. A change in colour of the bait has no effect on the acceptability of that bait to rats and mice.

Human Health:

The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0033µg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The colouring agent is the only formulant varying in the block formulation. The red colouring agent was evaluated by looking at the material safety data sheets. None of the colouring agents classify. The substitution of the red dye by the blue dye is 1:1 w/w and does not impact the levels of other co-formulants or the active substance in the formulation. The substitution of the red dye by the blue dye does not impact the classification of the block formulations with respect to the toxicological properties of the product. The Vertox Oktablok (blue) bait does not classify from a toxicological point of view.

Environment:

The applicant did not submit any new environmental fate and behaviour studies with this product. Therefore the conclusions made at the Annex I inclusion stage for the active substance stand. The uses of this product were assessed here under the TGD and the PT14 ESD and all PEC/PNEC ratios were <1. However there is a risk for primary and secondary poisoning for non-target vertebrates. These identified risks are mitigated by applying all appropriate and available risk mitigation measures.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). The colouring agent is the only formulant varying in the formulations; therefore the environment properties of other components were not evaluated here. The Vertox Oktablok (blue) bait does not classify from an environment point of view.

Conclusion:

During the active substance review of Brodifacoum by Italy, primary and secondary poisoning risks were identified for non-target organisms and for potential accidental poisoning incidents involving children. The assessment of those EU identified risks during the product authorisation evaluation of Brodifacoum have also indicated a potential risk of primary and secondary poisoning to non-target animals and the potential for the accidental primary poisoning of children. Due to these findings risk mitigation measures are applied to product authorisation.

Additionally, as the target rodents are vermin and are both direct transmitters of disease (such as through biting or contamination of food/feed by urine or faeces) or indirect carriers of disease (such as disease vectors, where fleas move from rat to humans) to humans and other animals. Transmitted diseases can include leptospirosis (or Weil's disease), trichinosis and salmonella. Authorisation of this product is considered necessary on the basis of public health grounds, since rodent populations are considered to constitute a danger to public health through the transmission of disease. However, risk mitigation measures and restrictions are required to prevent the possibility of the identified risks to non-target animals, companion animals and children.

The applicant requested an additional colour to the lead formulation Vertox Oktablok (IE/BPA 70232) from red (IE/BPA 70232-001) to blue (IE/BPA 70232-002). All the dyes are non-toxic at the concentrations proposed in the final product and will have no impact on the physical & chemical, environmental or toxicological profiles of the product, the only effect being the change of colour. The Vertox Oktablok (blue) bait does not classify from a physical & chemical point of view. The change in colour is acceptable.

Conditions of authorisation

Two authorisations should be issued. The first authorisation covers professional and trained professional use product. The second authorisation covers amateur use product.

This authorisation of Vertox Oktablok is for a period of 5-years with an annual renewal.

The concentration of the active substance, Brodifacoum, in Vertox Oktablok shall **not** exceed 0.05 g/kg (0.005% w/w).

Only ready-to-use Vertox Oktablok product is authorised.

As a poison control measure, the authorisation requires that the product shall contain an aversive, bittering agent.

The authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.

This product shall **not** be used as a tracking poison.

The product is authorised only for use against rats and mice (for example brown rats and house mice). Authorisation of this product does **not** allow use against non-target organisms.

The authorisation of this product for professionals and trained professionals only allows for use indoors and outdoors in the following areas: Indoors, including areas such as houses, warehouses, outbuildings and commercial premises. Outdoors uses only includes in-and-around buildings. The product can also be utilised in sewers. Brodifacoum baits must not be placed where food, feeding stuffs or drinking water can become contaminated.

The authorisation of this product for amateurs allows for use of this product indoors and outdoors around buildings in the following areas: Indoors, including only private houses and outbuildings. Outdoors uses, including only around private building premises and private gardens. Brodifacoum baits should not be placed where food, feeding stuffs or drinking water can become contaminated.

The product should be used for rodent control in tamper resistant, secured bait stations or other secure coverings. However, for use in sewers where there is no risk to children, companion animals and non-target species blocks should be secured to available structures by wire to ensure the block is not washed away.

Bait stations should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Wax blocks shall be secured to the bait station(s) so that rodents cannot remove bait from the bait box.

For amateur use products placed on the market in Ireland packaging restrictions are to be limited to pre-baited bait stations and refill packs with a maximum pack-size of 500g. Refill packs for amateurs must contain bait that is wrapped. Loose baits or grain (without wrapping) shall not be packaged for amateurs.

All product placed on the Irish market after the date of authorisation must be in compliance with the conditions of this authorisation and shall carry the approved label with the IE/BPA authorisation number and be packaged in the approved packaging.

Prior to any amendment relating to this authorised product, such as specification, use, labelling or administrative changes, application must be made to this Authority to do so

Upon annual renewal of the biocidal product, the authorisation holder shall provide statistics to PRCD on the import and export from Ireland and also manufacture statistics where appropriate for the product for the given full annual period or part thereof.

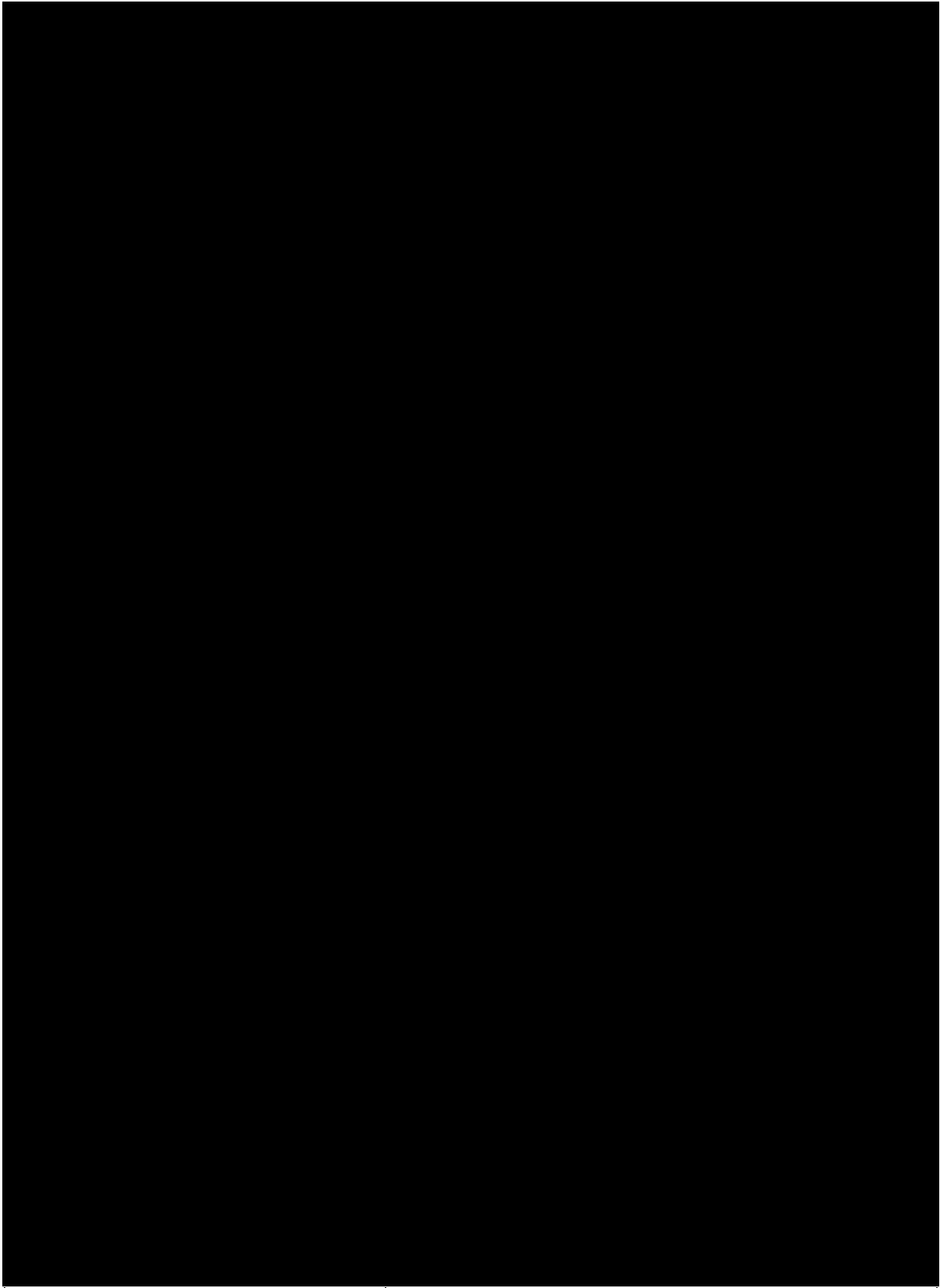
Authorisation of the biocidal product may be subject to review, following a detailed assessment of the risks involved, in accordance with the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001, as amended. This review may lead to changes in or revocation of this authorisation.

ANNEXES to Initial PAR - July 2013

Annex:

1. Confidential Information and Data
2. Summary of the Product Characteristics (SPC)
3. Study Summaries of Studies Reviewed
4. List of Studies Reviewed
5. Toxicology Calculations
6. Environmental Calculations
7. Residue Calculations

ANNEX I: Confidential Information and Data



17 All sites involved in the manufacturing process of each active substance and of the product must be listed.

[Redacted text block]

[Redacted text block]

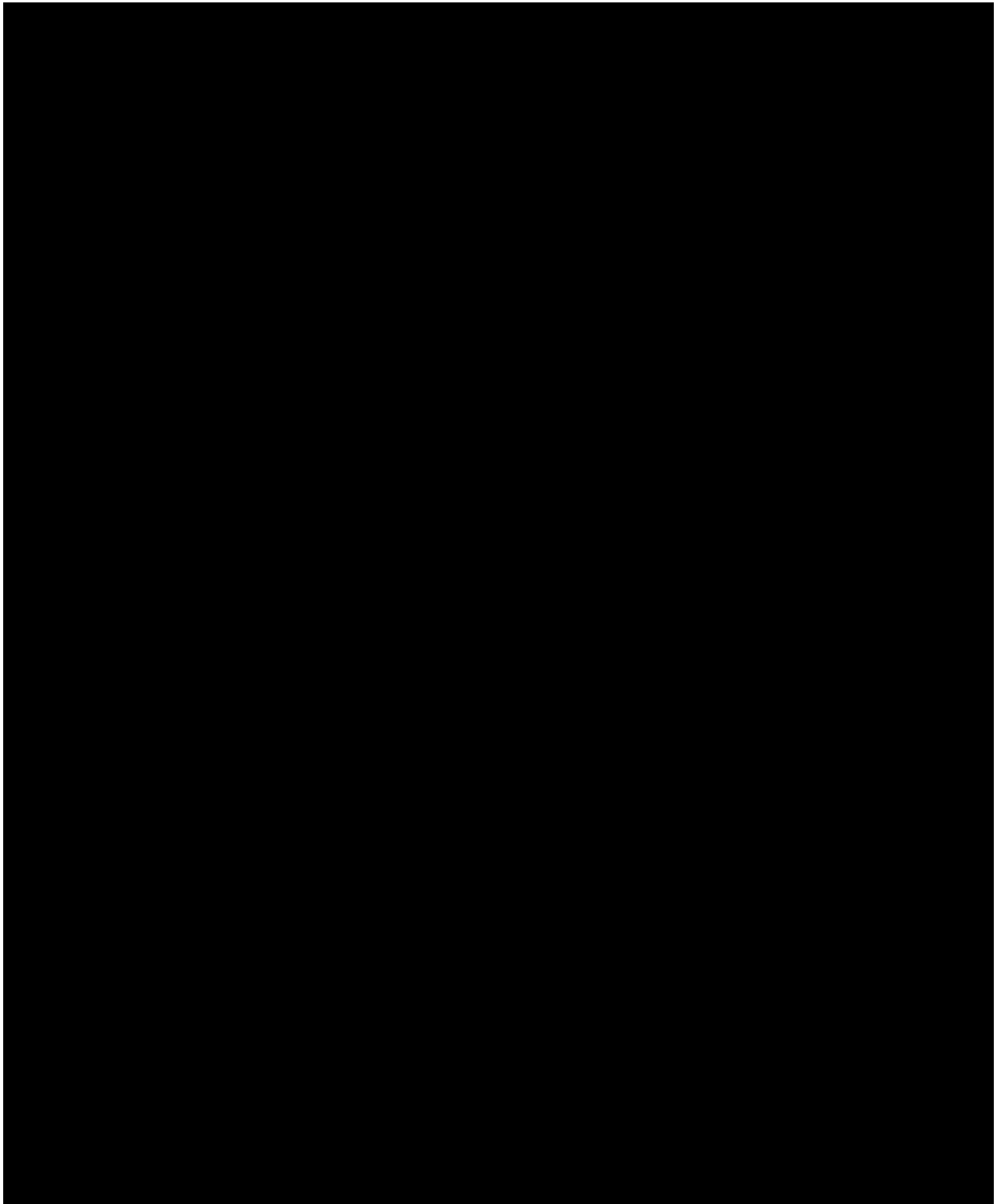
[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]



<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	<p>[Redacted]</p>

<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	<p>[Redacted]</p>
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	
<p>[Redacted]</p>	<p>[Redacted]</p>	<p>[Redacted]</p>

	<p>[Redacted text block]</p>	
<p>[Redacted text]</p>	<p>[Redacted text block]</p>	
<p>[Redacted text]</p>	<p>[Redacted text block]</p>	
	<p>[Redacted text block]</p>	

<p>[Redacted]</p>	<p>[Redacted]</p>	<p>[Redacted]</p>
-------------------	-------------------	-------------------

	<p>[Redacted text block]</p>	
--	------------------------------	--

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]					[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]				
[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

[Redacted]

[Redacted]				[Redacted]			[Redacted]	
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]				[Redacted]			[Redacted]	
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

18 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gram or per litre).

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
			[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		

Annex II: Summary of the Products Characteristics (SPC)

Please see separate SPC accompanying the PAR and authorisation certificate that have uploaded to the R4BP2.

Annex III: Study Summaries of Studies Reviewed

Insert study summaries with expert evaluation in data point order.

Study summaries of new data¹⁹ submitted in support of the evaluation of the active substance (IIIA)

Physical Chemical Characteristics:

New data was submitted in support of PelGar International Limited's Brodifacoum source of active substance. This included an assessment on the reactivity of the technical concentrate towards the container material. It was argued that there will be no chemical or physical reaction between the technical concentrate and container. This information was assessed by Germany and was found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Methods of Analysis

New data was submitted in support of PelGar International Limited's Brodifacoum source of active substance. This included a fully validated analytical method for the determination of Brodifacoum in soil. This information was assessed by Germany and found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Efficacy

There were no new additional studies submitted for product authorisation.

Toxicology

There were no new additional studies submitted for product authorisation.

Environment (including Eco-Toxicology)

There were no new additional studies submitted for product authorisation.

¹⁹ Data which have not been already submitted for the purpose of the Annex I inclusion.

Study summaries of new data submitted in support of the evaluation of the biocidal product (IIIB)

Physical Chemical Characteristics of VERTOX® OKTABLOK®

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Appearance (IIB III.3.1)								
3.1.1 Physical state and nature	Visual in accordance with Council Directive 98/8/EC, Annex IIB	0.005%	Opaque waxy octagonal block containing light brown grains and a small hole on top		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.1.2 Colour	Visual in accordance with Council Directive 98/8/EC, Annex IIB	0.005%	Dark red or blue (red formulation tested)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.1.3 Odour	Nasal inhalation	0.005%	Strong sweet odour (temperature: 20 ± 0.5°C)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2 Explosive properties (IIB III3.2)	None	0.005%	Not explosive	See justification for non-submission	N	N/A		
3.3 Oxidising properties (IIB III3.3)	None	0.005%	Not oxidising	See justification for non-submission	N	N/A		
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB III3.4)								
Flash point	None	0.005%	Not explosive		N	N/A		
Autoflammability	Method A16 of annex V of Directive 67/548/EEC	0.005%	237°C		Y	N/A	Fox JM and Mullee DM (2007) Report No.2254/0037	
Flammability	Method A10 of annex V of Directive 67/548/EEC	0.005%	Not highly flammable		Y	N/A	Fox JM and Mullee DM (2007) Report No.2254/0037	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Acidity/Alkalinity (IIB III.3.5)	None	0.005%	Not relevant to solid wax block baits which are not mixed with water	See justification for non- submission	N	n.a.		
3.6 Relative density/bulk density (IIB III.3.6)	Method A3 of annex V of Directive 67/548/EEC	0.005%	1.17 (temperature: 20 ± 0.5°C)		Y	1	Fox and Mullee (2007) SafePharm Laboratories Ltd., Report No. 2254/0037	
3.7 Storage stability - stability and shelf life (IIB III.3.7)								
Effects of temperature	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1	Thomas (1999) University of Wales Cardiff, Report No. 96021261	
Effects of light	Annex V	0.005%	Stable in unopened original container for more than 2 years	See justification for non- submission	N	1		

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Reactivity towards container material	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1		
Other	Annex V	0.005%	Stable in unopened original container for more than 2 years		N	1		
3.8 Technical characteristics (IIB III.8)								
Wettability/ Suspensibility	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non- submission	N	n.a.		
Wet sieve analysis	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non- submission	N	n.a.		
Emulsifiability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non- submission	N	n.a.		
Disintegration time	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non- submission	N	n.a.		

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Attrition/friability of granules; integrity of tablets	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Persistence of foaming	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Flowability/Pourability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
Dustability	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.9 Compatibility with other products (IIB III3.9)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 i Surface tension (IIB III0§)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 ii Viscosity (IIB III0§)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non-submission	N	n.a.		

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.11 Particle size distribution (IIIB III0§)	None	0.005%	Not relevant to a solid wax block bait which is not mixed with water	See justification for non- submission	N	n.a.		

Conclusion:

The block bait is not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view. The block bait is stable when stored for 2 weeks at 54°C, for 2 years at 40°C and for 3 years at ambient temperatures (20°C). The test item is a ready-to-use block bait and is not intended to be added or mixed with any other product.

Section B3.2 Annex Point IIB III.3.2	Explosive properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	<p>Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity.</p> <p>On the basis of the above, a derogation to perform this study is requested.</p>	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	Since none of the BP components is classified as explosive and on the basis of experience in use, no test for explosive properties is deemed necessary.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATES (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	

Section B3.2 Annex Point IIB III.3.2	Explosive properties
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	None.

Section B3.3 Annex Point IIB III.3.3	Oxidising properties	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	Product is a large solid wax block. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested.	
Evaluation by Competent Authorities		

Section B3.3 Annex Point IIB III.3.3	Oxidising properties
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)
Date	Jan 2008
Evaluation of applicant's justification	Since none of the BP components is classified as oxidiser and on the basis of experience in use, no test for oxidising properties is deemed necessary.
Conclusion	The Applicants' justification for the non-submission of data is acceptable.
Remarks	None.
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)
Date	25.5.2012
Evaluation of applicant's justification	Accept the applicant's justification.
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	None.

Section B3.5 Annex Point IIB III.3.5	Acidity/alkalinity and if necessary pH value (1 % in water)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	<p>Product is a large solid wax block composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances.</p> <p>On the basis of the above, a derogation to perform this study is requested.</p>	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	Since the BP is not liquid nor intended to be diluted with water, no information on the product pH is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.7 Annex Point IIB III.3.7	Storage stability: in sunlight	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure [X]	Other justification []	
Detailed justification:	The product is supplied and stored in its original packaging. Correct siting of baits also limits the length of time the product is exposed to sunlight to the length of time it takes to place the bait, and cover it or close the bait box. Due to the very short length of time of exposure, and the known stability at a temperature of 25°C for 2 years, it is considered that further information is unnecessary.	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section B3.8 Annex Point IIB III.3.8	Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	<p>Wax blocks are solid bait products, which are not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. Wax blocks are not friable and are not dusty.</p> <p>On the basis of the above, a derogation to perform this study is requested</p>	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)		
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, the above technical characteristics are not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)		
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	

Section B3.8 Annex Point IIB III.3.8	Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability
Remarks	None.

Section B3.9 Annex Point IIB III.3.9	Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	The product is not applied in mixture with other products. On the basis of the above, a derogation to perform this study is requested.	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Since the BP is not intended to be mixed with other products, no information regarding the physical and chemical compatibility with other products is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

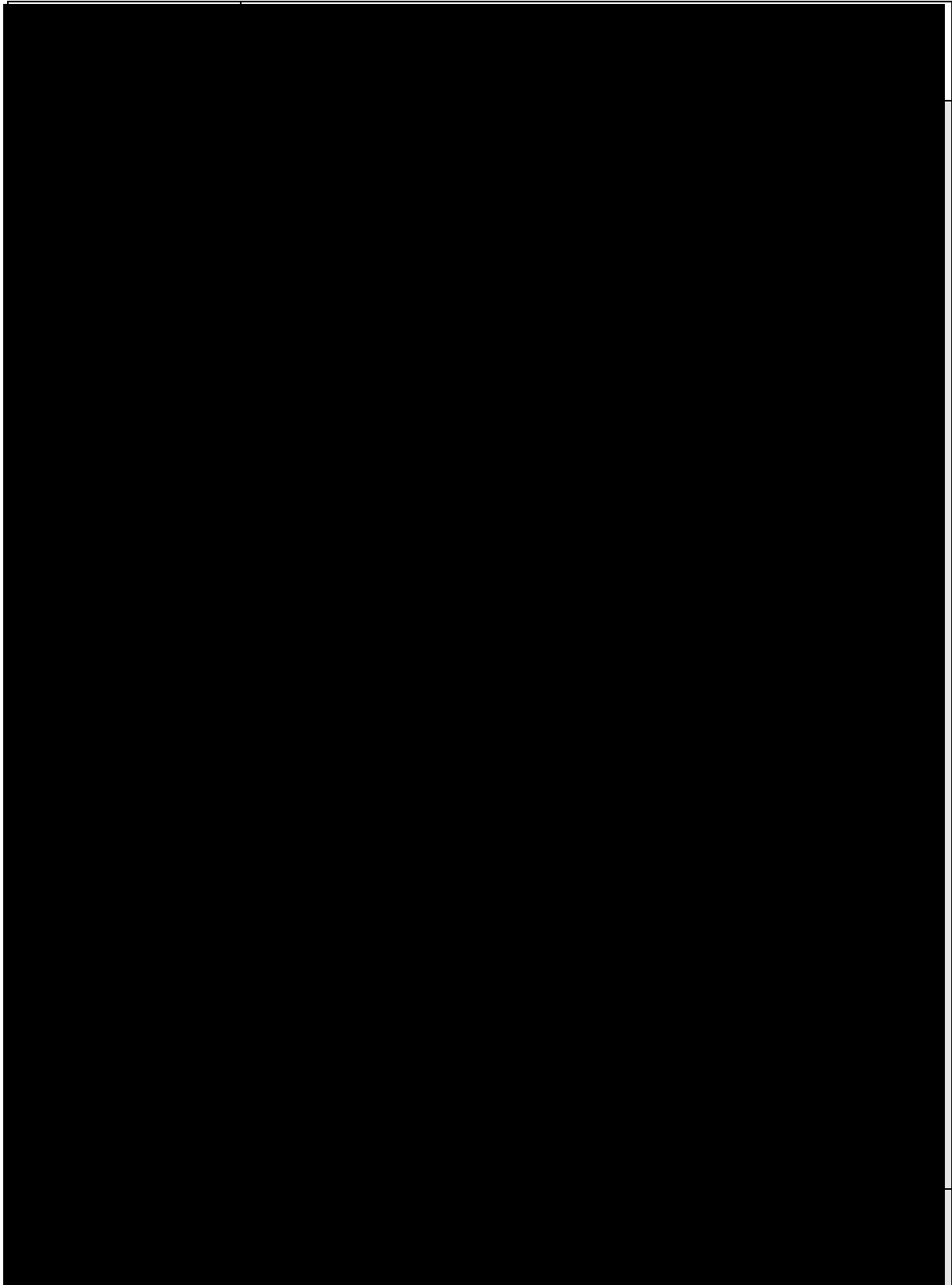
Section B3.10 I Annex Point III B III O §	Surface tension	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	<p>The product is a solid block at NTP. It is not a liquid, nor is it intended for liquefaction.</p> <p>On the above basis, a derogation to perform this study is requested.</p>	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, surface tension is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

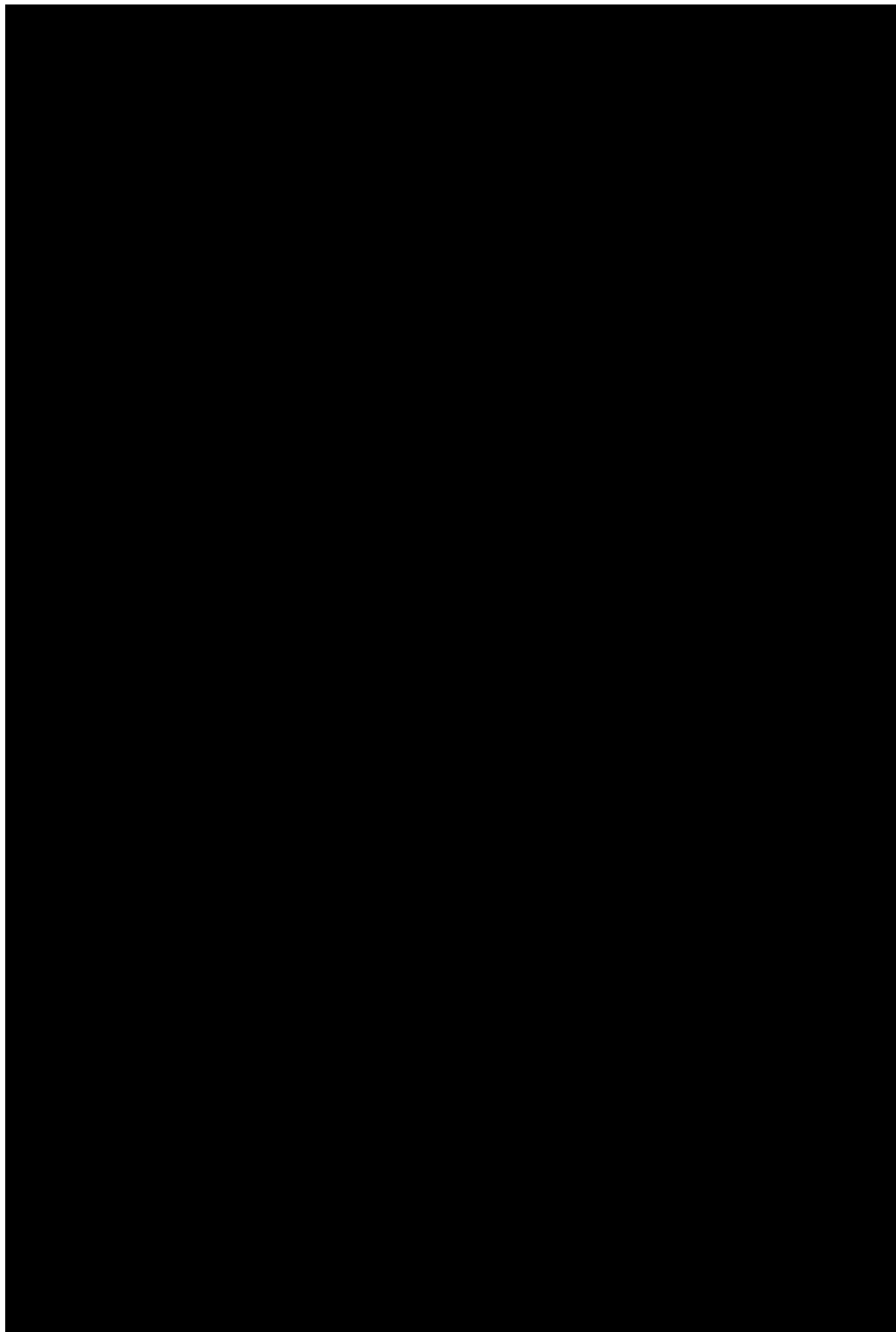
Section B3.10 II Annex Point III B III O §	Viscosity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified []	
Limited exposure []	Other justification []	
Detailed justification:	<p>The product is a solid block at NTP. It is not a liquid, nor is it intended for liquefaction.</p> <p>On the above basis, a derogation to perform this study is requested.</p>	
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)		
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, viscosity is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)		
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

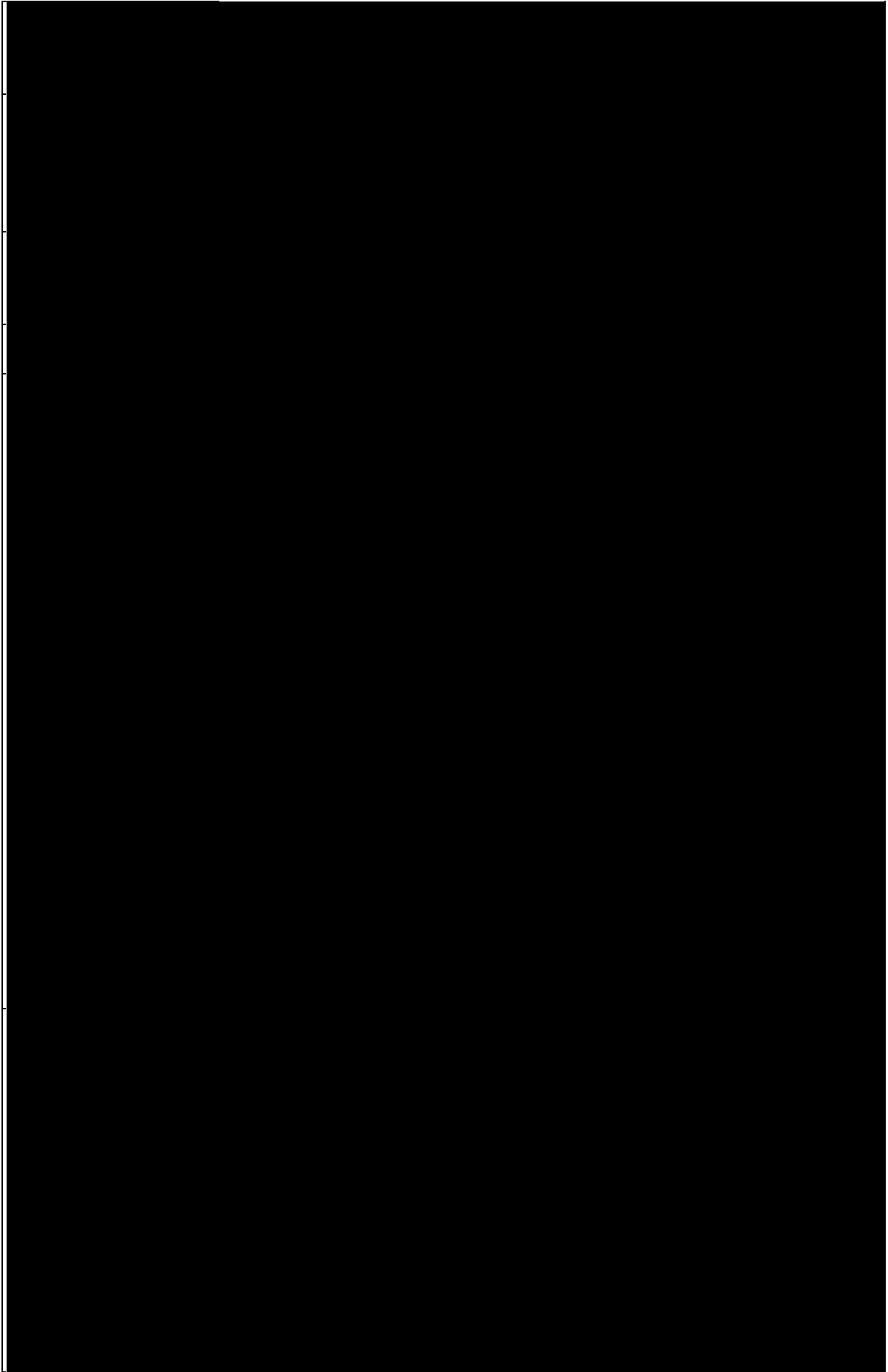
Section B3.11 Annex Point III B III O §	Particle size distribution	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	The product is a solid wax block bait . It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested.	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, particle size distribution is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

<p>[REDACTED]</p>	<p>[REDACTED]</p>	
<p>[REDACTED]</p>		
<p>[REDACTED]</p>	<p>[REDACTED]</p>	
<p>[REDACTED]</p>	<p>[REDACTED]</p>	
<p>[REDACTED]</p>		
<p>[REDACTED]</p>	<p>[REDACTED]</p>	
<p>[REDACTED]</p>	<p>[REDACTED]</p>	

[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]







<p>[REDACTED]</p>	<p>[REDACTED]</p>	
	<p>[REDACTED]</p>	
<p>[REDACTED]</p>	<p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>	
<p>[REDACTED]</p>	<p>[REDACTED]</p>	
	<p>[REDACTED]</p>	
	<p>[REDACTED]</p>	
<p>[REDACTED]</p>	<p>[REDACTED]</p>	

<p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p>

Section B4.2 (a) Annex Point IIB IV4.2	Methods of Identification and Analysis in Soil	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [<input type="checkbox"/>]	Technically not feasible [<input checked="" type="checkbox"/>] Scientifically unjustified [<input type="checkbox"/>]	
Limited exposure [<input type="checkbox"/>]	Other justification [<input checked="" type="checkbox"/>]	
Detailed justification:	<p>A new method of determination of the active ingredient has been provided Section IIIA2.4 (a).</p> <p>Of the other ingredients, only the human taste deterrent is labelled as hazardous for the environment. However, this ingredient is labelled R52/53 and is present at a concentration of just 0.001% w/w, and hence is not of concern as no labelling results under the Dangerous Preparations Directive.</p> <p>As the active ingredient is labelled R50/53, it is reasonable to expect that any environmental hazard presented by the product can be calculated on the basis of the active ingredient content and hazard.</p>	
Undertaking of intended data submission [<input checked="" type="checkbox"/>]		
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY REFERENCE MEMBER STATE (IRELAND)		
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA was not provided in the CAR for the determination of Brodifacoum in soil. However, a new MOA for the determination of Brodifacoum in soil was provided by PelGar post Annex I inclusion. This was assessed by Germany and found to be acceptable. Please see Annex III: Study Summaries of Studies Reviewed.	
	COMMENTS FROM OTHER MEMBER STATE (specify)	

Section B4.2 (a) Annex Point IIB IV4.2	Methods of Identification and Analysis in Soil
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B4.2 (b) Annex Point IIB IV4.2	Methods of Identification and Analysis in Air	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified [X]	
Limited exposure []	Other justification []	
Detailed justification:	As the active substance has a vapour pressure of <0.01 Pa (1.9×10^{-21} Pa at 25°C, Section A3.2, Annex Point IIA, III.3.2.) it is considered to be of low volatility. It is also not used in spray applications. Therefore, in accordance with the TNsG on Data Requirements for the Biocidal Products Directive, analytical methods for the biocidal product in air are not required. On this basis a derogation to perform this study is requested.	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)		
Date	Jan 2008	
Evaluation of applicant's justification	-	
Conclusion	The Applicants' justification for non-submission of data is acceptable.	
Remarks	None.	
COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)		
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	

Section B4.2 (b) Annex Point IIB IV4.2	Methods of Identification and Analysis in Air
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	None.

Section B4.2 (c) Annex Point IIB IV4.2	Methods of Identification and Analysis in Water	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [<input type="checkbox"/>]	Technically not feasible [<input checked="" type="checkbox"/>] Scientifically unjustified [<input type="checkbox"/>]	
Limited exposure [<input type="checkbox"/>]	Other justification [<input checked="" type="checkbox"/>]	
Detailed justification:	<p>The a.i. has very low solubility in water (5.80E-05 mg/L at pH7, 20°C). For determination of the concentration of the a.i. in water see new summary in section IIIA4.2 (c). Denatonium Benzoate has been classified as R52/53 in the MSDS (see Document I). This is for the 100% pure material. It states in the dangerous preparations directive (1999/45/EC), Part B (concentration limits to be used for the evaluation of environmental hazards), table 1, that if the compound with classification R52/53 is present at less than 25% in the preparation (in this case the wax block bait), the preparation will not be classified as R52/53. Denatonium benzoate is less than 25% in the wax block bait, therefore it is believed that an analytical method for denatonium benzoate in water is not required.</p> <p>On the above basis a derogation to perform this study is requested.</p>	
Undertaking of intended data submission [<input checked="" type="checkbox"/>]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	-	
Conclusion	The Applicant's justification is acceptable. As for the determination of <i>Brodifacoum</i> residues in water, please see RMS remarks in doc. IIIA, A4.2(c).	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	

Section B4.2 (c) Annex Point IIB IV4.2	Methods of Identification and Analysis in Water	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA for the determination of Brodifacoum in water was provided in the CAR.	
Section B4.2 (d) Annex Point IIB IV4.2	Methods of Identification and Analysis in Animal and human body fluids and tissues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure []	Other justification []	
Detailed justification:	<p>See the robust summary and data waiver in Section IIIA4.2 (d). There are no toxicologically relevant components in the product other than the active ingredient, excepting denatonium benzoate, a human taste deterrent, which is harmful if ingested in large amounts, with a concentration in the product lower than the a.i. concentration, and triethanolamine, which is irritating to eyes and skin, yet only present at a concentration of 0.06% w/w. The analysis in tissue and fluids, of the active component Brodifacoum, will be covered by studies on the active itself.</p> <p>On the above basis a derogation to perform this study is requested.</p>	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	

Section B4.2 (c) Annex Point IIB IV4.2	Methods of Identification and Analysis in Water
Evaluation of applicant's justification	-
Conclusion	The Applicant's justification is acceptable. Please, see RMS remarks in document IIIA, A4.2(d).
Remarks	None.
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)
Date	25.5.2012
Evaluation of applicant's justification	Accept the applicant's justification.
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	A suitable MOA for provided in the CAR for the determination of Brodifacoum in human and animal body tissues.

Section B4.2 (e) Annex Point IIB IV.4.2	Methods of Identification and Analysis in Treated Food or Feedingstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure []	Other justification [X]	
Detailed justification:	<p>Awaiting decision by the EU commission on which foodstuffs, residue determinations are required for. Additionally, see the robust summary in Section IIIA4.3, for the determination of the brodifacoum content of food and feedstuff.</p> <p>On the above basis, a derogation to perform this study is requested.</p>	
Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (ITALY)	
Date	Jan 2008	
Evaluation of applicant's justification	-	
Conclusion	The Applicants' justification is acceptable. Please, see RMS remarks in doc. IIIA, A4.3. Note that the study presented in Section IIIA4.3 is not related to <i>Brodifacoum</i> determination in wax wheat blocks and pellets, but to <i>Brodifacoum</i> determination in food and feedstuff.	
Remarks	None.	
	COMMENTS FROM REFERENCE MEMBER STATE (IRELAND)	
Date	25.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	

Section B4.2 (e) Annex Point IIB IV.4.2	Methods of Identification and Analysis in Treated Food or Feedingstuffs
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.
Remarks	A suitable MOA for the determination of Brodifacoum in treated food and feeding stuffs was given in the CAR.

Section B5**Effectiveness against target organisms and intended uses****Subsection
(Annex Point)****Of
fic
ial
us
e
o
nl
y****Product type(s) and
field(s) of use
envisaged
(IIB5.1)****Product type(s)**

Product type 14 – Rodenticides
Field of use indoor and outdoor use.
Field of use: Rodenticide
Amateur and professional use.

Overall use pattern

The active substance will be used as a rodenticide for the control, primarily, of commensal rodent species. The active substance will be used in rodenticide products (baited traps and protected bait points) for use by professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm buildings. Professional users can use the product in sewers.

**Method of
application
including
description of
system used
(IIB5.2)**

Product type 14 – Rodenticides
Field of use indoor and outdoor use.
The active substance in VERTOX® wax blocks is the anticoagulant rodenticide Brodifacoum. The product is formulated containing 0.005% a.i. (50 ppm, 50 mg/kg). These bait formulations are supplied ready-to-use. They are not diluted in any medium, mixed with other products, or sprayed, misted, dusted or applied to extensive areas as small particles. They are not applied to plants. The baits are made as large solid discrete pieces, which are placed,

Section B5**Effectiveness against target organisms and intended uses**

directly near areas where rodents frequent, and are eaten directly by the target animals.

Wax blocks are blocks with a matrix containing impregnated grain and wax. PelGar supplies wax blocks of 5g, 10g, 15g, 20g, 28g or 50 g, the 20g blocks being approximately 35 mm x 35 mm x 10 mm and the other blocks being proportionately larger or smaller. The treatment frequency is 2-4 applications per year, 3-6 month apart. The amount of used product per application is often 1-5 x 20g blocks (20-100 g) per baiting point. Bait points are placed typically every 5-10m for rats and 2-5m for mice. Closer placement is required for heavier infestations.

The product is placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used, such as sewers, the bait is covered such that non-target organisms cannot reach them. In some other areas, bait boxes may not be required, for example areas where non-target species and bystanders do not have access.

Rodents eat the bait once and die typically within the first 7 days of the campaign. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds.

When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.

Baiting programmes are repeated as necessary, due to re-infestation, typically every 3-6 months.

Application rate and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling

PelGar supplies wax blocks of various sizes from 5g to 50g but all containing 0.005% a.i. They are not diluted or sprayed. They are used as supplied without further treatment. The amount of product used per application is often 1-3 x 20g blocks (20-60 g) per manhole.

Wax blocks are applied in sewerage systems typically hanging in a wire fixed to the wall a few cm above the bottom of inspection covers.

Section B5**Effectiveness against target organisms and intended uses****water, surface****water, water used****for heating****purposes****(IIB5.3)**

Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals
(IIB5.4)

The product is a ready to use ready formulated bait which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields. The bait contains 0.005% a.i., and is in form of blocks, typically 20 g. One or more blocks are placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used or are not necessary, the bait is covered such that non-target organisms cannot reach them. Bait points are placed typically every 2 to 5 m for mouse infestation and 5 to 10 m for rat infestation. Closer placement is required for heavier infestations.

Baiting programmes are repeated as necessary, due to re-infestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks.

Rodents eat the bait once and die typically within the first 7 days of the campaign. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds.

When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.

Function
(IIB5.5)

Rodenticide

Pest organism(s) to be controlled and products, organisms or objects to be protected
(IIB5.6)

Section B5**Effectiveness against target organisms and intended uses****Pest organism(s) to be controlled**

Rats and mice: no code available
All ages; all sexes; all strains, all locations; all territories; at any time of year.

Products, organisms or objects to be protected

Humans, animals, food, commodities and buildings/structures and components thereof.
Objective: death of rats and mice and the protection of humans and animals from pathogen transmission and direct property damage.

Effects on target organisms (IIB5.7)

Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed leading ultimately to profuse haemorrhage. After feeding on bait containing the active ingredient for 2 – 3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. Death will usually occur within the first 7 days of the campaign and animals often die out of sight in their nest or burrow.

5.8 Mode of action (including time delay) in so far as not covered by section A5.4 (IIB5.8)

Brodifacoum is a vitamin K antagonist. The main site of its action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K1 epoxide reductase. Brodifacoum accumulates and is stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidotal therapy (vitamin K1).

User: industrial, professional, general public (non-professional) (IIB5.9)**1. Industrial**

Section B5**Effectiveness against target organisms and intended uses**

i) Open system	Industrial use. Manufacturing concentrate (0.25% technical concentrate) is used to prepare ready-to-use formulated baits containing 0.005% a.i. in covered systems.
ii) Closed system	The (0.25% technical concentrate is produced by dilution with glycols from the 5% master concentrate in fully enclosed systems.
2. Professional	
i) Open system	Professional use in and around buildings. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals In sewers, wax blocks may be applied by hanging them on a wire tied to the wall a few cm above the bottom of inspection covers. The product is not to be used in fields and has not been reviewed under the Plant Protection Products Directive.
ii) Closed system	
3. General public	
	Amateur use in and around buildings. Lockable, tamper-proof bait boxes are available for use by the general public. Bait boxes can be refilled. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals.

Section B5

Effectiveness against target organisms and intended uses

Efficacy data: The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate (IIB5.10)

Information on Label Claims, efficacy and resistance is presented below, in 5.10.1, 5.10.2 and 5.11 respectively.

5.10.1

Proposed label claims for the product

Control of rats and mice in and around domestic, industrial, commercial, institutional and agricultural buildings and structures including sewers.

VERTOX[®] wax blocks are effective against strains of rodent resistant to earlier anticoagulants such as warfarin etc.

The resistance status of the rat population should be taken into account when considering the choice of rodenticide to be used.

Please see the label for further information.

Efficacy data

See separate Doc III-B5.10.2.

Any other known limitations on efficacy including resistance (IIB5.10)

Resistance to anticoagulant rodenticides was first discovered in Norway rats (*Rattus norvegicus*) in the UK in 1958 and is currently found in many countries of the European Union, both in Norway rats and House mice (*Mus musculus* ssp.). The practical advantages of anticoagulants for rodent control, particularly their efficacy and safety, were such that more effective anticoagulants were sought to overcome resistance rather than the more conventional approach of searching for rodenticides with an alternative mode of action. Brodifacoum was the most potent of a series of novel, so called second-generation anticoagulant rodenticides, brought to the market with the

Section B5**Effectiveness against target organisms and intended uses**

express purpose of combating resistance to the earlier anticoagulants. A summary report is available, the objective of which is to review and summarise some of the published literature on the efficacy of brodifacoum against anticoagulant resistant Norway rats and House mice (see Ref B.5.11).

Uncertainty in the use of terms has sometimes confused the issue of anticoagulant resistance. Two definitions are now widely adopted. These are: 1) 'practical resistance' occurs when a strain of rodent is present which carries an inherited ability to resist an anticoagulant to the extent that a well-conducted control programme using it will not be fully effective and 2) 'technical resistance' is said to occur when an inherited resistance can be technically demonstrated but the degree of resistance has little or no measurable practical impact.

Several different methods are used to determine the resistance status of individual rodents. The 'lethal feeding period' method was widely used in early studies and allowed inferences on the practical significance of resistance. The 'blood clotting response test' does not permit such practical assessments but provides for the rapid and effective laboratory screening of rodents for anticoagulant resistance. A method is also available which allows resistant rodent infestations to be identified in the field. These techniques are used to establish resistance baselines and to permit identification of resistance to anticoagulants in Norway rats and House mice.

New DNA sequencing technology is now widely used to identify rodents carrying mutations of the VKORC1 gene which may confer resistance to anticoagulants. This novel method is very useful as it allows fast, cheap and certain diagnosis of the presence of resistance mutations. However, conventional laboratory and field evaluations are still required to identify the phenotypic effects of the mutated genes on the practical outcome of anticoagulant treatments. Studies of VKORC1 mutations have identified

Section B5**Effectiveness against target organisms and intended uses**

several different mutations in Norway rats and House mice found across the EU.

Blood clotting response tests of the intrinsic potency of brodifacoum against susceptible rodents have shown that it is the most potent of all anticoagulants. It is therefore reasonable to assume that brodifacoum will also be the most effective in controlling rodents that are resistant to other anticoagulants. Brodifacoum was developed in the UK after extensive laboratory testing and successful field trials against Norway rats and House mice. Tests of the efficacy of brodifacoum against resistant rodents were also carried out elsewhere in Europe. All tests conducted were found to confirm the efficacy of rodenticide baits containing 50 ppm brodifacoum for the control of both resistant Norway rats and House mice.

Commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials (Anon., 2008), are likely to be fully effective for the control of resistant rodents in the EU.

Use-related restrictions

Use in bait boxes or in covered or protected bait points that can prevent access by non-target organisms such as domestic animals.

Prevention of the development of resistance

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants brodifacoum, flocoumafen and difethialone and the non-anticoagulants calciferol and bromethalin (not supported in the EU), all appear to have a role in resistance management.

A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and

Section B5**Effectiveness against target organisms and intended uses**

then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical.

A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance.

Prevention of Resistance.

The following are considered the most feasible to limit the development of resistance to anticoagulants:

Maximum use of non-chemical control techniques.

Preferential use of rodenticides and formulations to which resistance rarely develops.

Ensure the complete eradication of the target population whenever a rodenticide is used.

Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.

5. Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.

**Concomittant use
with other (biocidal)
products**

The product is not suitable for mixing with other biocidal products being a solid bait material. There are no products with which it is likely to be used.

Section B5

Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities	
<i>Date</i>	March 2013
<i>Materials and methods</i>	Laboratory and field studies against synanthropic rodents (<i>Mus musculus</i> , <i>Rattus norvegicus</i>) were conducted under differing scenarios with varying levels of rodent infestation using methods compliant with current guidelines. The studies were conducted according to agreed guidelines in accordance with the TNsG on Product Evaluation Chapter 7 and its appendices – Product Type 14 – Rodenticides.
<i>Conclusion</i>	The studies provided are considered acceptable in support of the product authorisation of Vertox Oktablok ready-to-use block bait.
<i>Reliability</i>	1
<i>Acceptability</i>	Information is considered acceptable.
<i>Remarks</i>	None.
Comments from ...	
<i>Date</i>	Give date of comments submitted
<i>Results and discussion</i>	Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
<i>Conclusion</i>	Discuss if deviating from view of rapporteur member state
<i>Reliability</i>	Discuss if deviating from view of rapporteur member state
<i>Acceptability</i>	Discuss if deviating from view of rapporteur member state
<i>Remarks</i>	

Table A5-1: Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of dilutant(s)	Other substance(s) added	Application technique	Remarks
(1)	<i>Include respective code(s) for product type(s) given in section 5.1</i>	<i>Give name of substance including CAS No.</i>	<i>State the concentration in percentage of the biocidal product</i>	<i>Give name and CAS No. of any other substance(s) to the biocidal product and indicate purpose</i>	<i>Include the corresponding code as given in Appendix xyz, File 4, and the corresponding term</i>	
(2)	PT14	No substance is used for dilution – the product is supplied ready to use.	0.005%	No other substance is used for dilution – the product is supplied ready to use	<i>By placing of ready formulated, ready to use baits as supplied in vicinity of areas where target rodents are seen. Rodents then eat baits directly</i>	The product is not applied by spraying, dusting, or misting. It is not applied to plants
					There are no other methods of application	

The product is a ready to use ready formulated bait, which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields.

The bait contains 0.005% a.i., and is in form of blocks, typically 20g. One or more blocks are placed in a bait station or fixed to a structure such that rats and mice can eat them. In situations where bait boxes cannot be used, the bait is covered such that non-target organisms cannot reach them. Bait points are placed typically every 5-10m.

Rodents eat the bait over one or more days and die typically 1-5 days later. Baiting points are inspected frequently and replenished when bait has been eaten. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds.

When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.

Baiting programmes are repeated as necessary, typically every 3-6 months.

Table A5-2: Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
(1)	<i>Include respective code(s) for product type(s) given in section 5.1</i>	<i>Include respective code(s) for application type(s) given in section 5.2</i>	<i>Indicate the recommended number and timing, i.e. duration of application and possible reapplications</i>	<i>Indicate recommended waiting periods and their purpose</i>	<i>Where relevant, describe how the application should be varied in different parts of the Community depending on the geographical or climatic conditions</i>	
(2)	PT14	BAXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations. For heavier infestations, baits are more closely spaced; hence there will be more bait in the area.	Product is not applied to plants by spraying
(3)	PT14	BIXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations. For heavier infestations, baits are more closely spaced; hence there will be more bait in the area.	Product is not applied to plants by spraying

Section B5.10.2 (1) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Mice)

REFERENCE	
<i>Reference</i>	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Mice. [REDACTED] – July 2005. [REDACTED] Report number 19/2005.
<i>Data protection</i>	Yes
Data owner	[REDACTED]
Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.
<i>Guideline study</i>	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
<i>Deviations</i>	No
	Method
<i>Test Substance (Biocidal Product)</i>	As given in section 2
Trade name/ proposed trade name	VERTOX® Wax Blocks
Composition of Product tested	Brodifacoum 0.0052% w/w
Physical state and nature	Blue block
Monitoring of active substance concentration	No
Method of analysis	
<i>Reference substance</i>	Yes EPA Meal consisting of:

**Official
use
only**

Section B5.10.2 (1) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

	Cornmeal (whole yellow ground corn) 65% w./w	
	Rolled Oats Groats (ground) 25% w/w	
	Sugar (confectioners) 5% w/w	
	Corn oil 5% w/w	
Method of analysis for reference substance		
<i>Testing procedure</i>		
Test population / inoculum / test organism	See Table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Mice	
Controls	No separate control	
<i>Examination</i>		
Effect investigated	Mortality	X
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	
	Results	
<i>Efficacy</i>		

Section B5.10.2 (1) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
Begin and duration of effects	Mortality started 9 days after commencement of feeding on the test item and final death occurred 10 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed.
<i>Effects against organisms or objects to be protected</i>	No adverse effects noted on cages, feed or surroundings
<i>Other effects</i>	No other effects noted
<i>Efficacy of the reference substance</i>	No effects noted which can be attributed to the reference substance.
<i>Tabular and/or graphical presentation of the summarised results</i>	
<i>Efficacy limiting factors</i>	
Occurrences of resistances	No resistance noted
Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
<i>Reasons for laboratory testing</i>	Intake of test substance can be monitored more accurately.
<i>Intended actual scale of biocide application</i>	Not relevant to palatability study
<i>Relevance compared to field conditions</i>	
Application method	Yes
Test organism	Yes –Mice (<i>Mus musculus</i>)
Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies
<i>Relevance for read-across</i>	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.

Section B5.10.2 (1)
Annex Point IIB V.5.11

Efficacy Data

Laboratory Study of Wax Block Bait (Mice)

Applicant's Summary and conclusion	
<i>Materials and methods</i>	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
<i>1.1 Reliability</i>	1
<i>1.2 Assessment of efficacy, data analysis and interpretation</i>	Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice even when normal non-toxic food sources are available.
<i>1.3 Conclusion</i>	Product is palatable to mice and effective in killing them.
<i>1.4 Proposed efficacy specification</i>	100% effective against mice

Evaluation by Competent Authorities	
Evaluation by Rapporteur Member State	
Date	March 2013.
Materials and Methods	TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female). Effect observed included palatability and mortality.
Results and discussion	Mean bait intake 36% of the total food consumption. The mean consumption of the test product and the reference meal were 3.3 g and 5.9 g, respectively. 100% mortality 9-10 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>

Section B5.10.2 (1) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)


Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Tables for Method

1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)

Not relevant. Single test organism

1.2 Test organism (if applicable)

Criteria	Details
Species	Albino laboratory mouse (<i>Mus musculus</i>)
Strain	ICR outbred, SPF quality
Source	
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 22.1 – 24.1 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Mice are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

1.4 Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	2 years old
Other conditions	None

1.6 Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)		Dose (mg/kg)		Palatability ratio

		Initial	Final	Vertox Block s	EPA Meal	Day of death		Acceptan ce of test item (%)	
276/R	F	22.5	23.1	3.6	5.8	9	7.41	38.3	0.6
277/R	F	22.1	23.2	3.2	6.2	10	6.72	34.0	0.5
278/R	F	22.6	23.5	3.4	5.9	9	6.97	36.6	0.6
279/R	F	22.7	23.6	2.8	5.3	10	5.74	34.6	0.5
280/R	F	22.4	23.0	3.0	5.7	9	6.20	34.5	0.5
283/R	M	23.7	24.6	3.1	6.6	9	6.06	32.0	0.5
284/R	M	23.5	24.2	3.7	6.0	9	7.31	38.1	0.6
285/R	M	23.9	24.8	3.2	6.2	10	6.23	34.0	0.5
286/R	M	24.0	24.8	3.9	5.7	9	7.53	40.6	0.7
287/R	M	24.1	24.9	3.5	5.8	9	6.73	37.6	0.6
Mean		23.2	24.0	3.3	5.9	9.0	6.69	36.0	0.6
SD				0.3	0.4	0.0	0.62	2.6	0.1
Confidence 0.1		-	-	-	-	-	-	1.4	-
Confidence 0.05		-	-	-	-	-	-	0.7	-

Section B5.10.2 (2) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

		Official use only
1 Reference		
1.1 Reference	Report: Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Mice. ██████████ – July 2005 ██████████ - Report number 17/2005.	
1.2 Data protection	Yes	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3 Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
1.4 Deviations	No	
2 Method		
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/proposed trade name	VERTOX [®] Wax Blocks	
2.1.2 Composition of Product tested	Brodifacoum 0.0051% w/w	
2.1.3 Physical state and nature	Blue blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis		
2.2 Reference substance	Yes	

Section B5.10.2 (2) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

		EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
2.2.1	Method of analysis for reference substance		
2.3	Testing procedure		
2.3.1	Test population / inoculum / test organism	See table 1.2	X
2.3.2	Test system	See Table 1.3	
2.3.3	Application of TS	See Table 1.4	
2.3.4	Test conditions	See Table 1.5	
2.3.5	Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
2.3.6	Number of replicates performed	5 male and 5 female ICR outbred, SPF quality albino mice	
2.3.7	Controls	No separate controls	
2.4	Examination		
2.4.1	Effect investigated	Mortality and palatability	
2.4.2	Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
2.4.3	Intervals of examination	Daily	
2.4.4	Statistics	None applied	
2.4.5	Post monitoring of the test organism	Yes for a maximum of 20 days	

Section B5.10.2 (2) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

3 Results	
3.1 Efficacy	
3.1.1 Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2 Begin and duration of effects	Mortality started 8 days after commencement of feeding on the test item and final death occurred 9 days after commencement of feeding on the test item.
3.1.3 Observed effects in the post monitoring phase	No other effects observed. All animals died
3.2 Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
3.3 Other effects	No other effects noted
3.4 Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
3.5 Tabular and/or graphical presentation of the summarised results	
3.6 Efficacy limiting factors	
3.6.1 Occurrences of resistances	No resistance noted
3.6.2 Other limiting factors	No other limiting factors noted
4 Relevance of the results compared to field conditions	
4.1 Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
4.2 Intended actual scale of biocide application	Not relevant to palatability study
4.3 Relevance compared to field conditions	
4.3.1 Application method	Yes
4.3.2 Test organism	Yes –Mice (<i>Mus musculus</i>)

Section B5.10.2 (2) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Mice)

4.3.3 Observed effect Yes – Test Substance found to be 100% effective against mice, as expected in field studies

4.4 Relevance for read-across Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.

5 Applicant's Summary and conclusion

5.1 Materials and methods Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)

5.2 Reliability 1

5.3 Assessment of efficacy, data analysis and interpretation Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice, even when normal, non-toxic food sources are available.

5.4 Conclusion Product is palatable to mice and effective in killing them.

5.5 Proposed efficacy specification 100% effective against mice

Evaluation by Competent Authorities

Date 4 **Evaluation by Rapporteur Member State**

March 2013.

Materials and Methods **2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female).

Section B5.10.2 (2) Efficacy Data**Annex Point IIB V.5.11**


Laboratory Study of Wax Block Bait (Mice)

Results and discussion	Mean bait intake 38.1% of the total food consumption. The mean consumption of the test product and the reference meal were 3.7 g and 6.0 g, respectively. 100% mortality 8-9 d after the start of exposure.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)

Not relevant. Single organism population used.

1.2 Test organism (if applicable)

Criteria	Details
Species	Mice
Strain	ICR outbred, SPF quality
Source	
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 21.9 – 24.6 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

1.4 Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	No
Other conditions	<i>None</i>

1.6 Summary of results

Animal#	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	Vertox	EPA Meal				

				Block s					
246/R	F	22.3	22.9	3.9	5.9	8	8.06	39.8	0.7
247/R	F	22.7	23.4	3.5	6.1	9	7.06	36.5	0.6
248/R	F	21.9	22.6	3.5	6.0	9	7.32	36.8	0.6
249/R	F	22.5	23.1	3.8	6.1	9	7.72	38.4	0.6
250/R	F	22.8	23.6	3.9	6.0	8	7.83	39.4	0.7
252/R	M	24.2	24.9	3.7	5.9	9	7.01	38.5	0.6
253/R	M	23.8	24.6	3.7	5.8	8	7.14	38.9	0.6
254/R	M	23.7	24.5	3.5	6.0	9	6.81	36.8	0.6
255/R	M	24.3	24.9	3.5	5.9	9	6.68	37.2	0.6
256/R	M	24.6	25.3	3.8	6.0	9	7.17	38.8	0.6
Mean		23.3	24.0	3.7	6.0	9.0	7.28	38.1	0.6
SD				0.2	0.1	0.0	0.45	1.2	0.0
Confidence 0.1								0.6	
Confidence 0.05								0.3	

Section B5.10.2 (3) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

		Official use only
	1 Reference	
1.1 Reference	Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Rats. [REDACTED] July 2005 [REDACTED] - Report number 18/2005.	
1.2 Data protection	Yes	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3 Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
1.4 Deviations	No	
	2 Method	
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/proposed trade name	VERTOX® Wax Blocks	
2.1.2 Composition of Product tested	Brodifacoum 0.0051% w/w	
2.1.3 Physical state and nature	Blue blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis		
2.2 Reference substance	Yes	

Section B5.10.2 (3) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

	EPA Meal consisting of:	
	Cornmeal (whole yellow ground corn) 65% w./w	
	Rolled Oats Groats (ground) 25% w/w	
	Sugar (confectioners) 5% w/w	
	Corn oil 5% w/w	
2.2.1	Method of analysis for reference substance	
2.3	Testing procedure	
2.3.1	Test population / inoculum / test organism	See table 1.2
2.3.2	Test system	See Table 1.3
2.3.3	Application of TS	See Table 1.4
2.3.4	Test conditions	See Table 1.5
2.3.5	Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum
2.3.6	Number of replicates performed	5 male and 5 female Wistar Rats
2.3.7	Controls	No separate controls
2.4	Examination	
2.4.1	Effect investigated	Mortality and palatability
2.4.2	Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality
2.4.3	Intervals of examination	Daily
2.4.4	Statistics	None applied
2.4.5	Post monitoring of the test organism	Yes for a maximum of 20 days

X

Section B5.10.2 (3) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

	3 Results
3.1 Efficacy	
3.1.1 Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2 Begin and duration of effects	Mortality started 8 days after commencement of feeding on the test item and final death occurred 10 days after commencement of feeding on the test item.
3.1.3 Observed effects in the post monitoring phase	No other effects observed. All animals died
3.2 Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
3.3 Other effects	No other effects noted
3.4 Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
3.5 Tabular and/or graphical presentation of the summarised results	See Table 1.6
3.6 Efficacy limiting factors	
3.6.1 Occurrences of resistances	No resistance noted
3.6.2 Other limiting factors	No other limiting factors noted
	4 Relevance of the results compared to field conditions
4.1 Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
4.2 Intended actual scale of biocide application	Not relevant to palatability study
4.3 Relevance compared to field conditions	

Section B5.10.2 (3) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

4.3.1 Application method	Yes
4.3.2 Test organism	Yes –Rats (<i>Rattus norvegicus</i>)
4.3.3 Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
4.4 Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.
5 Applicant's Summary and conclusion	
5.1 Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
5.2 Reliability	5 1
5.3 Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats, even when normal, non-toxic food sources are available.
5.4 Conclusion	6 Product is palatable to rats and effective in killing them.
5.5 Proposed efficacy specification	7 100% effective against rats

8 Evaluation by Competent Authorities

9

Section B5.10.2 (3) Efficacy Data**Annex Point IIB V.5.11**


Laboratory Study of Wax Block Bait (Rats)

	10	Evaluation by Rapporteur Member State
Date	March 2013.	
Materials and Methods	2.3.1 TNsG on product evaluation recommends that twenty animals should be used (10 male and 10 female).	
Results and discussion	Mean bait intake 37% of the total food consumption. The mean consumption of the test product and the reference meal were 36.7 g and 62.3 g, respectively. 100% mortality 8-10 d after the start of exposure.	
Conclusion	Adopt applicant's version.	
Reliability	1	
Acceptability	Acceptable.	
Remarks	None.	
	COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>	
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>	
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)

Not relevant. Single organism population used.

1.2 Test organism (if applicable)

Criteria	Details
Species	Rats
Strain	Wistar outbred, SPF quality
Source	
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 228 – 245 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Section B5.10.2 (4) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

		Official use only
1 Reference		
1.1 Reference	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Rats. ██████████ – July 2005. ██████████ Report number 20/2005.	
1.2 Data protection	Yes	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
1.3 Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
1.4 Deviations	No	
2 Method		
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/proposed trade name	VERTOX® Wax Blocks	
2.1.2 Composition of Product tested	Brodifacoum 0.005% w/w	
2.1.3 Physical state and nature	Blue blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis		
2.2 Reference substance	Yes	

Section B5.10.2 (4) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

	EPA Meal consisting of:	
	Cornmeal (whole yellow ground corn) 65% w./w	
	Rolled Oats Groats (ground) 25% w/w	
	Sugar (confectioners) 5% w/w	
	Corn oil 5% w/w	
2.2.1	Method of analysis for reference substance	
2.3	Testing procedure	
2.3.1	Test population / inoculum / test organism	See Table 1.2
2.3.2	Test system	See Table 1.3
2.3.3	Application of TS	See Table 1.4
2.3.4	Test conditions	See Table 1.5
2.3.5	Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum
2.3.6	Number of replicates performed	5 male and 5 female Rats
2.3.7	Controls	No separate control
2.4	Examination	
2.4.1	Effect investigated	Mortality
2.4.2	Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality
2.4.3	Intervals of examination	Daily
2.4.4	Statistics	None applied
2.4.5	Post monitoring of the test organism	Yes for a maximum of 20 days
	3 Results	
3.1	Efficacy	

Section B5.10.2 (4) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

3.1.1	Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.
3.1.2	Begin and duration of effects	Mortality started 9 days after commencement of feeding on the test item and final death occurred 10 days after commencement of feeding on the test item.
3.1.3	Observed effects in the post monitoring phase	No other effects observed.
3.2	<i>Effects against organisms or objects to be protected</i>	No adverse effects noted on cages, feed or surroundings
3.3	<i>Other effects</i>	No other effects noted
3.4	<i>Efficacy of the reference substance</i>	No effects noted which can be attributed to the reference substance.
3.5	<i>Tabular and/or graphical presentation of the summarised results</i>	
3.6	<i>Efficacy limiting factors</i>	
3.6.1	Occurrences of resistances	No resistance noted
3.6.2	Other limiting factors	No other limiting factors noted
4 Relevance of the results compared to field conditions		
4.1	<i>Reasons for laboratory testing</i>	Intake of test substance can be monitored more accurately.
4.2	<i>Intended actual scale of biocide application</i>	Not relevant to palatability study
4.3	<i>Relevance compared to field conditions</i>	
4.3.1	Application method	Yes
4.3.2	Test organism	Yes –Rats (<i>Rattus norvegicus</i>)
4.3.3	Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
4.4	<i>Relevance for read-across</i>	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances

Section B5.10.2 (4) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.

5 Applicant's Summary and conclusion**5.1 Materials and methods**

Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats even when normal non-toxic food sources are available.

5.4 Conclusion

Product is palatable to rats and effective in killing them.

5.5 Proposed efficacy specification

100% effective against rats

Evaluation by Competent Authorities

11 Evaluation by Rapporteur Member State	
Date	March 2013.
Materials and Methods	<p>2.3.1 TNsG on product evaluation recommends that twenty animals should be used (10 male and 10 female).</p> <p>2.4.1 Effect observed included palatability and mortality.</p>
Results and discussion	<p>Mean bait intake 35.1% of the total food consumption. The mean consumption of the test product and the reference meal were 34.2 g and 63.1 g, respectively.</p> <p>100% mortality 9-10 d after the start of exposure.</p>
Conclusion	Adopt applicant's version.
Reliability	1

Section B5.10.2 (4) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

Acceptability	Acceptable.
Remarks	None.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

1.4 Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	No
Other conditions	None

1.6 Summary of Results

Animal	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	Vertox Blocks	EPA Meal				
260/R	F	231	238	38.2	60.8	9	7.67	38.6	0.6


261/R	F	211	215	31.7	66.6	10	6.39	32.2	0.5
262/R	F	204	211	35.5	60.7	10	6.96	36.9	0.6
263/R	F	213	219	35.0	60.5	9	7.00	36.6	0.6
264/R	F	208	217	32.4	63.9	9	6.59	33.6	0.5
266/R	M	221	229	34.9	67.6	9	6.82	34.0	0.5
267/R	M	227	237	36.1	66.9	10	6.94	35.0	0.5
268/R	M	228	237	43.8	58.0	9	8.52	43.0	0.8
269/R	M	229	236	40.9	59.1	8	7.75	40.9	0.7
270/R	M	226	237	38.0	59.0	9	7.29	39.2	0.6
Mean		236.1	245.4	36.7	62.3	9.2	7.19	37.0	0.6
SD				3.5	3.4	0.60	0.60	3.2	0.1
Confidence 0.1		-	-	-	-	-	-	1.7	-
Confidence 0.05		-	-	-	-	-	-	2.0	-

Tables for Method

1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)

Not relevant. Single test organism

1.2 Test organism (if applicable)

Criteria	Details
Species	Albino laboratory rats (<i>Rattus norvegicus</i>)
Strain	Wistar outbred, SPF quality
Source	
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 225 – 247 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Rats are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

1.4 Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	2 years old
Other conditions	None

1.6 Summary of results

Animal#	Sex	Body weight (g)	Consumption (g)		Dose (mg/kg)		Palatability ratio

		Initial	Final	Vertox Block s	EPA Meal	Day of death		Acceptan ce of test item (%)	
290/R	F	228	233	35.3	61.6	10	7.20	36.4	0.6
291/R	F	225	231	32.8	61.2	10	6.78	34.9	0.5
292/R	F	230	241	31.9	61.9	10	6.46	34.0	0.5
293/R	F	226	237	30.1	62.5	10	6.19	32.5	0.5
294/R	F	227	238	33.5	61.0	9	6.89	35.4	0.5
296/R	M	243	251	35.0	65.4	10	6.73	34.9	0.5
297/R	M	239	250	34.4	66.2	10	6.72	34.2	0.5
298/R	M	245	256	35.7	64.9	10	6.77	35.5	0.6
299/R	M	241	253	35.8	64.9	9	6.94	35.6	0.6
300/R	M	247	259	37.2	61.1	9	7.02	37.8	0.6
Mean		235.1	244.9	34.2	63.1	9.7	6.77	35.1	0.5
SD				2.0	1.9	0.46	0.27	1.4	0.0
Confidence 0.1		-	-	-	-	-		0.7	-
Confidence 0.05		-	-	-	-	-		0.8	-

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

		1 Reference	Official use only
1.1	Reference	██████████ Field trial report to determine the efficacy of Vertox Wax Block Bait containing 0.005% w/w brodifacoum for the control of an infestation of house mice (<i>Mus musculus</i>) in a stable block on a smallholding ██████████. Report Number: PEL/006/04	
1.2	Data protection	Yes	
1.2.1	Data owner	██████████	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
1.3	Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).	
1.4	Deviations	No strict guidelines were followed.	
		2 Method	
2.1	Test Substance (Biocidal Product)	As given in section 2	
2.1.1	Trade name/proposed trade name	VERTOX [®] Wax Block Bait	
2.1.2	Composition of Product tested	Brodifacoum 0.005% w/w	
2.1.3	Physical state and nature	Red wax blocks	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	N/A	
2.2	Reference substance		

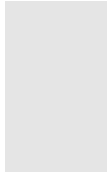
Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

2.2.1 **Method of analysis for reference substance** N/A

2.3 *Testing procedure*



Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

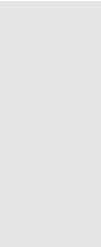
Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

2.3.1 Test population / inoculum / test organism

The field study was designed to investigate the efficacy of VERTOX® Wax Block Bait, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the loft above the stable area on a smallholding in





2.3.2 Test system

Bait boxes were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured approximately 14.75 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 1 or 2 grams.

Pre-treatment census

On the first day of the trial the census bait boxes were filled with 30g of dry whole wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait boxes (but not tracking patches) were removed and the site was left undisturbed for six days, when the bait boxes for the poison bait were laid (Day 10).

Poison bait treatment

Poison bait trays were placed in different positions near to those used for the census bait. Bait was laid on Day 14. Daily site visits were made to determine bait consumption and rodent tracking scores. Baits that had been eaten were replaced or topped up.

The poison treatment was concluded and all toxic baits removed from the site when there was little or no track score and poisoned bait take was less than 5% of the maximum between weighings.

Post-treatment lag period

The lag period was 3 days. During this period the only activity at the trial site was the placement of the empty census bait trays.

Post treatment census

A 4-day post treatment census was carried out with rodent tracking patches and census bait, as in the pre-treatment census.

2.3.3 Application of TS

In bait boxes in the field.

2.3.4 Test conditions

Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines,

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

		the bait trays were not placed in the same position as the census bait, but in the close proximity.
2.3.5	Duration of the test / Exposure time	The total test period was 29 days Poison baiting period was 8 days
2.3.6	Number of replicates performed	The test was only performed once but there were 19 bait trays involved in the poison baiting period.
2.3.7	Controls	Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were just as palatable as the untreated wheat bait and to estimate the mouse population.
2.4	Examination	
2.4.1	Effect investigated	mortality
2.4.2	Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
2.4.3	Intervals of examination	N/A
2.4.4	Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
2.4.5	Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.
		3 Results
3.1	Efficacy	Efficacy of the poison bait on the total census bait take was 100% Efficacy of the poison bait on the maximum track score was 100%

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

- 3.1.1 **Dose/Efficacy curve**
- 3.1.2 **Begin and duration of effects**
- 3.1.3 **Observed effects in the post monitoring phase**
- 3.2 *Effects against organisms or objects to be protected*
- 3.3 *Other effects*
- 3.4 *Efficacy of the reference substance*
- 3.5 *Tabular and/or graphical presentation of the summarised results*

N/A

Mice fed on the bait from the outset, 51 g being consumed over the first night and 67 g on the third night. The trend in bait take declined from the fourth day of baiting and reached zero on Day 21 of the trial, after only 8 days of poison baiting.

N/A

There was no evidence from this trial that the application of VERTOX® Wax Blocks is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.

None

N/A

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	61	0	100
Total census bait take (g)	206	0	100
Maximum	9	0	100

- 3.6 *Efficacy limiting factors*

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 Relevance of the results compared to field conditions

4.1 *Reasons for laboratory testing* N/A

N/A

11.1 *Intended actual scale of biocide application*

N/A

11.2 *Relevance compared to field conditions*

4.1.1 Application method N/A

4.1.2 Test organism N/A

4.1.3 Observed effect N/A

11.3 *Relevance for read-across* N/A

5 Applicant's Summary and conclusion

5.1 *Materials and methods*

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of a moderate mouse infestation active in the loft above the stable area where hay and foodstuff was stored. The position of bait placements and rodent tracking patches were determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with 30g of dry, whole wheat and the tracking trays were set with fresh sharp sand on

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait boxes (but no tracking patches) were removed from the trial site. With the exception of the placement of the empty poison bait boxes, the site was left undisturbed for a period of ten days.

Poison bait treatment

Poison bait boxes were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Baits that had been eaten were replaced or topped up.

Throughout the poison baiting period, daily searches for dead animals, whether rodents or non-target wildlife or domestic animals, were made by conducting a careful inspection of the site and adjacent land.

All poisoned bait was removed at the conclusion of treatment when there was little or no track score and bait consumption was less than 5% of the maximum between weighings.

Post-treatment lag period

A lag period of three days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. During this period, the only activity was the placement of empty bait boxes.

Post-treatment census

After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

5.2 *Reliability*

1

5.3 *Assessment of efficacy, data analysis and interpretation*

Initial Infestation

It was estimated from the pre-treatment census bait take of 206g and the highest daily pre-treatment track score total of 9 that there was a moderate mouse infestation active in the loft above the stable area where hay and foodstuff was stored.

Poison baiting

The quantity of poisoned bait consumed over the first night was 51g and 67g were consumed on the third night. This was the highest quantity of bait consumed in a 24-hour period.

The trend in bait take declined from the fourth day of baiting and reached zero on Day 21, the eighth day of poison baiting.

There was no indication of deaths of wildlife either by direct ingestion of bait or ingestion of rodent carcasses. Six dead mice were found during the trial. It would be expected that most mice would have died in their harbourages.

Post treatment

No bait takes or track scores were noted during the post-treatment census period.

5.4 *Conclusion*

The mouse infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was moderate and the mice were provided with ample alternative food. In spite of this, the poisoned bait proved efficacious and the mouse infestation was satisfactorily controlled at the site after 8 days of poisoned baiting.

There was no evidence from this trial that VERTOX Wax Blocks, when used according to label recommendations, pose any significant environmental hazard.

5.5 *Proposed efficacy specification*

The product showed good control of an infestation of House mice.

Evaluation by Competent Authorities

Section B5.10.2 (5)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on House mouse

	12 Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	2.4.1 Effect observed included palatability and mortality.
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

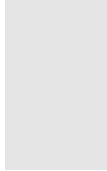
		Official use only
1 Reference		
1.1 Reference	██████████ (2004) Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w Brodifacoum, for the control of an infestation of house mice (<i>Mus musculus</i>). ██████████ Report Number: PEL/007/04	
1.2 Data protection	Yes	
1.2.1 Data owner	██████████	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
1.3 Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).	
1.4 Deviations	No strict guidelines were followed.	
2 Method		
2.1 Test Substance (Biocidal Product)	As given in section 2	
2.1.1 Trade name/proposed trade name	VERTOX® Wax Block Bait	
2.1.2 Composition of Product tested	Brodifacoum 0.005% w/w	
2.1.3 Physical state and nature	Red wax blocks	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis	N/A	
2.2 Reference substance		

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

-
- 2.2.1 Method of analysis for reference substance N/A
 - 2.3 *Testing procedure*



Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

**2.3.1 Test population /
inoculum /
test organism**

The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the kitchen area where some dried foodstuff was stored in a church hall in [REDACTED]

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

2.3.2 Test system

Bait boxes were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 14.75 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 1 to 2 grams.

Pre-treatment census

On the first day of the trial the census bait boxes were filled with 30g of dry whole wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait boxes (but not tracking patches) were removed and the site left undisturbed for 6 days when bait boxes for the poison bait were laid (Day 10).

Poison bait treatment

Poison bait boxes were placed in different positions near to those used for the census bait. Poison bait was laid on Day 14. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been significant take of bait, fresh bait was added. Throughout the main portion of the trial active searches for dead mice were undertaken.

The poison treatment was concluded and all toxic baits removed from the site when there was little or no track score and bait take was less than 5% of the maximum between weighings (Day 21).

Post-treatment lag period

The lag period was 3 days.

Post-treatment census

A 4 day post-treatment census was carried out with census bait points and rodent tracking patches.

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

2.3.3	Application of TS	In bait boxes in the field.
2.3.4	Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait boxes were not placed in the same position as the census bait, but in close proximity. Baits were applied within the hall, kitchen area and store room of the building, so were protected from the weather and from non-target animals. The bait boxes were hidden, as far as possible, by placing within or behind cupboard units and utilities.
2.3.5	Duration of the test / Exposure time	The total test period was 28 days Poison baiting period was 7 days
2.3.6	Number of replicates performed	The test was only performed once but there were 14 tracking patches used and 14 bait boxes involved in the poison baiting period.
2.3.7	Controls	Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were as palatable as the untreated wheat bait and to estimate the mouse population.
2.4 Examination		
2.4.1	Effect investigated	Mortality
2.4.2	Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
2.4.3	Intervals of examination	N/A
2.4.4	Statistics	Estimated % efficacy = 100 x [(post-treatment census data/ pre-treatment census data)]
2.4.5	Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.

3 Results

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

3.1	<i>Efficacy</i>	Efficacy of the poison bait on the total census bait take was 100% Efficacy of the poison bait on the maximum track score was 100%
3.1.1	Dose/Efficacy curve	N/A
3.1.2	Begin and duration of effects	From the outset, mice took the bait with 39 g being consumed over the first night of baiting and 52 g on the second night. The trend in bait take declined from the third day of baiting to reach zero on Day 21 (the seventh day of baiting). Track scores declined steadily from a high of 17 on Day 15 to 0 on the seventh day of baiting, Day 21. The remaining Vertox Wax Block bait was picked up on Day 21 when recording was completed.
3.1.3	Observed effects in the post monitoring phase	N/A
3.2	<i>Effects against organisms or objects to be protected</i>	There was no evidence from this trial that the application of VERTOX® Wax Block bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
3.3	<i>Other effects</i>	None
3.4	<i>Efficacy of the reference substance</i>	N/A

Section B5.10.2 (6)**Efficacy Data****Annex Point IIB5.10**

Field trial on the efficacy of Vertox Wax Blocks on House mouse

TNsG: Pt. I-B5.10,**Pt. III-Ch. 6**

3.5 *Tabular and/or graphical presentation of the summarised results*

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	53	0	100
Total census bait take (g)	162	0	100
Maximum track score	16	0	100

3.6 *Efficacy limiting factors*

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 **Relevance of the results compared to field conditions**

4.1 *Reasons for laboratory testing* N/A

N/A

12.1 *Intended actual scale of biocide application*

N/A

12.2 *Relevance compared to field conditions*

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

4.1.1	Application method	N/A
4.1.2	Test organism	N/A
4.1.3	Observed effect	N/A
12.3	Relevance for read-across	N/A

5 Applicant's Summary and conclusion

5.1 Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of a small mouse infestation localised in the kitchen area of the hall. The position of bait placements and rodent tracking patches were determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with 30g of whole, dry wheat and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait boxes (but no tracking patches) were removed from the trial site. The site was left undisturbed for 6 days, when empty bait boxes were re-introduced to the site and the treatment phase commenced four days after that.

Poison bait treatment

Poison bait boxes were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

scores. Where there had been significant take of bait, fresh bait was added. Daily searches were made for dead mice. Since no non-target animals had access to the building, no census of non-target animals was maintained. The poison treatment was terminated when there was little or no track score and poisoned bait take was less than 5% of the maximum between weighings.

Post-treatment lag period

A lag period of three days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. Empty bait boxes were laid throughout the site on the first day of the lag period, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post treatment census

After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the highest track score total on any day of 16 and the 162g of wheat census bait that was consumed in the

Section B5.10.2 (6)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on House mouse

4-day period that there was a small, localised infestation of mice within the kitchen area of the building.

Poison baiting

The quantity of poisoned bait consumed on the first day of baiting was 39g, increasing over the first two days and then declining to reach zero on the seventh day of baiting.

Track scores declined steadily from a high of 17 on the second day of baiting to zero 6 days after bait was laid.

No dead mice were found during the course of the trial.

Post treatment

No activity (bait or track scores) was found during the census period.

5.4 Conclusion

The mouse infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was small and localised and the mice were provided with alternative food. In spite of this, the mice fed freely from the poisoned bait and a significant level of control was already being achieved after a few days of treatment.

5.5 Proposed efficacy specification

The product showed a high level of control of an infestation of House mice.

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State	
Date	13 March 2013.
Materials and Methods	Agree with applicant's version
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

		1 Reference	Official use only
1.1	Reference	<p>██████████ (1995) Field trial report to determine the efficacy of Vertox Wax Block, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (<i>Rattus norvegicus</i>) on an agricultural holding ██████████ ██████████ Report Number: RFT/95/1905</p>	
1.2	Data protection	Yes	
1.2.1	Data owner	██████████	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
1.3	Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).	
1.4	Deviations	No strict guidelines were followed.	
		2 Method	
2.1	Test Substance (Biocidal Product)	As given in section 2	
2.1.1	Trade name/proposed trade name	VERTOX [®] Wax Block Bait	
2.1.2	Composition of Product tested	Brodifacoum 0.005% w/w	
2.1.3	Physical state and nature	Red wax blocks	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	N/A	
2.2	Reference substance		

Section B5.10.2 (7)**Efficacy Data****Annex Point IIB5.10**

Field trial on the efficacy of Vertox Wax Block Bait on Rats

TNsG: Pt. I-B5.10,

Pt. III-Ch. 6

2.2.1 Method of analysis for reference substance N/A

2.3 *Testing procedure*



Section B5.10.2 (7)**Annex Point IIB5.10**

TNsG: Pt. I-B5.10,

Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

**2.3.1 Test population /
inoculum /
test organism**

The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Norway rats infesting the buildings of a working dairy farm and associated buildings on the Anglo-Welsh border of the UK. The area is known as the Welsh resistance area and rat populations include a proportion of animals, often up to 90%, that are resistant to the first generation anticoagulants, such as warfarin and chlorophacinone.

2.3.2 Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 2 or 5 g.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 200g of dry whole wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed from the trial site. With the exception of the placement of empty bait trays on Day 10, the site was left undisturbed for a period of 10 days (Day 4 to Day 14).

Poison bait treatment

Poison bait trays were placed in different positions near to those used for the census bait and protected from the weather and non-target animals in the same way as were the census bait points. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point.

Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife were made by conducting an inspection of the site and of the areas of land adjacent to it.

The poison treatment was concluded and all toxic baits removed from the site when the track score and bait consumption reached zero.

Post treatment lag period

A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census bait. Empty bait trays were laid throughout the site 3 days before placement of the census baits, in the same

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

	positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.
	<u>Post treatment census</u>
	After the lag period finished, 200 g fresh whole wheat was added to each bait point. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
2.3.3 Application of TS	In bait trays in the field.
2.3.4 Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait boxes were not placed in the same position as the census bait but in close proximity and were protected from the weather and from non-target animals.
2.3.5 Duration of the test / Exposure time	The total test period was 36 days Poison baiting period was 15 days
2.3.6 Number of replicates performed	The test was only performed once but there were 27 bait trays involved in the poison baiting period.
2.3.7 Controls	Pre-treatment census data were collected to show if VERTOX® Wax Blocks were as palatable as the untreated wheat bait and to estimate the rat population.
2.4 Examination	

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

2.4.1	Effect investigated	mortality
2.4.2	Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of rats. A track score was also provided which is rated 1-4 to give a field indication.
2.4.3	Intervals of examination	N/A
2.4.4	Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
2.4.5	Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.

3 Results

3.1	<i>Efficacy</i>	Efficacy of the poison bait on the total census bait take was 99.7% Efficacy of the poison bait on the total track score was 97.5%
------------	-----------------	---

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

3.1.1	Dose/Efficacy curve	N/A
3.1.2	Begin and duration of effects	<p>A total of 304 g of rodenticide was taken from 17 of the 27 bait points on the first day of baiting. This was less than the amount of census bait eaten in an equivalent stage of the pre-baiting period (471 g). This indicates that the rats found the wax blocks less palatable than the plain whole wheat used as the pre-treatment census bait. The quantity of Vertox Wax Block bait consumed in a 24-hour period increased to a maximum on treatment day 4 when 897 g was consumed and then declined steadily until the end of the treatment period. This indicated that as the rats became more familiar with the novel bait compared to their normal diet, they overcame their natural caution to a novel foodstuff. By the fifteenth day of poisoned baiting, all bait takes ceased. Tracking activity showed a similar pattern.</p> <p>No dead rats were recovered from the site, all having died out of sight in their harbourages.</p>
3.1.3	Observed effects in the post monitoring phase	N/A
3.2	<i>Effects against organisms or objects to be protected</i>	<p>There was no evidence from this trial that the application of VERTOX® Wax Block bait is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.</p>
3.3	<i>Other effects</i>	None
3.4	<i>Efficacy of the reference substance</i>	N/A

Section B5.10.2 (7)**Efficacy Data****Annex Point IIB5.10**

Field trial on the efficacy of Vertox Wax Block Bait on Rats

TNsG: Pt. I-B5.10,**Pt. III-Ch. 6****3.5** *Tabular and/or graphical presentation of the summarised results*

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	1439	11.0	99.2
Total census bait take (g)	4284	11.0	99.7
Mean census bait take (g)	1071	2.8	99.7
Maximum track score	26	1.0	96.2
Total track	81	2.0	97.5

3.6 *Efficacy limiting factors***3.6.1** **Occurrences of resistances**

N/A

3.6.2 **Other limiting factors**

N/A

4 **Relevance of the results compared to field conditions****4.1** *Reasons for laboratory testing*

N/A

N/A

13.1 *Intended actual scale of biocide application***13.2** *Relevance compared to*

N/A

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

	<i>field conditions</i>	
4.1.1	Application method	N/A
4.1.2	Test organism	N/A
4.1.3	Observed effect	N/A
13.3	<i>Relevance for read-across</i>	N/A

5 Applicant's Summary and conclusion

5.1 Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative sources of food. The survey confirmed the presence of a heavy rat infestation in the study area. The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait trays were charged with 200g of dry whole wheat and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for ten days, apart from the placement of the empty bait trays which were introduced to the site on Day 10, 4 days before poison baiting commenced.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. The poisoned bait trays were protected

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

from the weather and from non-target animals in the same way as the census bait points. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been a partial take of bait, old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point. Daily searches were made for dead animals, whether rodents or non-target organisms.

The poison treatment was concluded and all poisoned baits were removed from the site when the track score and census bait consumption reached nil.

Post-treatment lag period

A lag period of four days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. During this period, empty bait trays were laid throughout the site in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

5.2 Reliability

1

5.3 Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the maximum of 1439g of wheat census bait that was consumed in a 24 hour period that there was a large infestation present in the study area. Calculations suggest that there were about 103 rats on the site but this is a minimum estimate as it is based on the assumption that the rats feed entirely on census bait and it is likely that the census bait

Section B5.10.2 (7)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Block Bait on Rats

comprised only a proportion of the total food consumption of the rats.

Poison baiting

The total bait consumed on the first day of baiting was 304 g. This was taken from 17 of the 27 bait stations. The amount consumed increased to a maximum on treatment day 4 and then declined steadily until the end of the treatment period.

This showed that as the rats became more familiar with the novel bait, the palatability of the bait overcame their natural caution to a new foodstuff.

By the fifteenth day of poison baiting, all bait takes ceased.

Tracking activity showed a similar pattern.

No dead rats were recovered from the site, all having died out of sight in their harbourages.

Post treatment

During the post-treatment census period, a total of 11 g was taken from one census bait point. Activity was also seen on 2 out of a total of 27 tracking patches.

5.4 Conclusion

The rat infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was heavy and the rats were abundantly supplied with alternative sources of food throughout the trial site. Despite this, they fed freely on the poisoned bait from the first day of application, indicating that the bait was highly palatable to rats. A very high level of control of this warfarin-resistant Norway rat infestation was achieved after only 15 days of baiting.

5.5 Proposed efficacy specification

The product showed a high level of control of a heavy infestation of Brown rats.

Evaluation by Competent Authorities

Section B5.10.2 (7)**Efficacy Data****Annex Point IIB5.10**

Field trial on the efficacy of Vertox Wax Block Bait on Rats

TNsG: Pt. I-B5.10,**Pt. III-Ch. 6**

	14 Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Adopt applicant's version
Results and discussion	Efficacy based on total census bait take = 99.7% Efficacy based on total track score = 97.5%.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

		1 Reference
1.1	Reference	<p>██████████ 1996) Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (<i>Rattus norvegicus</i>) on an agricultural holding ██████████ ██████████ Report Number: RFT/96/1907</p>
1.2	Data protection	Yes
1.2.1	Data owner	██████████
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval
1.3	Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).
1.4	Deviations	No strict guidelines were followed.
		2 Method
2.1	Test Substance (Biocidal Product)	As given in section 2
2.1.1	Trade name/ proposed trade name	VERTOX® Wax Blocks
2.1.2	Composition of Product tested	Brodifacoum 0.005% w/w
2.1.3	Physical state and nature	Red wax blocks
2.1.4	Monitoring of active substance concentration	No
2.1.5	Method of analysis	N/A
2.2	Reference substance	

Official
use
only

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

-
- 2.2.1 Method of analysis for reference substance N/A
 - 2.3 *Testing procedure*



Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

**2.3.1 Test population /
inoculum /
test organism**

The field study was designed to investigate the efficacy of VERTOX® Wax Blocks, containing 0.005 % brodifacoum, for the control of an infestation of Brown rats in farm buildings.



2.3.2 Test system

Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site.

Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm.

A balance was used that was capable of weighing up to 2 kg in graduations of 2 g up to 500 g and in 5 g intervals above 500 g.

Pre-treatment census

On the first day of the trial the census bait trays were filled with 200g of whole, dry wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established.

Pre-treatment lag period

At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site was left undisturbed for 6 days, when empty bait trays were reintroduced to the site and the treatment phase commenced four days later.

Poison bait treatment

Poison bait trays were placed in different positions to those used for the census bait. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point. Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife were made by conducting an inspection, not only of the immediate trial area but by means of a wider site survey.

The poison treatment was concluded and all toxic baits removed from the site when bait consumption and tracking scores reached nil.

Post-treatment lag period

A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census bait. Empty bait trays were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

-
- After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
- 2.3.3 Application of TS** In bait trays in the field.
- 2.3.4 Test conditions** Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in close proximity and were protected from the weather and from non-target animals.
- 2.3.5 Duration of the test / Exposure time** The total test period was 36 days
Poison baiting period was 15 days
- 2.3.6 Number of replicates performed** The test was only performed once but there were 35 bait boxes involved in the poison baiting period.
- 2.3.7 Controls** Pre-treatment census data were collected to show if the poisoned VERTOX® Wax Blocks were just as palatable as the untreated wheat bait and to estimate the rat population.
- 2.4 Examination**
- 2.4.1 Effect investigated** Mortality
- 2.4.2 Method for recording / scoring of the effect** The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of rats.
A track score was also provided which is rated 1-4 to give a field indication.
- 2.4.3 Intervals of examination** N/A
- 2.4.4 Statistics** Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
- 2.4.5 Post monitoring of the test organism** Yes. A 4-day post-treatment census was carried out.

3 Results

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

3.1	<i>Efficacy</i>	<p>Efficacy of the poison bait on the total census bait take was 99.4%</p> <p>Efficacy of the poison bait on the maximum track score was 95.2%</p>
3.1.1	Dose/Efficacy curve	N/A
3.1.2	Begin and duration of effects	<p>From the outset, rats fed on the bait and 307 g was consumed over the first night increasing to 862 g on the fourth night. The trend in bait take declined steadily from the fourth day of baiting until the end of the study.</p> <p>Track scores showed a similar pattern.</p> <p>The remaining bait was picked up at the end of the treatment period when recording was completed.</p>
3.1.3	Observed effects in the post monitoring phase	N/A
3.2	<i>Effects against organisms or objects to be protected</i>	<p>There was no evidence from this trial that the application of VERTOX® Wax Blocks is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.</p>
3.3	<i>Other effects</i>	None
3.4	<i>Efficacy of the reference substance</i>	N/A

Section B5.10.2 (8)**Efficacy Data****Annex Point IIB5.10**

Field trial on the efficacy of Vertox Wax Blocks on Rats

TNsG: Pt. I-B5.10,**Pt. III-Ch. 6**

3.5 *Tabular and/or graphical presentation of the summarised results*

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Mean census bait take	1062	6.5	99.4
Maximum census bait take (g)	1439	15.0	99.0
Total census bait take (g)	4248	26.0	99.4
Mean track score	18.75	0.5	97.3

3.6 *Efficacy limiting factors*

3.6.1 **Occurrences of resistances**

N/A

3.6.2 **Other limiting factors**

N/A

4 Relevance of the results compared to field conditions

4.1 *Reasons for laboratory testing*

N/A

N/A

14.1 *Intended actual scale of biocide application*

14.2 *Relevance compared to field conditions*

N/A

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

4.1.1	Application method	N/A
4.1.2	Test organism	N/A
4.1.3	Observed effect	N/A
14.3	Relevance for read-across	N/A

5 Applicant's Summary and conclusion

5.1 Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative source of food. The survey confirmed the presence of a moderate infestation of rats was active at the site. The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with 200g of dry whole wheat and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait boxes (but not tracking patches) were removed from the trial site. The site was left undisturbed for a period of 6 days, when the bait boxes for the poison bait were laid.

Poison bait treatment

Poison bait boxes were laid out in different positions to those used for the census bait. The poison bait was applied 4 days after the bait boxes were laid. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

scores. Where there had been significant take of bait, more bait was added. Daily searches were made for dead animals, whether rodents or non-target organisms.

Post-treatment lag period

A lag period of 3 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. During the lag period, empty bait boxes were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

After the lag period finished, 200 g fresh whole wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

5.2 *Reliability*

1

5.3 *Assessment of efficacy, data analysis and interpretation*

Initial Infestation

It was estimated from the maximum census bait take in 24 hours of 1439 g and the highest track score total on any day of 21, that a moderate rat infestation was present at the site (103 rats).

It is considered likely that the census bait comprised only a proportion of the rats' daily food intake, as alternative foodstuffs were readily available. Therefore the number present was considerably more than the estimate.

Poison baiting

Rats fed on the bait from the outset and 307g was consumed over the first night from 15 bait stations, increasing to 862 g on the fourth night. The trend in bait take declined steadily until the end of the treatment period. This indicated that as the rats became more familiar with the novel bait compared to their

Section B5.10.2 (8)
Annex Point IIB5.10
TNsG: Pt. I-B5.10,
Pt. III-Ch. 6

Efficacy Data

Field trial on the efficacy of Vertox Wax Blocks on Rats

normal; diet, the palatability of the bait overcame their natural caution to novel foodstuffs.

By the fifteenth day of baiting all bait takes ceased. Tracking activity showed a similar pattern.

Post-treatment

During the census period a total of 26 g was taken from 2 census points. Activity was also seen on 2 out of a total of 35 tracking patches.

5.4 Conclusion

The rat infestation encountered at this trial site was typical of those found on other agricultural premises. The infestation was moderate and although alternative foodstuffs were readily available, the rats fed freely on the poisoned bait.

The infestation was eliminated very quickly and poison bait consumption ceased only 15 days after the start of baiting. Very limited activity was found in the post-treatment census.

5.5 Proposed efficacy specification

The product showed a very high level of control of an infestation of Brown rats.

Evaluation by Competent Authorities

15 Evaluation by Rapporteur Member State	
Date	March 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	Efficacy based on total census bait take = 99.4% Efficacy based on maximum track score = 95.2%
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B5.10.2 (9) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

		Official I use only
	5 Reference	
5.1 Reference	Wade JO 2005 Determination of mould growth on standard wax blocks stored under simulated sewage inspection chamber conditions. – May 2005, Pelgar International - Report number PEL/01/05.	
5.2 Data protection	Yes	
5.2.1 Data owner	PelGar International Limited	
5.2.2 Companies with access to data	Activa srl (only for use in Annex I listing of difenacoum)	
5.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
5.3 Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
5.4 Deviations	N/A	
	6 Method	
6.1 Test Substance (Biocidal Product)		
6.1.1 Trade name/proposed trade name	ROBAN® Wax Bock Bait, formulation code PF 015	
6.1.2 Composition of Product tested	Difenacoum 0.005 w/w in a commercial wax block formulation	
6.1.3 Physical state and nature	Octagon shaped blocks	
6.1.4 Monitoring of active substance concentration	No	
6.1.5 Method of analysis	N/A	
6.2 Reference substance	No	
6.2.1 Method of analysis for reference substance	N/A	
6.3 Testing procedure		

Section B5.10.2 (9) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

6.3.1 Test population / inoculum / test organism	In this case the test population can be considered to be the wax blocks. There were 36 used in the test.
6.3.2 Test system	<p>The study was performed in a glass tank measuring 125cms x 40cms x 30cms tall into which three rows of bricks were evenly spaced in the bottom of the tank to create three ledges each 10cms in height, 80cms in length and 6cms wide. The tank was filled to a depth of 6cms with septic effluent. 12 wax blocks were evenly spaced along each ledge such that there was approximately 4cm between blocks (to prevent possible cross contamination), on a dry surface approximately 4cms above the level of the effluent. The tank had a tap fitted into the rear left hand corner to facilitate emptying of the tank without disturbing the general set-up.</p> <p>A sheet of glass covered the top of the tank. Temperature and humidity in the tank was continually monitored using a (calibrated) thermo hydrograph (approximately 40cm long and 20cm wide).</p>
6.3.3 Application of TS	N/A
6.3.4 Test conditions	<p>Septic effluent was removed from the tank daily, via the tap, and replaced with a fresh sample. The tank was maintained at 20°C for the duration of the test. This was a relatively high temperature compared to the normal temperature found in sewer inspection chambers, but one that would promote and accentuate microbial growth. Other than during inspection the tank was kept in the dark to replicate conditions found in a sewer system.</p>
6.3.5 Duration of the test / Exposure time	28 days
6.3.6 Number of replicates performed	N/A
6.3.7 Controls	No separate controls
6.4 Examination	
6.4.1 Effect investigated	Mould growth
6.4.2 Method for recording / scoring of the effect	<p>Blocks were examined, in-situ, for signs of mould growth. Additionally blocks were removed at intervals and examined under a compound binocular microscope. This block was then cut in half</p>

Section B5.10.2 (9) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

	and the inside matrix of the block examined. The cut block was discarded after examination.
6.4.3 Intervals of examination	For in-situ examination interval was 0 hrs, 1 day, 2 days, 3 days, 7 days, 14 days, 21 days and 28 days. Additionally at 0 hrs, 1 day, 3 days, 7 days, 14 days, 21 days and 28 days one block was removed for the microscope assessment.
6.4.4 Statistics	None applied
6.4.5 Post monitoring of the test organism	N/A
7 Results	
7.1 Efficacy	
7.1.1 Dose/Efficacy curve	N/A
7.1.2 Begin and duration of effects	N/A
7.1.3 Observed effects in the post monitoring phase	N/A
7.2 Effects against organisms or objects to be protected	The appearance of the blocks was unchanged up to 14 days. At 21 days the surface of 6 blocks appeared mottled but detailed examination indicated this was due to a change in colour of the wax with no visual evidence of mould or other microbial growth. At 28 days all blocks (29 out of 29) showed varying degrees of surface mottling (ranging from 60-80% of the visible surface being affected) but microscopic examination did not indicate microbial or mould growth. When cut the internal surface of the blocks appeared the same throughout the duration of the experiment.
7.3 Other effects	No other effects noted
7.4 Efficacy of the reference substance	N/A.
7.5 Tabular and/or graphical presentation of the summarised results	See report
7.6 Efficacy limiting factors	N/A
7.6.1 Occurrences of resistances	N/A
7.6.2 Other limiting factors	N/A

Section B5.10.2 (9) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

8 Relevance of the results compared to field conditions	
8.1 <i>Reasons for laboratory testing</i>	To evaluate the resistance to mould growth of standard wax blocks when maintained over a period of time to conditions that simulate those found in sewage inspection chambers where baits would normally be laid.
8.2 <i>Intended actual scale of biocide application</i>	Rat control in sewers, in this case.
8.3 <i>Relevance compared to field conditions</i>	The conditions used are designed to simulate the conditions found in a sewage inspection chamber for up to 4 weeks.
8.3.1 Application method	Yes
8.3.2 Test organism	N/A
8.3.3 Observed effect	Yes – no mould was evident either on the surface of the blocks or in the matrix of the blocks at any time point during the study, which is desired in field applications.
8.4 <i>Relevance for read-across</i>	Yes. The wax blocks could be used as a substrate for other rodenticides such as brodifacoum.
9 Applicant's Summary and conclusion	
9.1 <i>Materials and methods</i>	The materials used appear valid, as does the method used. In this case the lack of GLP does not appear to be a problem as it was performed to normal QA standards and the report is signed for authenticity.
9.2 <i>Reliability</i>	2
9.3 <i>Assessment of efficacy, data analysis and interpretation</i>	Lack of mould growth indicates that the wax blocks would be effective within the criteria required i.e. not prone to deterioration whilst in field conditions.
9.4 <i>Conclusion</i>	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the wax block is resistant to mould under the conditions required.
9.5 <i>Proposed efficacy specification</i>	N/A

Section B5.10.2 (9) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

Evaluation by Competent Authorities	
16 Evaluation by Rapporteur Member State	
Date	May 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	No specific agreed guidelines are in place for testing rodenticide baits which are intended for use in sewers or in similar warm, humid conditions. The study demonstrates the baits inherent aerobic stability even after being subject to high humidity and temperature for 28 days.
Conclusion	Agree with applicant's conclusion, the test demonstrates the blocks ability to withstand harsh environmental conditions.
Reliability	1
Acceptability	Acceptable.
Remarks	Whilst not a standard study the results are considered as supporting data indicating that the bait is robust enough to withstand under adverse environmental conditions such as those encountered in a sewer system.
17 Comments from ... (specify)	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

1.1 (mixed) Population / Inoculum (if necessary; include separate table for different samples)

1.2 Test organism (if applicable)

Criteria	Details
Species	
Strain	
Source	
Laboratory culture	
Stage of life cycle and stage of stadia	
Mixed age population	
Other specification	
Number of organisms tested	
Method of cultivation	
Pretreatment of test organisms before exposure	
Initial density/number of test organisms in the test system	

1.3 Test system

Criteria	Details
Culturing apparatus / test chamber	Glass tank (125cm x 40cm x 30cm) filled with sewer effluent. Effluent replaced daily with fresh sample.
Number of vessels / concentration	36 wax blocks
Test culture media and/or carrier material	
Nutrient supply	
Measuring equipment	

1.4 Application of test substance

Criteria	Details
Application procedure	
Delivery method	
Dosage rate	
Carrier	
Concentration of liquid carrier	
Liquid carrier control	
Other procedures	

1.5 Test conditions

Criteria	Details
Substrate	
Incubation temperature	19.5-20.6 °C
Moisture	Relative humidity > 95%
Aeration	No
Method of exposure	
Aging of samples	
Other conditions	

Section B5.10.2 (10) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

		Official use only
1 Reference		
1.1 Reference	██████████ 2010, An evaluation of bait consumption by <i>Rattus norvegicus</i> of environmentally stressed Oktablok (I) block. – December 2010, ██████████ - Report number TIL/PI/251110/01.	
1.2 Data protection	Yes	
1.2.1 Data owner	████████████████████	
1.2.2 Companies with access to data	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
1.3 Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
1.4 Deviations	N/A	
2 Method		
2.1 Test Substance (Biocidal Product)		
2.1.1 Trade name/proposed trade name	Wax block blank bait	
2.1.2 Composition of Product tested	Blank wax block formulation with no AS concentrate added	
2.1.3 Physical state and nature	Solid wax block	
2.1.4 Monitoring of active substance concentration	No	
2.1.5 Method of analysis	N/A	
2.2 Reference substance	No	
2.2.1 Method of analysis for reference substance	N/A	

Section B5.10.2 (10) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

2.3 Testing procedure

2.3.1 Test population / inoculum / test organism	Captive semi-wild brown rats (<i>Rattus norvegicus</i>)
2.3.2 Test system	The samples were kept in the dark in an environmentally controlled room at 30±3°C and greater than 90% RH for 5 days. Comparative palatability was assessed using a mixed population of rats held in an open pen of approximately 120 square metres.
2.3.3 Application of TS	N/A
2.3.4 Test conditions	30±3°C and greater than 90% RH.
2.3.5 Duration of the test / Exposure time	5 days treatment of wax blocks. Palatability tested over 3 days.
2.3.6 Number of replicates performed	N/A
2.3.7 Controls	No separate controls
2.4 Examination	
2.4.1 Effect investigated	Palatability
2.4.2 Method for recording / scoring of the effect	During storage in sewer conditions, samples were examined every 24 hours to ensure equipment was functioning correctly and to record any change in the integrity of the product. Information regarding storage conditions were monitored automatically and stored electronically. In the palatability part of the study, baits were weighed twice daily and replenished where necessary.
2.4.3 Intervals of examination	Storage – every 24 hours Palatability – baits weighed twice daily, at 09.00 and 21.00h.
2.4.4 Statistics	None applied
2.4.5 Post monitoring of the test organism	N/A

3 Results**3.1 Efficacy**

3.1.1 Dose/Efficacy curve	N/A
----------------------------------	-----

Section B5.10.2 (10) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Wax Block Bait (Rats)

3.1.2 Begin and duration of effects N/A

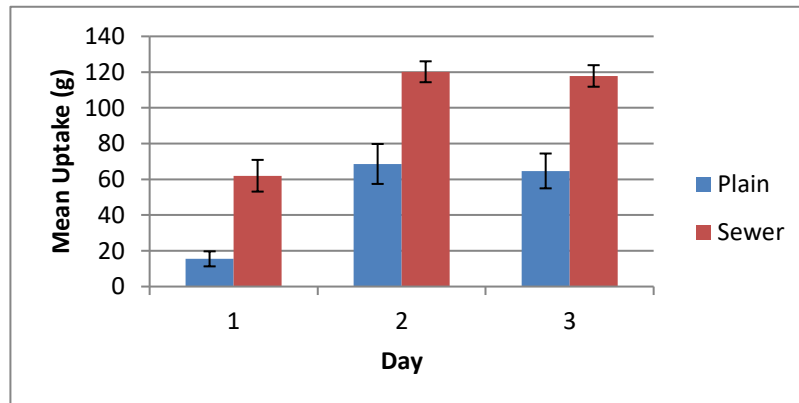
3.1.3 Observed effects in the post monitoring phase N/A

3.2 Effects against organisms or objects to be protected The sewer-treated bait comprised 66.8% of the total bait consumed over the entire 3-day period of the trial. This bait was clearly preferred by the Brown rats.

3.3 Other effects No other effects noted

3.4 Efficacy of the reference substance N/A.

3.5 Tabular and/or graphical presentation of the summarised results



Mean bait consumption in g during the three-day exposure to a captive population of Brown rats.

3.6 Efficacy limiting factors N/A

3.6.1 Occurrences of resistances N/A

3.6.2 Other limiting factors N/A

4 Relevance of the results compared to field conditions

4.1 Reasons for laboratory testing To evaluate the effects on bait palatability of exposure to high humidity and temperature conditions similar to those likely to be found in sewers in order to confirm that the bait is suitable for use in sewers.

4.2 Intended actual scale of biocide application Rat control in sewers.

Section B5.10.2 (10) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

4.3	Relevance compared to field conditions	The conditions used are designed to simulate the conditions found in a sewage inspection chamber.
4.3.1	Application method	Yes
4.3.2	Test organism	N/A
4.3.3	Observed effect	The sewer-treated bait was more palatable than the bait stored in dry conditions.
4.4	Relevance for read-across	Yes. The data could be used to support similar wax block bait formulations containing any AS.
5 Applicant's Summary and conclusion		
5.1	Materials and methods	The materials used appear valid, as does the method used. In this case the lack of GLP does not appear to be a problem as it was performed to normal QA standards and the report is signed for authenticity.
5.2	Reliability	2
5.3	Assessment of efficacy, data analysis and interpretation	The increased palatability, when compared with fresh blank bait, indicates that the wax block bait would be effective within the criteria required i.e. when used in sewers.
5.4	Conclusion	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the wax block maintains palatability under the conditions required.
5.5	Proposed efficacy specification	N/A

Evaluation by Competent Authorities
--

Section B5.10.2 (10) Efficacy Data**Annex Point IIB V.5.11**

Laboratory Study of Wax Block Bait (Rats)

18 Evaluation by Rapporteur Member State	
Date	March 2013.
Materials and Methods	Adopt applicant's version.
Results and discussion	No specific agreed guidelines are in place for testing rodenticide baits which are intended for use in sewers or in similar warm, humid conditions. The study is satisfactory as it demonstrates the baits inherent palatability even after being subject to extremes of humidity and temperature with the treated baits proving even more palatable than the untreated control. No detrimental effect on palatability following storage of wax block bait in sewer conditions for 5 days. The sewer-treated bait comprised 66.8% of the total bait consumed.
Conclusion	Agree with applicant's conclusion, the test is acceptable to demonstrate the baits' palatability under "sewer-like" conditions.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
19 Comments from ... (specify)	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B6.1.1**Acute Toxicity****Annex Point IIA VI.6.1.1**Acute oral toxicity test in the rat (LD₅₀)

	10	Reference	
10.1	Reference	[REDACTED] 2007) Brodifacoum wax block: Acute Oral Toxicity in the Rat – Fixed Dose Method. [REDACTED] Report No. 2254/0021	
10.2	Data protection	Yes	
10.2.1	Data owner	[REDACTED]	
10.2.2	Companies with Access to data	None	
10.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
	11	Guidelines and Quality Assurance	
11.1	Guideline study	OECD 420 Method B1 <i>bis</i> Acute Toxicity (Oral) of Commission Directive 2004/73/EC	
11.2	GLP	Yes	
11.3	Deviations	No	
	12	MATERIALS AND MethodS	
12.1	Test material	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
12.1.1	Lot / Batch number	61309601	
12.1.2	Specification	The product used in the study is a wax block bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report	
12.1.2.1	Description	Red wax block bait	
12.1.2.2	Purity	0.005% brodifacoum	
12.1.2.3	Stability	Stable under test conditions	
12.2	Test Animals		
12.2.1	Species	Rats	
12.2.2	Strain	Sprague-Dawley CD (CrI:CD® (SD) IGS BR)	
12.2.3	Source	[REDACTED]	

Official
use
only

Section B6.1.1**Acute Toxicity****Annex Point IIA VI.6.1.1** Acute oral toxicity test in the rat (LD₅₀)

12.2.4	Sex	Female
12.2.5	Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Female 207 - 217g
12.2.6	Number of animals per group	1 animal treated, then a further 4 animals treated
12.2.7	Control animals	No
12.3	Administration/Exposure	Oral
12.3.1	Postexposure period	14 days
12.3.2		Oral
12.3.3	Type	Gavage
12.3.4	Concentration	0.005% w/w
12.3.5	Vehicle	Arachis oil BP
12.3.6	Concentration in vehicle	200 mg/ml
12.3.7	Total volume applied	Single dose of 2000 mg/kg in 10 ml/kg of arachis oil BP
12.3.8	Controls	None
12.4	Examinations	Clinical observations, mortality, body weight, necropsy
12.5	Method of determination of LD ₅₀	Estimated. Classified using the Globally Harmonised Classification System
12.6	Further remarks	None

13 Results and Discussion

13.1	Clinical signs	There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period. There were no deaths. No abnormalities were noted at necropsy.
13.2	Pathology	There were no treatment related findings in animals.
13.3	Other	No other significant effects noted.

Section B6.1.1**Acute Toxicity****Annex Point IIA VI.6.1.1**Acute oral toxicity test in the rat (LD₅₀)**13.4** *LD₅₀*

Females: estimated to be > 2000 mg/kg bodyweight (Globally Harmonised Classification System – Unclassified)

14.1 *Materials and methods***14 Applicant's Summary and conclusion**

Determination of oral LD₅₀ in the rat according to OECD Guideline No. 420 and Method B1 bis Acute Toxicity (Oral) of Commission Directive 2004/73/EC

A single fasted nulliparous, non-pregnant female rat was treated with the test material at a dose level of 2000 mg/kg bodyweight. This was followed by a further group of four fasted females at the same dose level.

The test material was administered orally as a suspension in arachis oil BP. The concentration of the test suspension was 200 mg/ml and each rat was dosed with a volume of 10 ml/kg bodyweight. All animals were dosed once only by gavage using a metal cannula attached to a graduated syringe.

Clinical observations were made 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for fourteen days. Morbidity and mortality checks were made twice daily.

Individual bodyweights were recorded prior to dosing and seven and fourteen days after treatment.

At the end of the observation period, the animals were killed by cervical dislocation. All animals were subjected to gross pathological examination. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.

14.2 *Results and discussion*

Following a dose of 2000 mg/kg to all animals, none of the animals died. There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period.

There were no abnormalities noted at necropsy.

14.3 *Conclusion*

Acute oral LD₅₀ for the female rat is estimated to be > 2000 mg/kg

14.3.1 *Reliability*

1

X

Section B6.1.1 Acute Toxicity

Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD₅₀)

14.3.2 Deficiencies No

Evaluation by Competent Authorities

Section B6.1.1 Acute Toxicity**Annex Point IIA VI.6.1.1 Acute oral toxicity test in the rat (LD₅₀)**

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>20 Evaluation by Rapporteur Member State</p> <p><i>1 March 2013</i></p> <p>Date</p> <p><i>5.1 The test material was ground, sieved through a 500um sieve and suspended in arachis oil BP. The oil is probably appropriate considering the nature of the substance. However, the effect of this process on the actual dose delivered is unknown.</i></p> <p>Materials and Methods</p> <p><i>Accept applicants version</i></p> <p>Results and discussion</p> <p><i>Accept applicants version</i></p> <p>Conclusion</p> <p><i>1</i></p> <p>Reliability</p> <p><i>Acceptable</i></p> <p>Acceptability</p> <p><i>A post processing concentration would have helped.</i></p> <p>Remarks</p>
	<p>21 Comments from ...</p> <p><i>Give date of comments submitted</i></p> <p>Date</p> <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p>Materials and Methods</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Results and discussion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Conclusion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Reliability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Acceptability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Remarks</p>

Table B6_1-1. Table for Acute Toxicity

<i>Dose [unit]</i>	<i>Number of dead / number of investigated</i>	<i>Time of death (range)</i>	<i>Observations</i>
2000 mg/kg	0/5	-	No abnormalities detected
LD ₅₀ value	Females: > 2000 mg/kg		

Section B6.1.2 Acute Toxicity**Annex Point IIA VI.6.1.2** Acute dermal toxicity study in the rat

	15 Reference	
15.1 Reference	[REDACTED] 2007) Brodifacoum Wax Block: Acute Dermal Toxicity (Limit Test) in the Rat, [REDACTED], Report No. 2254/0022	
15.2 Data protection	Yes	
15.2.1 Data owner	[REDACTED]	
15.2.2 Companies with Access to data	None	
15.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
	16 Guidelines and Quality Assurance	
16.1 Guideline study	OECD 402 Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC	
16.2 GLP	Yes	
16.3 Deviations	No	
	17 MATERIALS AND MethodS	
17.1 Test material	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
17.1.1 Lot / Batch number	61309601	

Official
use
only

Section B6.1.2**Acute Toxicity****Annex Point IIA VI.6.1.2**

Acute dermal toxicity study in the rat

17.1.2	Specification	The product used in the study is a wax block bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report
17.1.2.1	Description	Red wax block bait
17.1.2.2	Purity	0.005% brodifacoum
17.1.2.3	Stability	Stable under test conditions
17.2	Test Animals	
17.2.1	Species	Rats
17.2.2	Strain	Sprague-Dawley CD (CrI:CD® (SD) IGS BR)
17.2.3	Source	
17.2.4	Sex	Male and Female
17.2.5	Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Male 231g - 253g Female 211g – 232g
17.2.6	Number of animals per group	10 animals/group (5 male and 5 female)
17.2.7	Control animals	No
17.3	Administration/ Exposure	Dermal
17.3.1	Postexposure period	14 days
		Dermal
17.3.2	Area covered	Approx 10% of the total body surface area
17.3.3	Occlusion	Semi-occlusive
17.3.4	Vehicle	No vehicle used (material moistened with distilled water)
17.3.5	Concentration in vehicle	Not applicable
17.3.6	Total volume applied	2000 mg/kg
17.3.7	Duration of exposure	24 hours
17.3.8	Removal of test substance	Residual formulation was cleansed with swabs of absorbent cotton wool moistened with distilled water.

Section B6.1.2**Acute Toxicity****Annex Point IIA VI.6.1.2**

Acute dermal toxicity study in the rat

17.3.9	Controls	None
17.4	Examinations	Clinical observations, mortality, body weight, necropsy
17.5	Method of determination of LD₅₀	Not stated
17.6	Further remarks	None
18 Results and Discussion		
18.1	Clinical signs	<p>There were no deaths.</p> <p>There were no signs of systemic toxicity.</p> <p>There were no signs of dermal irritation.</p> <p>All animals showed expected gains in bodyweight over the study period.</p>
18.2	Pathology	No abnormalities were noted at necropsy.
18.3	Other	No other significant effects were noted.
18.4	LD₅₀	Males and females: > 2000 mg/kg
19 Applicant's Summary and conclusion		
19.1	Materials and methods	<p>The study was conducted according to OECD 402 and Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC. Five male and five female rats were used in this study. On the day before treatment, the back and flanks of each animal were clipped free of hair.</p> <p>The dose level, 2000 mg/kg of the formulation moistened with distilled water, was applied as evenly as possible to an area of shorn skin (approximately 10% of the total body surface area). A piece of surgical gauze was placed over the treatment area and semi-occluded with a piece of self-adhesive bandage. The animals were caged individually for the 24-hour exposure period. Shortly after dosing, the dressings were examined to ensure that they were securely in place.</p> <p>After the 24-hour contact period, the bandage was carefully removed and the treated skin and surrounding hair wiped with</p>

Section B6.1.2**Acute Toxicity****Annex Point IIA VI.6.1.2**

Acute dermal toxicity study in the rat

cotton wool moistened with distilled water to remove any residual test material.

The animals were observed for deaths or overt signs of toxicity 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days.

After removal of the dressings and subsequently once daily for fourteen days, the test sites were examined for evidence of primary irritation and scored according to the Draize scale for erythema and eschar formation and oedema formation. Any other skin reactions, if present were also recorded.

Individual bodyweights were recorded prior to application of the test material on Day 0 and on Days 7 and 14.

At the end of the study all animals were killed humanely and subjected to gross necropsy. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.

19.2 Results and discussion

There were no deaths.

There were no signs of dermal irritation.

All animals showed expected gains in bodyweight over the study period.

No abnormalities were noted at necropsy.

The acute dermal LD₅₀ for the formulation to male and female rats was found to be greater than 2000 mg/kg bodyweight.

19.3 Conclusion

Acute dermal LD₅₀ for male and female rats is > 2000 mg/kg

19.3.1 Reliability

1

19.3.2 Deficiencies

No

Evaluation by Competent Authorities

Section B6.1.2 Acute Toxicity**Annex Point IIA VI.6.1.2 Acute dermal toxicity study in the rat**

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>22 Evaluation by Rapporteur Member State</p> <p><i>Date</i> 1 March 2013</p> <p><i>Materials and Methods</i> 5.1 The test material was ground, sieved through a 500um sieve and moistened with water. However, the effect of this process on the actual dose delivered is unknown.</p> <p><i>Results and discussion</i> Adopt applicants version</p> <p><i>Conclusion</i> Adopt applicants version</p> <p><i>Reliability</i> 1</p> <p><i>Acceptability</i> Acceptable</p> <p><i>Remarks</i></p>
	<p>23 Comments from ...</p> <p><i>Date</i> Give date of comments submitted</p> <p><i>Materials and Methods</i> Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</p> <p><i>Results and discussion</i> Discuss if deviating from view of rapporteur member state</p> <p><i>Conclusion</i> Discuss if deviating from view of rapporteur member state</p> <p><i>Reliability</i> Discuss if deviating from view of rapporteur member state</p> <p><i>Acceptability</i> Discuss if deviating from view of rapporteur member state</p> <p><i>Remarks</i></p>

Table B6_1-1 **Table for Acute Toxicity**

<i>Dose [unit]</i>	<i>Number of dead / number of investigated</i>	<i>Time of death (range)</i>	<i>Observations</i>
2000 mg/kg	0/10	-	There were no signs of dermal irritation.
LD ₅₀ value	The acute dermal LD ₅₀ for formulation to male and female rats is greater than 2000 mg/kg		

Section B6.1.3 Acute toxicity - Inhalation		
Annex Point IIB VI.6.1.3		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [<input checked="" type="checkbox"/>]	Technically not feasible [<input checked="" type="checkbox"/>]	Scientifically unjustified [<input checked="" type="checkbox"/>]
Limited exposure [<input checked="" type="checkbox"/>]	Other justification [<input type="checkbox"/>]	
Detailed justification:	<p>Active substance is of low vapour pressure at NTP. The product is formulated as a solid wax block using mostly food grade materials , which are solid at NTP and of low vapour pressure. The wax block is not friable or dusty such that airborne particles can be produced. It is therefore not respirable, does not produce respirable particles and does not produce respirable vapours.</p> <p>An acute inhalation study on the biocidal product is not scientifically justified as the ingredients in the product do not enhance the toxicity of the active substance, and are not themselves classified, so these end points can be satisfied by the dose-response relationship established for the technical active ingredient.</p> <p>Due to the low vapour pressure of the a.s and the physical state of the product, the amount of potential exposure through inhalation is minimal. Acute inhalation toxicity of the product can be extrapolated from data on the technical active substance.</p>	
Undertaking of intended data submission [<input type="checkbox"/>]	Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)	
Evaluation by Competent Authorities		

Section B6.1.3	Acute toxicity - Inhalation	
Annex Point IIB VI.6.1.3		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
	24	Evaluation by Rapporteur Member State
Date	1 March 2013	
Evaluation of applicant's justification	The justification is acceptable	
Conclusion	<i>The justification is acceptable</i>	
Remarks	<i>None</i>	
	25	Comments from ...
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks	<i>Discuss if deviating from view of rapporteur member state</i>	
Section B6.1.4	Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate	
Annex Point IIB VI.6.1.4		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	

Section B6.1.4 Annex Point IIB VI.6.1.4	Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate
Detailed justification:	Brodifacoum wax block bait is not intended to be authorised for use with other biocidal products. Therefore these data are not required.
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
Date	26 Evaluation by Rapporteur Member State 1 March 2013
Evaluation of applicant's justification	The justification is acceptable
Conclusion	<i>The justification is acceptable</i>
Remarks	<i>None</i>
Date	27 Comments from ... <i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	<i>Discuss if deviating from view of rapporteur member state</i>

Section B6.2 (1)**Acute Dermal Irritation****Annex Point IIB VI.6.2**

Skin irritation to the rabbit

		20 Reference	Official use only
20.1 Reference		[REDACTED] (2007) Brodifacoum wax block: Acute dermal irritation in the rabbit. [REDACTED], Report No. 2254/0023	
20.2 Data protection		Yes	
20.2.1 Data owner		[REDACTED]	
20.2.2 Companies with access to data		None	
20.2.3 Criteria for data protection		Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
		21 Guidelines and Quality Assurance	
21.1 Guideline study		OECD 404 Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC	
21.2 GLP		Yes	
21.3 Deviations		No	
		22 MATERIALS AND MethodS	
22.1 Test material		Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
22.1.1 Lot/Batch number		61309601	
22.1.2 Specification		The product used in the study is a wax block bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.	
22.1.2.1 Description		Red wax blocks	
22.1.2.2 Purity		0.005% brodifacoum	
22.1.2.3 Stability		Stable under test conditions	
22.2 Test Animals			
22.2.1 Species		Rabbit	

Section B6.2 (1)	Acute Dermal Irritation	
Annex Point IIB VI.6.2	Skin irritation to the rabbit	
22.2.2	Strain	New Zealand White
22.2.3	Source	Accredited supplier
22.2.4	Sex	Male
22.2.5	Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
22.2.6	Number of animals per group	3
22.2.7	Control animals	No
22.3	Administration/ Exposure	Dermal
22.3.1	Application	
22.3.1.1	Preparation of test substance	Test substance, 0.5 g moistened with 0.5 ml distilled water prior to application.
22.3.1.2	Test site and Preparation of Test Site	Hair was removed from the dorsal/flank area of each animal
22.3.2	Occlusion	Not stated
22.3.3	Vehicle	The test material was moistened with 0.5 ml water.
22.3.4	Concentration in vehicle	n/a
22.3.5	Total volume applied	0.5g test material in 0.5 ml water
22.3.6	Removal of test substance	The application site was cleansed free using clean swabs of cotton wool soaked in distilled water
22.3.7	Duration of exposure	4 h
22.3.8	Postexposure period	3 days
22.3.9	Controls	None
22.4	Examinations	
22.4.1	Clinical signs	Not stated
22.4.2	Dermal examination	Yes

Section B6.2 (1) Acute Dermal Irritation**Annex Point IIB VI.6.2** Skin irritation to the rabbit

22.4.2.1	Scoring system	Draize method
22.4.2.2	Examination time points	60min, 24h, 48h, 72h
22.4.3	Other examinations	
22.5	Further remarks	

23 Results and Discussion**23.1** *Average score*

23.1.1 Erythema Average score for all animals at 24h = 0.3, 48h = 0, 72h = 0

23.1.2 Oedema Average score for all animals at 24h = 0.3, 48h = 0, 72h = 0

23.2 Reversibility N/A

23.3 *Other examinations*

23.4 Overall result Mild irritant

24 Applicant's Summary and conclusion**24.1** *Materials and methods*

The study follows OECD guideline 404 and Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC. 0.5 g of formulation in 0.5 ml distilled water was applied to the test site of 2.5 cm x 2.5 cm. The test site was covered with a piece of cotton gauze, secured in position with surgical adhesive tape and wrapped in an elasticated corset and the dressings left in position for 4 hours. The degree of erythema and oedema was assessed after 60 mins, 1, 2 and 3 days after removal of the dressings.

A mean erythema and oedema score was calculated by adding together the individual scores at the 1, 2 and 3 day readings and dividing by nine (one site on each of three rabbits scored 1, 2 and 3 days after treatment)

Section B6.2 (1)**Acute Dermal Irritation****Annex Point IIB VI.6.2**

Skin irritation to the rabbit

24.2	<i>Results and discussion</i>	Following a single 4 hour application of 0.005% w/w brodifacoum wax block formulation, very slight erythema and very slight oedema was found at one treated skin site. Two treated skin sites appeared normal throughout the study and the remaining treated skin site appeared normal at the 48-hour observation.
24.3	<i>Conclusion</i>	The test material produced a primary irritation index of 0.3 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.
24.3.1	Reliability	1
24.3.2	Deficiencies	No

Evaluation by Competent Authorities

Section B6.2 (1)**Acute Dermal Irritation****Annex Point IIB VI.6.2**

Skin irritation to the rabbit

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>28 Evaluation by Rapporteur Member State</p> <p><i>1 March 2013</i></p> <p>Date</p> <p><i>5.1 It is not clear if wrapping was occlusive or semi-occlusive in nature. It has been assumed to be semi-occlusive in nature.</i></p> <p>Materials and Methods</p> <p>Accept applicants version.</p> <p>Results and discussion</p> <p>Accept applicants version..</p> <p>Conclusion</p> <p>1</p> <p>Reliability</p> <p>Acceptable</p> <p>Acceptability</p> <p>Remarks</p>
	<p>29 Comments from ...</p> <p><i>Give date of comments submitted</i></p> <p>Date</p> <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p>Materials and Methods</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Results and discussion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Conclusion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Reliability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Acceptability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Remarks</p>

Section B6.2 (1) Acute Dermal Irritation**Annex Point IIB VI.6.2** Skin irritation to the rabbit**Table A6_1-4S-1. Table for skin irritation study**

score (average animals investigated)	time	Erythema	Edema
average score Draize scores (0 to maximum 4)	60 min	0	0
	24 h	0.3	0.3
	48 h	0	0
	72 h	0	0
average score	24h, 48h, 72h	0.1	0.1
reversibility: *		c	c
average time for reversibility		24 h	24 h
* c : completely reversible n c : not completely reversible n : not reversible			

Section B.6.2 (2) Acute Eye Irritation
Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

		25 Reference	
25.1	Reference	[REDACTED] (2007) Brodifacoum wax block: Acute Eye Irritation in the Rabbit. [REDACTED]. Report No. 2254/0024	
25.2	Data protection	Yes	
25.2.1	Data owner	[REDACTED]	
25.2.2	Companies with access to data	None	
25.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
		26 Guidelines and Quality Assurance	
26.1	Guideline study	OECD 405 Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC	
26.2	GLP	Yes	
26.3	Deviations	No	
		27 MATERIALS AND MethodS	
27.1	Test material	Brodifacoum 0.005% w/w wax block bait (VERTOX® Wax Blocks)	
27.1.1	Lot/Batch number	61309601	
27.1.2	Specification	The product used in the study is a wax block bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.	
27.1.2.1	Description	Red wax block bait	
27.1.2.2	Purity	0.005% brodifacoum	
27.1.2.3	Stability	Stable under test conditions	

**Official
use only**

Section B.6.2 (2) Acute Eye Irritation
Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit

27.2	<i>Test Animals</i>	
27.2.1	Species	Rabbit
27.2.2	Strain	New Zealand White
27.2.3	Source	Accredited supplier, unnamed
27.2.4	Sex	Male
27.2.5	Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg
27.2.6	Number of animals per group	3
27.2.7	Control animals	The left eye of each rabbit was left untreated and served as a control
27.3	<i>Administration/ Exposure</i>	
27.3.1	Preparation of test substance	Test substance was ground to a powder and sieved prior to application
27.3.2	Amount of active substance instilled	0.1ml
27.3.3	Exposure period	Eye was held closed for 1 second after instillation of the test substance.
27.3.4	Postexposure period	3 days
27.4	<i>Examinations</i>	
27.4.1	Ophthalmoscopic examination	yes
27.4.1.1	Scoring system	Draize
27.4.1.2	Examination time points	60min, 24h, 48h and 72h
27.4.2	Other investigations	
27.5	<i>Further remarks</i>	

Section B.6.2 (2)**Acute Eye Irritation****Annex Point IIB, VI. 6.2**

Eye Irritation to the Rabbit

28 Results and Discussion

28.1	<i>Clinical signs</i>	No corneal or iridial effects were noted during the study. Moderate conjunctival irritation was noted in all treated eyes at the 24-hour observation. Minimum conjunctival irritation persisted in one treated eye at the 48-hour observation. Two treated eyes appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.
28.2	<i>Average score</i>	
28.2.1	Cornea	Average score for all animals at 24h=0, 48h=0, 72h=0
28.2.2	Iris	Average score for all animals at 24h=0, 48h=0, 72h=0
28.2.3	Conjunctiva	
28.2.3.1	Redness	Average score for all animals at 24h=1, 48h=0.3, 72h=0
28.2.3.2	Chemosis	Average score for all animals at 24h=0, 48h=0, 72h=0
28.3	<i>Reversibility</i>	Yes
28.4	<i>Other</i>	
28.5	<i>Overall result</i>	Mild irritant

Section B.6.2 (2)**Acute Eye Irritation****Annex Point IIB, VI. 6.2**

Eye Irritation to the Rabbit

29.1 <i>Materials and methods</i>	<p>29 Applicant's Summary and conclusion</p> <p>The study follows OECD guideline 405 and Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC</p> <p>0.1ml of 0.005% w/w brodifacoum wax block bait was ground to a powder, sieved and instilled into the right eye of one rabbit. After consideration of the ocular responses produced in the first treated animal, two additional animals were treated. The examination period was extended for 3 days.</p> <p>Assessment of the initial pain reaction was made using a standard six-point scale.</p>
29.2 <i>Results and discussion</i>	<p>Instillation of 0.1ml 0.005% w/w brodifacoum wax block bait caused slight initial pain in all three animals.</p> <p>The application produced moderate conjunctival irritation. Two treated eyes appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.</p>
29.3 <i>Conclusion</i>	<p>Brodifacoum 0.005% w/w wax block bait produced a maximum group mean score of 8.0 and was classified as a mild irritant (Class 4 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.</p>
29.3.1 Reliability	1
29.3.2 Deficiencies	No

Evaluation by Competent Authorities
--

Section B.6.2 (2) Acute Eye Irritation**Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit**

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>30 Evaluation by Rapporteur Member State</p> <p><i>1 March 2013</i></p> <p>Date</p> <p><i>20 It is not clear from the study if the eyes were rinsed with saline post dose.</i></p> <p>Materials and Methods</p> <p><i>Accept applicants version</i></p> <p>Results and discussion</p> <p><i>Accept applicants version</i></p> <p>Conclusion</p> <p><i>1</i></p> <p>Reliability</p> <p><i>Acceptable</i></p> <p>Acceptability</p> <p><i>Scoring was by kay and Calandra method. Based on EU methods mean scores of less than 1 for all elements at 24, 48 and 72 h do not precipitate classification.</i></p> <p>Remarks</p>
	<p>31 Comments from ...</p> <p><i>Give date of comments submitted</i></p> <p>Date</p> <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p>Materials and Methods</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Results and discussion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Conclusion</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Reliability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Acceptability</p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p>Remarks</p>

Section B.6.2 (2) Acute Eye Irritation**Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit****Table A6_1_4E-1. Results of eye irritation study (results based on 0.1ml volume)**

	Cornea	Iris	Conjunctiva		
			discharge	redness	chemosis

Section B.6.2 (2) Acute Eye Irritation**Annex Point IIB, VI. 6.2 Eye Irritation to the Rabbit**

score (average of animals investigated)	0 to 4	0 to 2	0 to 3	0 to 3	0 to 4
60 min	0	0	1	2	1
24 h	0	0	0.3	1	0
48 h	0	0	0	0.3	0
72 h	0	0	0	0	0
Average 24h, 48h, 72h	0	0	0.1	0.43	0
Area effected	0	-	-	-	-
Maximum average score (including area affected, max 110)	0	0	1	2	1
Reversibility*	n/a	n/a	c	c	c
average time for reversion (day of no reactions)	n/a	n/a	1 day	2 days	1 day
<p><i>Maximum average score was derived using the Draize method :</i></p> <p><i>For cornea: Score = (Opacity(A) x Area (B) x 5)</i></p> <p><i>For iris(C): Score = (Cx5)</i></p> <p><i>For Conjunctiva: Score = (Redness (D) x Chemosis (E) x Discharge (F) x2).</i></p> <p><i>Maximum average score = 7.0</i></p> <p><i>A modification of the Kay and Calendra system (1962) was used to interpret and classify the scores</i></p> <p>* <i>c : completely reversible</i> <i>n c : not completely reversible</i> <i>n : not reversible</i></p>					

Section B6.3		Skin sensitisation
Annex Point IIB VI.6.3		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	Buehlers test in guinea pigs has been performed on the active substance and no indication of skin sensitizing properties were identified The other ingredients of the product are not expected to cause skin sensitization. Also, direct dermal exposure is not expected to occur since the use of gloves is probable when handling highly toxic products and when performing tasks in an environment where rodent borne diseases may be present.	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
	32	Evaluation by Rapporteur Member State
Date	1 March 2013	
Evaluation of applicant's justification	Agree not justified considering the likely exposure	
Conclusion	Justification accepted	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	

Section B6.3 Annex Point IIB VI.6.3	Skin sensitisation
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B6.4 (1)

Percutaneous absorption (in vitro test)

Annex Point IIA6.2

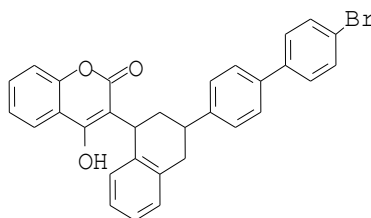
Official

33 A BRIDGING CASE TO DIFENACOUM DATA IS PROPOSED

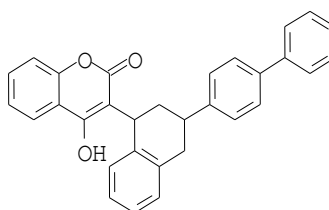
Brodifacoum and difenacoum are second generation anticoagulant rodenticides, which cause death of target organisms due to massive internal haemorrhages. All the coumarin derivatives act as vitamin K antagonists through inhibition of vitamin K reductase leading to depletion of a number of carboxylated blood coagulation factors. The effect is cumulative in nature. Haemorrhaging and subsequent death is the only effect observed in acute and repeated-dose toxicity tests. Prolongation of prothrombin time is usually observed before clinical signs of toxicity.

Both compounds are very toxic by inhalation, in contact with skin and if swallowed.

Brodifacoum and difenacoum are very similar in structure, as can be seen from the structural diagrams below.



Brodifacoum



Difenacoum

The compounds also have very similar physico-chemical properties, the Log P, molecular weight and water solubility values being as follows:

Brodifacoum	Difenacoum
4.92	-
8.51 (calculated)	7.62 (calculated)

Log P*	523.4	444.5	use only
	2.4x10 ⁻⁴ g/l (pH7.4)	4.83x10 ⁻⁴ g/l (pH6.5)	
Mol wt			
Water solubility (20°)	* Initially, the difenacoum log P value appears significantly higher than that for brodifacoum. However, the difenacoum value is a calculated figure while an experimental value is given for brodifacoum. Using a like-for-like comparison of calculated values, the log P both compounds is shown to be similar.		

Both compounds have a high log P and molecular weight and are of low solubility in water. It is widely accepted that compounds with high Log P values and high molecular weight will show poor skin permeability. Given the similarity of structure and physico-chemical properties for both compounds, their skin penetration properties are also likely to be comparable.

The following experimental data for dermal penetration were submitted as part of the EU review:

Difenacoum Wax blocks 0.047% Paste 0.046%

The Italian RMS accepted a bridging approach for the representative use, the wax block formulation. The figure of 0.047% from the difenacoum data for wax blocks was proposed by the RMS to be used as the dermal penetration figure for a wax block formulation.

Details of the difenacoum dermal penetration study on wax block and paste bait formulations are given below. The wax block/paste bait study was reviewed by the relevant RMS as part of the AS dossier.

**Offici
al
use
only**



Section B6.4 (1)

Percutaneous absorption (in vitro test)

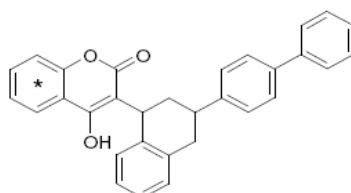
Annex Point IIA6.2

Official
use
only

	30 Reference	
30.1 Reference	Davies DJ (2007) <i>In vitro</i> absorption of difenacoum from wax block and pasta bait through human epidermis. PelGar International study report JV2001.	
30.2 Data protection	Yes	
30.2.1 Data owner	PelGar International and Activa s.r.l	
30.2.2 Companies with access to data	PelGar International Ltd. Activa srl	
30.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I authorisation.	
	31 Guidelines and Quality Assurance	
31.1 Guideline study	Yes OECD 428	
31.2 GLP	Yes	
31.3 Deviations	No	
	32 MATERIALS AND MethodS	
32.1 Test material	As given in section 2.	
32.1.1 Lot/Batch number	Difenacoum technical 03661 [coumarin benzene ring-U- ¹⁴ C]-Difenacoum Code CFQ14457 Batch 1	
32.1.2 Specification	As given in section 2.	

Section B6.4 (1) Percutaneous absorption (in vitro test)**Annex Point IIA6.2**

32.1.2.1	Description	Difenacoum technical: off white powder
32.1.2.2	Purity	Difenacoum technical 99.5% (w/w)
32.1.2.3	Stability	Not specified
32.1.2.4	Radiolabelling	[coumarin benzene ring-U- ¹⁴ C]-Difenacoum radiochemical purity of 96.1%



* denotes the position of [¹⁴C]-labelled atoms.

32.2 Test Animals

32.2.1	Species	Human
32.2.2	Strain	Not applicable
32.2.3	Source	Human skin samples were obtained at surgery or post mortem
32.2.4	Sex	Not specified
32.2.5	Age/weight at study initiation	Not specified

32.2.6	Number of animals per group	At least 2 different donors were used
32.2.7	Control animals	Not specified
32.3	Administration/ Exposure	Dermal
32.3.1	Preparation of test site	The skin samples were immersed in water at 60°C for 40 – 45 secs and the epidermis teased away from the dermis. Membranes were stored frozen at approximately -20°C on aluminium foil until required for use. Discs of approximately 3.3 cm diameter of prepared skin membrane were mounted, dermal side down in diffusion cells held together with individually numbered clamps and placed in a water bath maintained at 32°C ± 1°C. Membrane integrity was determined by measurement of the electrical resistance across the skin membrane. Membranes

Official
use
only

Section B6.4 (1)**Percutaneous absorption (in vitro test)****Annex Point IIA6.2**

	<p>wit ha measured resistance of <10KΩ were regarded as having a lower integrity than normal and not used for exposure to the test materials. Prior to application, 25.4 µL of physiological saline was applied to the exposed surface of each membrane in order to moisten the application site and maximise the contact between the formulation and the skin surface. Cells were selected such that each application was represented by 6 intact membranes from at least 2 different donor. The receptor fluid ensured that the test substance could freely partition into the receptor fluid from the skin membrane and never reaches a concentration that would limit its diffusion.</p>
32.3.2 Concentration of test substance	<p>Wax block (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 20.6 µg difenacoum/cm².</p> <p>Pasta bait (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 19.4 µg difenacoum/cm².</p>
32.3.3 Specific activity of test substance	Not specified.
32.3.4 Volume applied	Not specified, total target weight of dose applied was 1000 mg for both pasta bait and wax block formulations.
32.3.5 Size of test site	3.3 cm diameter
32.3.6 Exposure period	8 hours, followed by a skin wash and absorption was measured for a further 16 h period (24 h total).
32.3.7 Sampling time	24 h after initiation of skin contact.
32.3.8 Samples	<p>Receptor fluid samples. A pre-treatment sample was taken from each receptor chamber for analysis by LSC. The volume of fluid in the receptor chamber was maintained by the replacement of a volume of receptor fluid, equal to the sample volume immediately after each sample was taken. After the 8 h receptor fluid sample had been taken, the cells were removed from the water bath.</p> <p>Any residual formulation left remaining on the skin was tipped into ethanol and once dissolved a sub-sample was taken for analysis by LSC. The epidermal surface of the skin was decontaminated by gently swabbing the application site with natural sponges wetted with 3% Teepol L[®] and with further sponges pre-wetted with water. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The sponges were digested in Soluene</p>

**Official
use
only**

Section B6.4 (1)

Percutaneous absorption (in vitro test)

Annex Point IIA6.2

350[®] and made up to a recorded volume. A sample was taken for analysis. After the final receptor fluid sample had been taken, the remaining fluid in the receptor chamber was stored frozen for possible further analysis. The donor chamber was carefully removed and the underside of the donor chamber wiped with a single sponge pre-wetted with 3% Teepol L[®] which was added to the wash sponges. The donor chamber was washed with ethanol and the sample analysed by LSC.

The surface of the skin was allowed to dry naturally. To assess penetration through the stratum corneum, successive layers of the skin surface were removed by the repeated application of adhesive tape, to a maximum of 5 strips. A strip of adhesive strips were soaked in ethanol to extract any test material. The extracts were sequentially numbered and analysed by LSC. The remaining epidermis was carefully removed from the receptor chamber, digested in Soluene 350[®] and the whole digest analysed.

33 Results and Discussion

- | | | |
|------|--------------------------------------|---|
| 33.1 | <i>Toxic effects, clinical signs</i> | None specified |
| 33.2 | <i>Dermal irritation</i> | None specified |
| 33.3 | <i>Recovery of labelled compound</i> | Mean recovery of radiolabelled test material was 96.7% and 104% of the applied dose for the wax block and pasta bait formulations, respectively. For the wax block and pasta bait formulations, the majority of applied dose, 96.7% and 103%, respectively remained on the skin surface or was removed by gentle skin washing 8 h after application. Minimal amounts (0.043% and 0.62% for the wax block and pasta bait respectively) were removed by further washing procedures 16 h later. The mean proportion of the applied dose present in receptor fluid following the total 24 h exposure was 0.011% for wax block and 0.012 % for pasta bait. In terms of actual amounts, these percentages equate to 0.002 µg/cm ² and 0.002 µg/cm ² , respectively. A total of 0.037% (wax block) and 0.038% (pasta bait) of the applied dose remained in the epidermal membrane following 24 h exposure. Of this total, 0.001% (wax block) and |

Section B6.4 (1)

Percutaneous absorption (in vitro test)

Annex Point IIA6.2

		0.004% (pasta bait) was present in the outer layers of the strata corneum.
33.4	<i>Percutaneous absorption</i>	<p>Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 µg/cm²/h. Between 6 – 12 h, absorption increased slightly to 0.00017 µg/cm²/h. Between 12 – 24 h, absorption slowed to 0.00004 µg/cm²/h. Between 0 – 24 h absorption through the membrane was 0.00011 µg/cm²/h. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0,00181 µg/cm², respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 µg/cm² (0.0014% of the applied dose).</p> <p>Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 µg/cm²/h. Between 8 – 24 h, absorption increased slightly to 0.00012 µg/cm²/h. Between 0 – 24, absorption through the membrane was 0.0001 µg/cm²/h. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 µg/cm², respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 µg/cm² (0.01220% of the applied dose).</p>
34.1	<i>Materials and methods</i>	<p>34 Applicant's Summary and conclusion</p> <p>The purpose of this study was to determine the <i>in vitro</i> percutaneous absorption of difenacoum through human skin over an 8 h exposure period to aid quantitative assessment of the hazard from human skin contact with a wax block and pasta bait formulation containing 0.005% (w/w) difenacoum,. The distribution of difenacoum within the test system following the 8 h exposure and a 16 h post exposure period (24 h total) was also determined.</p>
34.2	<i>Results and discussion</i>	<p>The absorbed (systemically available) dose is considered to be the difenacoum detected in the receptor fluid. Material removed from the surface of the epidermis by the washing procedure and in tape strips is regarded as unabsorbed. Difenacoum recovered</p>

Official use only

Section B6.4 (1)**Percutaneous absorption (in vitro test)****Annex Point IIA6.2**

from the epidermis at the end of the exposure is considered to be absorbed, although it is recognised that a proportion of this material may not be absorbed beyond the duration of the exposure investigated in this study. In vivo, the majority of the dose in the epidermis, especially that recovered from the stratum corneum would eventually be lost by desquamation.

Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 $\mu\text{g}/\text{cm}^2/\text{h}$. Between 6 – 12 h, absorption increased slightly to 0.00017 $\mu\text{g}/\text{cm}^2/\text{h}$. Between 12 – 24 h, absorption slowed to 0.00004 $\mu\text{g}/\text{cm}^2/\text{h}$. Between 0 – 24 h absorption through the membrane was 0.00011 $\mu\text{g}/\text{cm}^2/\text{h}$. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0.00181 $\mu\text{g}/\text{cm}^2$, respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 $\mu\text{g}/\text{cm}^2$ (0.0014% of the applied dose).

Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 $\mu\text{g}/\text{cm}^2/\text{h}$. Between 8 – 24 h, absorption increased slightly to 0.00012 $\mu\text{g}/\text{cm}^2/\text{h}$. Between 0 – 24, absorption through the membrane was 0.0001 $\mu\text{g}/\text{cm}^2/\text{h}$. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 $\mu\text{g}/\text{cm}^2$, respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 $\mu\text{g}/\text{cm}^2$ (0.01220% of the applied dose).

34.3 Conclusion

The results obtained in this study indicate that difenacoum is absorbed through human epidermis, from the wax block and pasta bait formulations at an extremely slow rate. The vast majority of the applied dose either remained on the skin surface or was removed by gently skin washing at 8 h. These data predict that difenacoum absorption through human epidermis was fastest between 6 – 12 h (0.00017 $\mu\text{g}/\text{cm}^2/\text{h}$) for the wax block formulation and 8 – 24 h (0.00012 $\mu\text{g}/\text{cm}^2/\text{h}$) for the pasta bait. As absorption continued after the formulations were removed from the skin surface it can be assumed that radioactivity

Section B6.4 (1)**Percutaneous absorption (in vitro test)****Annex Point IIA6.2**

remaining in the epidermis 24 h after application will be absorbed. Consequently the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046 % respectively.

34.3.1 Reliability

1

34.3.2 Deficiencies

No

Evaluation by Competent Authorities

Section B6.4 (1)

Percutaneous absorption (in vitro test)

Annex Point IIA6.2

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>34 Evaluation by Rapporteur Member State – FINLAND FOR DIFENACOUM</p>
<i>Date</i>	16 January 2007
<i>Materials and Methods</i>	Point 3.3.5: The actual exposed membrane area is 2.54 cm ² .
<i>Results and discussion</i>	<p>Agree with applicant's version.</p> <p>See remarks</p>
<i>Conclusion</i>	<p>Agree with applicant's version.</p> <p>Under the test conditions (a nominal 1000 mg sample of the formulation (0.005%, w/w) applied for 8 hours on excised human skin) the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046%, respectively, during 24 hours. The amount of difenacoum in <i>stratum corneum</i> is not included.</p> <p>Dermal absorption of 0.047% is taken forward to risk characterisation</p>
<i>Reliability</i>	1
<i>Acceptability</i>	Acceptable
<i>Remarks</i>	<p>Point 1.1: The study report number is JV2011-REG</p> <p>It is obvious that 'percentage of dose absorbed' is not an ideal measure of substance penetration through skin. However, that is the way it has to be expressed in order to be able to use dermal absorption study results for exposure assessment according to the prevailing guidance and practice. The formulation type (wax bound block) most probably retains quite effectively a fat-soluble and hydrophobic substance like difenacoum.</p> <p>Key study</p>

Section B6.4 (1) Percutaneous absorption (in vitro test)**Annex Point IIA6.2**

	35	Comments from ...Ref MS - Ireland
<i>Date</i>		April 2013
<i>Materials and Methods</i>		N/A
<i>Results and discussion</i>		N/A
<i>Conclusion</i>		N/A
<i>Reliability</i>		N/A
<i>Acceptability</i>		N/A
<i>Remarks</i>		Agree with Finnish evaluation and conclusions.

Table 6.4- 1 Summary of difenacoum distribution in the test system (Added by RMS)

Wax block formulation:

Test Compartment n = 6	µg difenacoum per cm ²		% of applied dose	
	Mean	SEM	Mean	SEM
Residual formulation	19.9	0.082	96.6	0.397
Decontamination (8h)	0.020	0.003	0.099	0.012
*Donor chamber	0.001	<0.001	0.003	0.001
Skin wash (24h)	0.009	0.001	0.043	0.007
*Stratum corneum	<0.001	<0.001	0.001	0.001
Remaining epidermis	0.007	0.001	0.036	0.007
Receptor fluid	0.002	<0.001	0.011	0.002
Total recovered	20.0	0.083	96.7	0.402
Absorbed	0.010	0.002	0.047	0.008

Pasta bait formulation:

Test Compartment n = 5	$\mu\text{g difenacoum per cm}^2$		% of applied dose	
	Mean	SEM	Mean	SEM
Residual formulation	18.9	0.83	97.4	4.26
Decontamination (8h)	1.06	0.81	5.47	4.20
*Donor chamber	0.007	0.003	0.037	0.018
Skin wash (24h)	0.121	0.086	0.623	0.442
* <i>Stratum corneum</i>	0.001	<0.001	0.004	0.001
Remaining epidermis	0.007	0.002	0.034	0.012
Receptor fluid	0.002	0.001	0.012	0.005
Total recovered	20.1	0.325	104	1.68
Absorbed	0.009	0.003	0.046	0.017

*Where flagged, the mass balance data were either close to or below the LOQ. To achieve reportable values, these data have not been raised to LOQ.

Stratum corneum = amount in tape strips; Remaining epidermis = epidermal tissue remaining after tape stripping; Absorbed = amount in remaining epidermis plus receptor fluid

Section B6.5 Annex Point IIB VI.6.5	Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	The product is a wax block bait composed of a toxic active substance, and ingredients that are not substances of concern. The ingredients are mostly food-grade substances which themselves do not contain any substances of concern. The dyestuff preparation is declared as containing no hazardous ingredients according to 91/155/EEC.	

Section B6.5	Available toxicological data relating to toxicologically
Annex Point IIB VI.6.5	relevant non-active substances (i.e. substances of concern)
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	21.11.2006
Evaluation of applicant's justification	Applicant's justification is applicable
Conclusion	Applicant's justification is acceptable
Remarks	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

				Official use only												
	35 Reference															
		For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.														
35.1 Reference		Chambers, J.G. and Snowdon, P.J., 2004, Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits, Synergy laboratories Ltd, Study N ^o SYN/1302														
35.2 Data protection		Yes														
35.2.1 Data owner		CEFIC/EBPF Rodenticides data development group														
35.2.2 Companies with access to data		Pelgar International Ltd.														
35.2.3 Criteria for data protection		Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I														
	36 Guidelines and Quality Assurance															
36.1 Guideline study		No no guidelines available														
36.2 GLP		Yes														
36.3 Deviations		n/a														
	37 MATERIALS AND MethodS															
		<i>In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.</i>														
37.1 Test material		<table border="1"> <thead> <tr> <th>N^o</th> <th>Task</th> <th>Test item</th> <th>AS</th> </tr> </thead> <tbody> <tr> <td>4</td> <td>Securing wax blocks in bait stations</td> <td>Compressed wax blocks</td> <td>Flocoumafen</td> </tr> <tr> <td>5</td> <td>Clean up and disposal of wax blocks</td> <td>Compressed wax blocks</td> <td>Flocoumafen</td> </tr> </tbody> </table>			N ^o	Task	Test item	AS	4	Securing wax blocks in bait stations	Compressed wax blocks	Flocoumafen	5	Clean up and disposal of wax blocks	Compressed wax blocks	Flocoumafen
N ^o	Task	Test item	AS													
4	Securing wax blocks in bait stations	Compressed wax blocks	Flocoumafen													
5	Clean up and disposal of wax blocks	Compressed wax blocks	Flocoumafen													

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

• Lot/Batch number	40205												
• Specification	Flocoumafen in the form of “Storm Secure 20G” wax blocks												
• Description	Wax block												
• Purity	0.004%												
37.1.1.1 Stability	Stable under test conditions												
37.2 Method of analysis	Residues of flocoumafen were extracted from the dosimeters by shaking with pre-dried acetone followed by concentration either under rotary evaporation or under a stream of air on a Dri-block. When required extracts were cleaned using solid phase extraction (SPE) cartridges. After addition of a known amount of an appropriate HPLC marker compound, residues were determined by reversed phase HPLC with fluorescence detection. LOQ = 0.05µg												
37.3 Exposure	Dermal exposure to the hands only												
37.3.1 Reasons of exposure	The purpose of the study was to simulate anticipated exposure through the use of the product.												
37.3.2 Frequency of exposure	<table border="1"> <thead> <tr> <th>Manipulations per replicate</th> <th>Nº of replicates</th> <th>Dosimeters sampled per trial</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>10</td> <td>Hand</td> </tr> <tr> <td>5</td> <td>10</td> <td>Hand</td> </tr> <tr> <td>10</td> <td>10</td> <td>Hand</td> </tr> </tbody> </table>	Manipulations per replicate	Nº of replicates	Dosimeters sampled per trial	1	10	Hand	5	10	Hand	10	10	Hand
Manipulations per replicate	Nº of replicates	Dosimeters sampled per trial											
1	10	Hand											
5	10	Hand											
10	10	Hand											
37.3.3 Sampling	For dermal exposure, white cotton gloves were used as dosimeters.												
• Description of exposure patterns	<p>Securing wax blocks in bait stations: A standard manipulation for this test was defined as the securing of five wax blocks into a single bait station which was then placed in a corner on the floor of the test site.</p> <p>Clean up and disposal of wax blocks: A standard manipulation for this test was defined as the emptying of a loaded bait station containing five wax blocks by sliding the blocks of the steel mounting rod into a bucket and cleaning out the bait station</p> <p>The clean up and disposal test was run directly after the securing test.</p>												

Section B6.6(i)**Information related to the exposure of the biocidal product****Annex Point IIB VI.6.6**

37.3.4 Duration of single exposure	<p>Not stated.</p> <p>The study design assumes that the level of exposure is related to the number of bait manipulations.</p>
<ul style="list-style-type: none"> • Test design 	<p>The test was designed to simulate potential exposure during the use of wax bait rodenticides.</p> <p>Each task was tested ten times (replicates) in trials involving 1, 5 or 10 manipulations. Where a manipulation represented a single operation, each separate task was conducted by five operators who each carried out two replicates.</p> <p>New dosimeters were fitted prior to each replicate of each trial and removed for analysis afterwards.</p>
<ul style="list-style-type: none"> • Calculations 	<p>The amount of product was extrapolated from the quantity of active detected on the dosimeter based on 0.004% concentration of the active in the product.</p>
<ul style="list-style-type: none"> • Remarks 	<p>Although the study included tests on the use of grain based baits, only the sections relating to the use of wax blocks has been summarised as that is the form taken by the product and it was deemed unnecessary to include sections that bore no relevance to the dossier submitted.</p>

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

38 Results and Discussion

- *Securing wax blocks in bait stations*

Flocoumafen residues in gloves following a single manipulation ranged from 0.55 to 3.71 µg/sample (equivalent to 13.7 to 92.8 mg product/sample). Following 5 manipulations, levels ranged from 2.98 to 6.66 µg/sample (74.5 to 166 mg product/sample) and for 10 manipulations from 5.33 to 11.2 µg/sample (133 to 280 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	1.29	32.19	4.12	103.15	7.20	180.05

- *Clean-up and disposal*

Flocoumafen residues determined during wax block clean-up were less than those measured for loading due to less direct hand contact with the product. Levels in gloves following a single manipulation ranged from 0.05 to 0.36µg/sample (equivalent to 1.27 to 9.04 mg product/sample). Following 5 manipulations, levels ranged from 0.37 to 1.75µg/sample (9.29 to 43.6 mg product/sample) and for 10 manipulations from 1.20 to 3.13 µg/sample (29.9 to 78.3 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	0.16	4.01	1.00	24.9	2.07	51.23

- **Applicant's Summary and conclusion**

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

- | | |
|--|--|
| <ul style="list-style-type: none"> • <i>Materials and methods</i> | <p>Potential exposure of professional and non-professional users during handling of anticoagulant rodenticide baits formulated as wax blocks was simulated by measurement of potential dermal residues during loading of bait stations and clean up and disposal.</p> <p>Wax blocks containing 0.004% w/w Flocoumafen were used as surrogate test items. Each task was tested ten times (replicates) in trials involving either 1, 5 or 10 manipulations, where a manipulation represented a single operation (for example loading one bait station with five wax blocks). Each separate task was conducted by five operators who each carried out two replicates. The analytical procedure was based upon extraction of the a.s. with pre-dried acetone, concentration and clean-up by solid-phase extraction (SPE) as necessary before determination by high performance liquid chromatography (HPLC) with fluorescence detection.</p> <p>Exposure to product was calculated by extrapolation from the active substance content of the bait.</p> |
| <ul style="list-style-type: none"> • <i>Results and discussion</i> | <p>Levels of Flocoumafen residue were dependant on the number of manipulations performed. There were considerable fluctuations between operators and replicates.</p> <p>The performance of 10 bait placing manipulations, involving handling of 50 bait blocks, resulted in product residues on the hands of
185.75 mg product/person (mean) (18.58mg per bait station)</p> <p>The performance of 10 clean-up manipulations resulted in product residues on the hands of
51.23 mg product/person (mean)(5.12mg per bait station)</p> <p>The performance of 1 bait placing manipulation, involving handling 5 bait blocks, resulted in product residues on the hands of
36.98 mg product/person (mean)</p> <p>The performance of 1 clean up manipulation resulted in product residues on the hands of 4.01mg product/person (mean)</p> |
| <p>38.1 Conclusion</p> | <p>Non-entry field</p> |
| <p>38.1.1 Reliability</p> | <p>1</p> |

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

38.1.2 Deficiencies No

35.1.1

Evaluation by Competent Authorities

Section B6.6(i)

Information related to the exposure of the biocidal product

Annex Point IIB VI.6.6

35.1.2	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
<p><i>Date</i></p> <p><i>Materials and Methods</i></p> <p><i>Results and discussion</i></p> <p><i>Conclusion</i></p> <p><i>Reliability</i></p> <p><i>Acceptability</i></p> <p><i>Remarks</i></p>	<p>36 Evaluation by Rapporteur Member State</p> <p><i>April 2007</i></p> <p>Applicants version is acceptable</p> <p>Adopt applicant's version</p> <p>Appropriate reliability indicator</p> <p>Acceptable</p> <p>Applicants version is acceptable</p>
<p><i>Date</i></p> <p><i>Materials and Methods</i></p> <p><i>Results and discussion</i></p> <p><i>Conclusion</i></p> <p><i>Reliability</i></p> <p><i>Acceptability</i></p> <p><i>Remarks</i></p>	<p>37 Comments from ...</p> <p><i>Give date of comments submitted</i></p> <p><i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>

Table B6.6- 1: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from deploying wax block baits in bait boxes (5 blocks per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	1.65	41.2	5.16	129.06	7.08	177.01
	2	1.67	41.74	3.59	89.82	6.47	161.87
2	1	0.72	17.96	4.76	118.97	9.59	239.72
	2	1.19	29.69	4.73	118.27	6.87	171.73
3	1	1.25	31.36	2.98	74.5	7.38	184.44
	2	0.96	24.11	3.22	80.39	5.36	134.06
4	1	2.01	50.37	5.42	135.54	9.43	235.8
	2	3.71	92.75	6.66	166.42	11.21	280.2
6	1	0.55	13.7	3.15	78.78	5.58	139.53
	2	1.08	26.91	3.13	78.31	5.33	133.14
50th percentile		1.22	30.525	4.16	104.045	6.975	174.37
75th percentile		1.665	41.605	5.06	126.5375	8.9175	222.96
90th percentile		2.18	54.608	5.544	138.628	9.752	243.768
geometric mean		1.28784	32.18889	4.124405	103.1179	7.201804	180.0469
Mean		1.479	36.979	4.28	107.006	7.43	185.75
Standard Error		0.285359	7.137958	0.395255	9.877688	0.636235	15.90229
Median		1.22	30.525	4.16	104.045	6.975	174.37
Standard Deviation		0.902385	22.57221	1.249907	31.23599	2.011953	50.28744
Sample Variance		0.814299	509.5045	1.562267	975.6871	4.047956	2528.827
Kurtosis		4.23184	4.214188	-0.56625	-0.57575	-0.44449	-0.44609
Skewness		1.850004	1.84583	0.65193	0.649119	0.793366	0.792521
Range		3.16	79.05	3.68	91.92	5.88	147.06
Minimum		0.55	13.7	2.98	74.5	5.33	133.14
Maximum		3.71	92.75	6.66	166.42	11.21	280.2
Sum		14.79	369.79	42.8	1070.06	74.3	1857.5
Count		10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)							
		1.479	36.979	0.856	21.4012	0.743	18.575

Table B6.6- 2: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from clean-up and disposal of wax block baits from bait boxes (one box per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	0.22	5.62	1.02	25.62	1.2	29.91
	2	0.05	1.27	0.55	13.63	1.74	43.55
2	1	0.14	3.42	1.19	29.75	2.28	57.03
	2	0.18	4.43	0.77	19.33	1.21	30.17
3	1	0.08	2.07	1.05	26.28	2.15	53.69
	2	0.18	4.59	1.07	26.75	2.72	68.05
4	1	0.36	9.04	1.16	28.9	3.13	78.32
	2	0.23	5.67	1.75	43.63	2.83	70.7
6	1	0.08	2.02	1.03	25.83	1.37	34.16
	2	0.08	2	0.37	9.29	1.87	46.75
50th percentile		0.16	3.925	1.04	26.055	2.01	50.22
75th percentile		0.21	5.3625	1.1375	28.3625	2.61	65.295
90th percentile		0.243	6.007	1.246	31.138	2.86	71.462
geometric mean		0.135686	3.410269	0.922594	23.07048	1.942384	48.52657
Mean		0.16	4.013	0.996	24.901	2.05	51.233
Standard Error		0.03	0.751153	0.119492	2.979104	0.218724	5.481339
Median		0.16	3.925	1.04	26.055	2.01	50.22
Mode		0.08	#N/A	#N/A	#N/A	#N/A	#N/A
Standard Deviation		0.094868	2.375355	0.377865	9.420754	0.691665	17.33351
Sample Variance		0.009	5.642312	0.142782	88.75061	0.4784	300.4507
Kurtosis		0.798413	0.844559	1.239799	1.212496	-1.30767	-1.3038
Skewness		0.927211	0.95074	0.245626	0.224021	0.206223	0.204209
Range		0.31	7.77	1.38	34.34	1.93	48.41
Minimum		0.05	1.27	0.37	9.29	1.2	29.91
Maximum		0.36	9.04	1.75	43.63	3.13	78.32
Sum		1.6	40.13	9.96	249.01	20.5	512.33
Count		10	10	10	10	10	10
quantity per bait station (mean /no of manipulations)		0.16	4.013	0.1992	4.9802	0.205	5.1233

B6.6(2)

For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.

<p style="text-align: center;">TMIITOX-item4- Bait Handling-REPORT.doc</p> <p style="text-align: center;">Estimation of the Frequency of Dermal Exposure</p> <p style="text-align: center;">During the Occupational Use of Rodenticides</p> <p style="text-align: center;">28th July 2006</p>
--



D. Vetter & T. Sendor

EBRC Consulting
Zeppelinstr. 8
30175 Hannover
Germany

<p style="text-align: center;">This report has been prepared by EBRC Consulting under contract to the CEFIC Rodenticides Working Group.</p>
--

39 Introduction

In the current evaluation of rodenticides (inclusion of active substances in Annex I of the Biocides Directive 98/8/EC), the assessment of dermal exposure of professional pest control technicians (PCTs) to rodenticide baits is currently inconsistent: In particular, the assumptions regarding the frequency of bait handling are contradictory among various dossiers. The TNsG on Human Exposure (EU, 2002) and the User Guidance to the TNsG (EU, 2004) provide a variety of assumed bait handling frequencies, but no clear guidance. This has resulted in divergent exposure estimates among the CA reports for active substances published so far. Consequently, the need for agreed default exposure frequencies was identified at the Technical Meeting “Subgroup Anticoagulants” held on 18th May 2006 at the JRC, Ispra. Industry was requested to propose default values for bait handling, based on actual user data.

Some Member States also announced to provide data on bait handling frequency to the chairman of the CEFIC Rodenticide Working Group. The only contributions received in this context were general exposure scenario documents from DK and NL, as well as a written communication by DE, stating a figure of up to 300 wax blocks that may be deployed daily. However, these sources of information were not considered in the subsequent evaluation since they are not based on actual user data. Recent surveys at three pest control companies provided extensive information on handling patterns of occupationally exposed pest control technicians (PCT) in 15 European countries (EU, N, CH). Data were requested with respect to the most relevant bait types in professional rodent control, i.e. grain bait, wax block bait, and paste bait. As a first step of analysis, this information was assessed in terms of representativeness and quality. The number of exposure events was then estimated based on the given data as presented and discussed below.

40 Objective of this report

This paper aims at providing useful and reliable estimates of the number of exposure events a PCT may experience during the occupational handling of different types of rodenticide baits. The objective of the current paper is therefore to propose scientifically acceptable figures for the daily bait handling frequencies. The relevant endpoints were identified as the:

typical case (median value)

and

reasonable worst case (75th percentile),

based on the presumption (see TNsG on human exposure, part 2, section 1.6) that the data base is representative and appropriate. Corresponding figures were derived for the individual bait types, respectively.

41 Description of data sources

The following analysis is based on data from three sources covering large parts of the EU (see below). Three pest control companies submitted data from surveys based on a common questionnaire (see “Appendix II: Used questionnaire”). Short descriptions of the respective subsets are given below and further summarised in “Appendix I: Used data”:

- Company 1: Multinational pest control company; the survey was conducted by sending a written questionnaire to the head office of the company involved in each European country where the company was represented. Thus, the raw data from company 1 constitute a country-by-country summary over 15 European countries.
- Company 2: UK rodenticide manufacturer, providing data from customers (pest control) at company level (i.e. raw data represent averages of three specific UK companies).
- Company 3: German rodenticide manufacturer and pest control company. Data were collected at the level of individual technicians. In order to avoid any bias from introducing individual data in the total data-base, the individual data were aggregated to result in average numbers across all technicians and bait types of this company, which were then integrated into the data base already comprising information from companies 1 and 2. For a detailed analysis of this data-set please review Appendix III.
- Company 3 (supplementary data): An additional survey was provided by company 3, reporting numbers of deployed bait stations per day when PCTs work at the same object during their entire shift. This represents a clear worst case situation since no travelling between sites and only minimal administrative work is included, so that a maximum portion of the working time is dedicated to pest control tasks. The study only considered wax block baits. Since this survey employs a different approach these results were only used for comparison as a plausibility check but not included in the statistical analysis.

Table 1: Characteristics of the raw data, as provided by the participating companies.

Source	Countries involved	Number of data points	Type of data	Aggregation level
Company 1	15 European countries	15	Aggregated	Country
Company 2	UK	3	Aggregated	Company
Company 3	D	10	Individual	Technician
Company 3	D	7	Individual	Technician/Site

The data specified in Table 1 were collated into a common data base (except supplementary data from company 3). Data from company 1 and 2 were considered as equivalent, respectively, since the aggregation level of country head office (company 1) and customer (company 2) represent approximately the same level of hierarchy. The 10 individual responses from company 3 were aggregated into one data point (also see Appendix III), and are hence considered to be comparable to the former. This resulted in a data base with a sample size of $n = 19$.

42 Assessment of representativeness and reliability of used data

Whereas the data originate directly from the pest control business and should therefore reflect common practice, a definitive assessment of representativeness for the EU cannot be made: The sector coverage is currently unknown since figures for total volume of rodenticide consumption in the EU are not available. Furthermore, the data were not randomly collected but provided by companies which were interested to participate in this assessment.

It should be noted that data from Company 1 represent country-specific figures, while data from Company 2 represent company-specific averages for which neither the variation nor the number of used data points are reported. Furthermore, it is important to note that all submitted questionnaires represent some kind of expert judgement in the sense that apparently only supervisors completed them. Although they are considered to be very close to reality, it should be kept in mind that the data

do not originate from direct observation of workers (i.e. the data do not reflect handling patterns of individual PCTs, but instead average figures on the specific aggregation level, as presented in Table 1).

43 Methods

43.1 Selection of relevant data

The questionnaire used for the data collection comprised 10 questions related to the handling of rodenticides ("Appendix II: Used questionnaire"). In order to estimate the number of events in which dermal exposure to rodenticides may occur, two endpoints (see "Appendix I: Used data" for raw data) were identified as relevant. Both endpoints comprise data for each bait type separately and are characterised as follows:

- Question 7 (Number of handlings of rodenticides per day): This question aimed at asking for the number of sites visited per day. The data obtained by this question were used to estimate the exposure frequency regarding paste bait only, for the following reasons: According to company 1 (for whose PCTs paste bait application makes up significant parts of the business), this bait type is deployed using pre-filled cartridges. Due to the resulting spatial segregation between user and bait material, dermal exposure is only possible at removal and re-attachment of the nozzle's protection cap. This event is assumed to occur only before the first and after the last bait placing on a given site. Consequently, the number of exposure events per day to be included in the analysis was obtained by multiplying the number of sites per day by a factor of 2.

It is acknowledged that also other application types for paste bait exist on the market (e.g. pre-packed foil sachets) which may be related to different exposure patterns. These were, however, not considered in the current analysis since only data for cartridge are available.

- Question 10 (Number of bait stations per day): In the case of loose grain and wax block bait, the number of bait stations handled per day is considered to be the relevant exposure determinant, i.e. each handling of a bait station is equivalent to an exposure event. Thus, the respective figures were used to directly estimate the number of exposure events (i.e. the data were used as given).

43.2 Statistical procedures

An appropriate distribution was fitted to the data (log-normal or gamma, see below). for each bait type, respectively. The program @risk 4.5.4 (Palisade Corporation) was used to fit the data to the most appropriate distribution. Tests for the goodness of fit (GoF) were carried out to validate the fitted distributions. Based on the appropriate probability distribution fitted to the data, the median and the 75th percentile were calculated.

44 Results

The bait-type specific parameters of the fitted distributions are presented in Table 2 and Figures 1–3. According to the assumption that contact to paste bait is only possible at removal and re-attachment of the protection cap, exposure frequencies were estimated to be lowest with this bait type, whereas higher and very similar figures were obtained for loose grain bait and wax blocks.

Table 2: Number exposure events per day and PCT.

	Loose grain	Wax block	Paste bait	All bait types
Median	16.1	13.1	4.5	43.6
Mean	34.9	33.1	6.2	66.9
75 th percentile	37.3	32.7	8.6	n.a.
90 th percentile	79.3	74.9	14.0	n.a.
n	19	19	19	19
Fitted distribution	lognormal	lognormal	gamma	lognormal
Anderson-Darling GoF				
Critical value $\alpha=0.05$	0.752	0.752	0.752	0.752
Test statistic	0.540	0.241	0.681	0.490
Accepted	Yes	Yes	Yes	Yes
Chi ² GoF				
p	0.520	0.984	0.091	0.701

Evaluation of the responses to the questionnaires revealed that a PCT would normally apply more than one bait type on given working day. Conclusions as regards the actual distribution of used bait types are, however, not possible due to the degree of aggregation of the data sets. To address the case where more than one bait type is used in one day, however, it is not appropriate to add up the 75th percentiles of the various bait types, nor would a 75th percentile across all bait types be adequate, since this would correspond to an accumulation of worst cases. Such over-conservative approaches should be avoided in risk assessment.

Instead, to account for the alternation between bait types on a given working day, the median of the bait handling frequency across all bait types was calculated in addition to the bait-type specific estimates. This was done by adding up the relevant reported exposure frequencies per data set (e.g. for C1-01: 10 + 10 + 3 = 23, etc., cf. Appendix I) and fitting an appropriate distribution (see Table 2). Accordingly, the typical number of exposure events of a PCT using several bait types during his entire shift is given as 44 (median). Other parameters are not provided since this would be misleading for the reasons given above.

It is further noted that according to the responses to the questionnaire it is likely that also baits based on several active substances are used alternately. Thus, the presented figures entail an additional inherent conservatism with respect to exposure to a specific active substance.

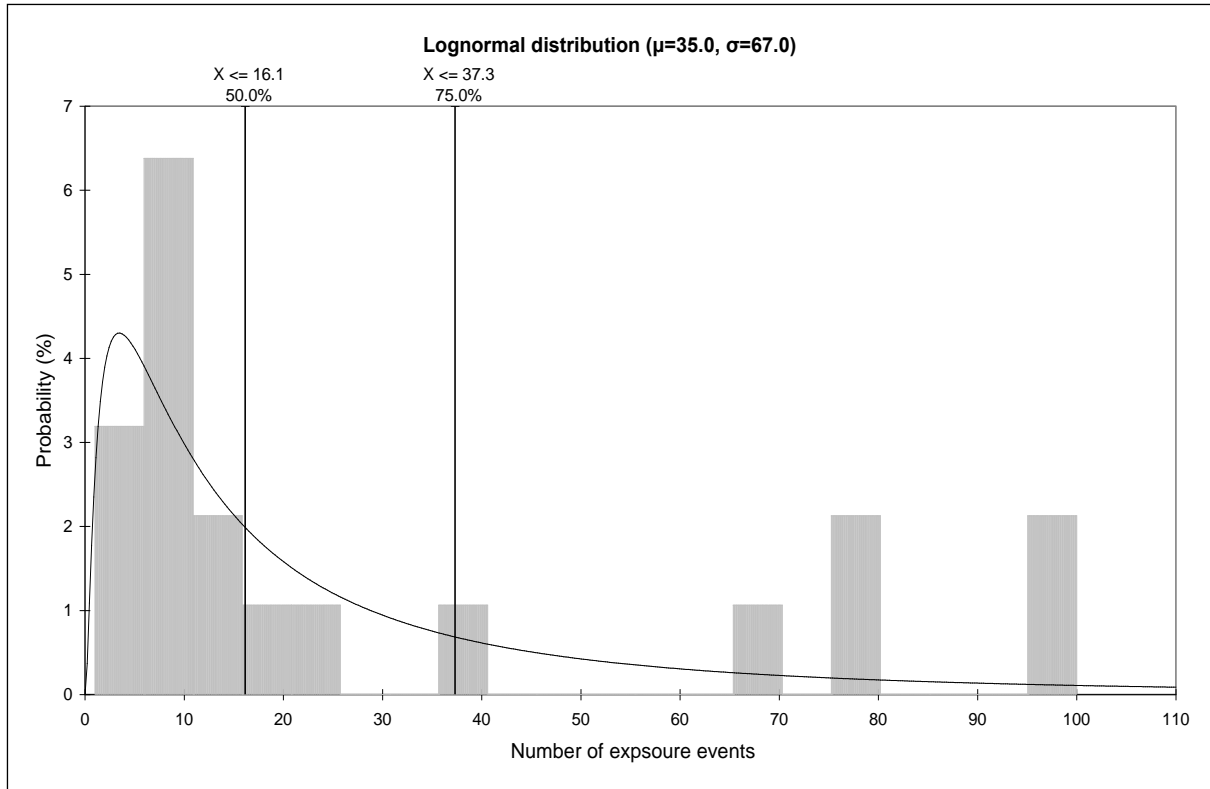


Figure 1: Frequency vs. fitted distribution for the number of exposure events during the use of loose grain bait.

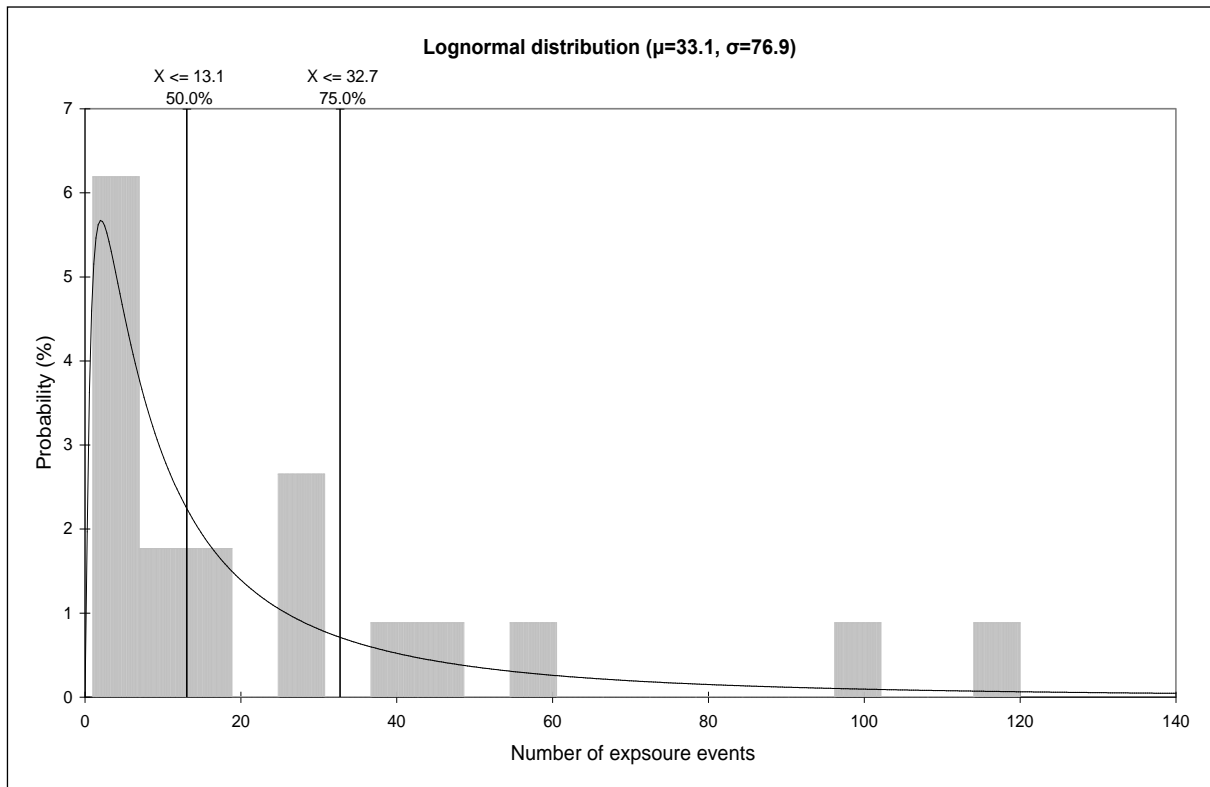


Figure 2: Frequency vs. fitted distribution for the number of exposure events during the use of wax block bait.

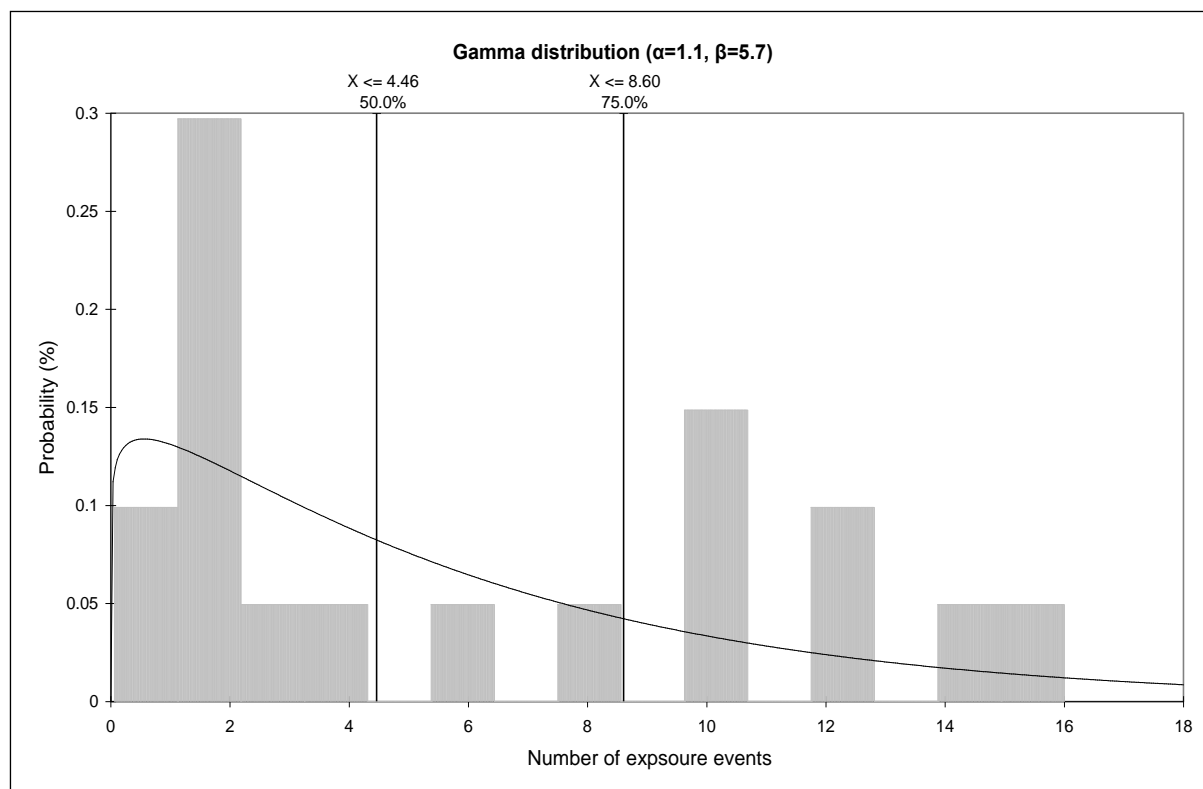


Figure 3: Frequency vs. fitted distribution for the number of exposure events during the use of paste bait.

45 Discussion and conclusions

Based on the submitted user survey data, PCTs alternating between several bait types on a normal full working day may be expected to experience 44 exposure events per day (typical case, median).

The figures for the bait-type specific reasonable worst case presented here are considered as sufficiently conservative estimates, for the following reasons: In Appendix IV, a case study under the worst case assumption of continuous rodent control work at one large site (i.e. no travelling and no other tasks not directly related to rodent control) is presented. The mean maximum number of bait stations is given as 91, and the overall maximum as 130.

Thus, the 75th percentiles of 37, 33 and 9 exposure events identified as the reasonable worst cases here are considered as highly relevant figures for risk assessment. Even if the spectrum of used baits is shifted towards wax blocks or grain bait (which reveal very similar exposure frequencies), the data in Appendix IV show that the maximum number of bait contacts is limited to a range of approx. 50 to 130. This is, however, only valid in the exceptional case of continuous rodent control work at large sites (no travelling etc.). It is further emphasised in this context that a PCT's working day is usually not exclusively made up of rodent control, but also other pest control activities like insecticide treatment etc. occur.

Since the current analysis is based on data obtained from a EU-wide survey, it may be considered as sufficiently representative.

In conclusion, the following reasonable worst case figures for the frequency of exposure of a PCT during a representative full working day to the respective bait types are proposed:

Loose grain bait:	37
Wax block bait:	33
Paste bait:	9

46 References

EU (2002): Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on exposure estimation. European Chemicals Bureau, Ispra, Italy, Report No. B4-3040/2000/291079/MAR/E2, June 2002

(http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

EU (2004): Human exposure to biocidal products (TNsG June 2002) – user guidance version 1. European Chemicals Bureau, Ispra, Italy, October 2004

(http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

38

Appendix I: Used data

Submission	Loose Grain		Bait Block		Paste Bait	
	Application	Bait station	Application	Bait station	Application	Bait station
C1-01	1.0	10.0	1.0	10.0	3.0	30.0
C1-02	9.0	20.0	6.0	120.0	6.0	120.0
C1-03	8.0	10.0	3.0	5.0	8.0	80.0
C1-04	2.0	10.0	1.5	10.0	1.0	10.0
C1-05	1.0	40.0	1.0	30.0	2.0	80.0
C1-06	5.0	4.0	2.0	1.0	5.0	25.0
C1-07	2.0	80.0	4.0	60.0	0.4	10.0
C1-08	1.0	12.0	1.0	15.0	1.0	15.0
C1-09	1.0	25.0	1.0	26.0	1.0	100.0
C1-10	5.0	6.6	5.0	6.6	5.0	6.6
C1-11	5.0	100.0	1.0	41.0	6.0	160.0
C1-12	2.0	100.0	6.0	100.0	1.0	100.0
C1-13	0.2	1.0	0.2	1.0	4.0	20.0
C1-14	2.0	80.0	0.4	25.0	5.0	200.0
C1-15	7.0	10.0	7.0	2.0	7.0	50.0
C2-01	7.0	70.0	2.0	15.0	1.0	15.0
C2-02	4.0	4.0	6.0	6.0	1.0	1.0
C2-04	1.6	6.6	1.6	6.6	1.6	6.6
C3-01	0.12	3.7	n.d.	47	0.04	n.d.

QUESTIONNAIRE ABOUT RODENTICIDE USE IN EUROPE

- Please answer the following 10 questions.
- Questions refer to the use of ready-to-use formulations only. (Information about concentrates, gels, dusts and fumigants are not required).
- Only estimates and average figures are required.

1. Which ready-to-use rodenticides are used? Also, please specify the active ingredient and %

Loose grain baits:

Bait block formulations:

Paste baits:

2. How much rodenticide is purchased by Pest Control each year? (Average figures in kilos).

Loose grain baits:

Bait block formulations:

Paste baits:

3. What is the advised dosage per bait station? (Average figures in grams)

Loose grain ready-to-use baits:

Bait block formulations:

Paste baits:

4. How many Pest Control Technicians are there in your Company?

5. Do all Pest Control Technicians handle rodenticides in their normal job? (If no, please specify how many Technicians handle rodenticides).

6. How long is the average working day? (in hours)

7. How often does a Pest Control Technician handle rodenticides? (e.g. how many times per day or per week or per month or per year).

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

8. For what part of his working time does a Pest Control Technician handle rodenticides? Give an indication: 0% to 100%.

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

9. How long does it take for a Pest Control Technician to inspect and fill rodenticide at a bait station? Give an estimate in minutes/seconds and only include from opening to closing the bait station. (DO NOT include cleaning out.)

Loose grain ready-to-use baits:

Bait block formulations

Paste baits:

10. On average, how many bait stations would a Pest Control Technician fill per day?

Loose grain ready-to-use baits:

Bait block formulations:

Paste baits:

END. Thank you.

DATE.....

NAME.....

POSITION.....

COMPANY.....

COUNTRY.....

40 **Appendix III: Summary of data from Company 3**

As described above, the data subset submitted by company 3 consists of 10 values for individual technicians. To avoid any bias by giving too much weight to these data (the data represent only one company but comprise 10 observations), the average numbers were used in the analysis. The submitted data and the used average numbers are displayed in the table below.

Table 3: Data of Company 3 forming the basis of the aggregation procedure.

Technician	Loose Grain		Bait Block		Paste Bait	
	Application	Bait station	Application	Bait station	Application	Bait station
01	0.02	20	n.d.	50	0.01	n.d.
02	0.01	5	n.d.	20	0.00	n.d.
03	0.20	5	n.d.	50	0.05	n.d.
04	0.20	1*	n.d.	50	0.00	n.d.
05	0.01	1*	n.d.	50	0.00	n.d.
06	0.15	1*	n.d.	40	0.10	n.d.
07	0.10	1*	n.d.	80	0.02	n.d.
08	0.05	1*	n.d.	50	0.05	n.d.
09	0.40	1*	n.d.	30	0.02	n.d.
10	0.05	1*	n.d.	50	0.10	n.d.
Company average	0.12	3.7	n.a.	47	0.04	n.a.

n.d.: no data provided;

*: values were stated to be close to zero and therefore set to 1 as a conservative approach

41 Appendix IV: Summary of rodent control on large sites (company 3)

Company 3 provided an additional user survey reflecting the worst case assumption that a PCT is exclusively working at only one large site during his entire working day, so that no travelling etc. takes place. The survey was conducted at a company located in Germany using predominantly block bait formulations. Figures were presented for one application in the sewerage (only maximum value given) and six other objects (average and maximum values). The provided data are presented in the table below:

Table 4: Data of Company 3 for continuous rodent control work on a given working day.

Application	Arithmetic mean	Maximum
Sewerage	n.d.	100
Object 1	45	75
Object 2	20	100
Object 3	30	105
Object 4	35	82
Object 5	20	50
Object 6	55	130
All (arithmetic mean)	34	91

n.d.: no data provided

The above data are not included in the statistical analysis for deriving exposure frequencies since they were obtained in a different context and are therefore incompatible with the user survey. Instead, they may serve as a plausibility check as follows: The mean maximum exposure frequency in the case of continuous pest control work at a large site is 91 (also see table above). This is slightly higher than the 75th percentile estimated from the user survey data (81 bait points handled per day). Therefore, the 75th percentile (which is related to the typical case of more erratic work at several smaller sites) can be considered as a sufficiently conservative estimate for the reasonable worst case.

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product	
		Official use only

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product																									
6.6.1 Human exposure towards biocidal product																										
6.6.1.1 Production	<p>Table 2. The most relevant route of exposure to the active substance is the dermal route. The active substance has a low vapour pressure, therefore the potential for evaporation is low, Hence, the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. Any potential oral exposure will be indirect exposure via possible release to the environment.</p> <p>Table 3. Use in Product type 14</p> <table border="1" data-bbox="531 846 1321 1099"> <thead> <tr> <th>Exposure path</th> <th>Industrial use</th> <th>Professional use</th> <th>General public</th> <th>Via the environment</th> </tr> </thead> <tbody> <tr> <td>Inhalation</td> <td>No</td> <td>No</td> <td>No</td> <td>No</td> </tr> <tr> <td>Dermal</td> <td>No</td> <td>Yes</td> <td>Yes</td> <td>Yes</td> </tr> <tr> <td>Oral</td> <td>No</td> <td>No</td> <td>No</td> <td>Yes</td> </tr> </tbody> </table>					Exposure path	Industrial use	Professional use	General public	Via the environment	Inhalation	No	No	No	No	Dermal	No	Yes	Yes	Yes	Oral	No	No	No	Yes	
Exposure path	Industrial use	Professional use	General public	Via the environment																						
Inhalation	No	No	No	No																						
Dermal	No	Yes	Yes	Yes																						
Oral	No	No	No	Yes																						
6.6.1.2 Intended use(s)	<p>It is proposed that the product will be used as a rodenticide for the control, primarily, of commensal rodent species (<i>Rattus norvegicus</i>, <i>Rattus rattus</i>, and <i>Mus domesticus</i>) by both professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm building. Use of this product in fields is not supported. Bait boxes for use by the general public are supplied as lockable units and can be refilled. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals.</p> <p>The blocks have a central hole so that they can be fixed into position, either within bait boxes or by tying to a fixed object, and so that rodents and water flows cannot dislodge them. The bait is then eaten <i>in situ</i> by target rodents.</p>																									

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product	
<p>6.6.1.3 Professional exposure</p>	<p>Table 4. Dermal exposure</p> <p>Table 5. Professional exposure arises from loading the bait into the bait point, applying the bait blocks in sewers and disposal of empty bait points.</p> <p>Table 6. Exposure can be estimated using the results from the CEFIC exposure study.</p> <p>The CEFIC exposure study also assumes that there will be no PPE when a more realistic scenario would assume that the majority of professional use would be covered by gloves as a minimum requirement.</p> <p>Inhalation exposure</p> <p>The only potential inhalation exposure to professionals will be from dusts containing the active substance, formed during the final mixing of the dry mix and the wax in the formulation process. LEV is not available at the formulation site.</p> <p>Oral exposure</p> <p>Workers and pest control operatives are not expected to be exposed by the oral route to the active substance or product. Although the active substance is very toxic by acute oral exposure (LD50 rat, oral = <5 mg/kg) good industrial hygiene, such as washing before eating or smoking will reduce the risk of accidental oral exposure.</p>	
<p>6.6.1.4 Consumer and secondary exposure</p>	<p>Dermal exposure</p> <p>The dermal exposure scenario for disposal of old bait and carcasses for non-professional use is the same as that for professional users (see section 1.2.2.3)</p> <p>The use of the CEFIC exposure study scenario, assuming one exposure task per day, gives an estimated dermal systemic exposure for non professional use.</p> <p>Inhalation exposure</p> <p>There will be no inhalation exposure to the biocidal product from amateur use.</p> <p>Oral exposure</p> <p>Users are instructed to wash hands after placing the bait box and after disposing of the bait box and carcasses. There will therefore be no oral exposure to the active substance or biocidal product from amateur use.</p>	

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product	
6.6.2 Human exposure towards substances of concern within the biocidal product	Table 7. There are no substances of concern within the biocidal product.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.	
	Evaluation by Rapporteur Member State	
<i>Date</i>	<p>PELGAR COMMENT: This section from the original EU submission has been amended. The original submission referred to amateur products being only supplied in pre-filled sealed bait boxes. In reality, if supplied in bait boxes, these are lockable and may be refilled. Where bait boxes are not suitable or necessary, baits may be applied in covered/protected bait points.</p> <p>Secondly, this section has been extensively amended to remove exposure calculations, which the RMS stated should only be included in IIB and IIC.</p>	
<i>Materials and methods</i>		
<i>Conclusion</i>		
<i>Reliability</i>		
<i>Acceptability</i>		
<i>Remarks</i>		
	Comments from....	

Section B6.6 Annex Point IIB.VI.6.6	Exposure data relating to the biocidal product	
<i>Date</i>	<i>Give date of comments submitted</i>	
<i>Results and discussion</i>	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
<i>Conclusion</i>	<i>Discuss if deviating from view of rapporteur member state</i>	
<i>Reliability</i>	<i>Discuss if deviating from view of rapporteur member state</i>	
<i>Acceptability</i>	<i>Discuss if deviating from view of rapporteur member state</i>	
<i>Remarks</i>		

Section B6.7.1.1 Annex Point III B XI 1.1	Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/> Technically not feasible <input type="checkbox"/> Scientifically unjustified <input checked="" type="checkbox"/> Limited exposure <input type="checkbox"/> Other justification <input type="checkbox"/>		
Detailed justification:	Rodenticide wax block bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Wax block bait is used in situations where foods or feedingstuff are not present or are unlikely to be contaminated.	
Undertaking of intended data submission <input type="checkbox"/>	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		

Section B6.7.1.1 Annex Point III B XI 1.1	Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin	
	<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>April 2007</i>	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		
Section B6.7.1.2 Annex Point III B XI.1.2	Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified []
Limited exposure []	Other justification []	
Detailed justification:	Rodenticide wax block bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Wax block bait is used in situations such as sewers where foods or feedingstuff are not present or where they are unlikely to be contaminated.	

Section B6.7.1.2	Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
Annex Point III B XI.1.2	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>April 2007</i>
Evaluation of applicant's justification	Applicant's justification is considered acceptable
Conclusion	Adopt applicant's version
Remarks	None
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B6.7.2 Annex Point III B XI 2	Other test(s) related to the exposure to humans Suitable test(s) and a reasoned case will be required for the biocidal product	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified []
Limited exposure []	Other justification []	
Detailed justification:	<p>Rodenticide wax block bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Wax block bait is used in situations such as sewers where foods or feedingstuff are not present.</p> <p>Active substance is poorly absorbed by dermal route (as shown by acute oral toxicity compared to dermal toxicity) and does not vaporise readily at NTP. Product does not contain any other substances of concern, and most are food-grade materials. The product is used primarily in situations like sewers where good hygiene standards are necessary because of biological hazards, including wearing gloves and other protective clothing.</p>	
Undertaking of intended data submission []	<p><i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i></p>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	April 2007	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	
Remarks	None	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>		
Date	<i>Give date of comments submitted</i>	

Section B6.7.2	Other test(s) related to the exposure to humans
Annex Point III B XI 2	Suitable test(s) and a reasoned case will be required for the biocidal product
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.1	Forseeable routes of entry into the environment on the basis of the use envisaged	
Annex Point IIB, VII.7.1		Official use only
7.1.1 Environmental Exposure towards biocidal Product		
7.1.1.1 Intended use(s)	<p>It is proposed that the product will be used as a rodenticide for the control, primarily, of commensal rodent species (<i>Rattus norvegicus</i>, <i>Rattus rattus</i>, <i>Mus musculus</i>, <i>Mus domesticus</i>) by both professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm building. Use of this product in fields will be covered under the Plant Protection Product Directive.</p> <p>Bait boxes for use by the general public are lockable and tamper-proof. They can be refilled but should then be locked, using the key supplied. The product is placed in a protected bait point, bait station or place packs may be fixed to a structure such that rats and mice can eat it. In situations where bait boxes cannot be used, the bait is covered or protected such that non-target organisms cannot reach it.</p> <p>The active substance is used in wax block baits used in bait boxes or protected bait points around industrial, commercial and residential buildings and "as is" in sewer systems.</p>	
7.1.1.2 Affected compartments	<p>Use in Sewers</p> <p>Uneaten bait and animal carcasses are not removed from sewer systems after a campaign. The effected compartments would then be STP, sediment, soil (via the spreading of sewage sludge onto farmland) and surface water. The PEC for STP, sediment and surface water emissions can be estimated from the EUSES models for the active ingredient.</p> <p>Use of bait boxes</p> <p>This would affect soil as rodents consume the product and return to their burrows and die, or return to their burrows with pieces of bait. The soil</p>	

Section B7.1 Annex Point IIB, VII.7.1	Forseeable routes of entry into the environment on the basis of the use envisaged	
	pore water PEC can be derived from the ESD scenario for use of wax blocks in bait boxes.	
7.1.1.3 Predicted environmental concentrations	PECs are calculated for the active substance, and not for the biocidal product.	
7.1.2 Environmental exposure towards substances of concern within the biocidal product	There are no substances of concern within the biocidal product	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	30/11/06	
Materials and methods		
Conclusion	Agreed with notifier	
Acceptability		
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Section B7.2 Annex Point IIB VII.7.2	Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/> Technically not feasible <input type="checkbox"/> Scientifically unjustified <input checked="" type="checkbox"/> Limited exposure <input type="checkbox"/> Other justification <input checked="" type="checkbox"/>		
Detailed justification:	<p>There are no data, which are available which are considered to suggest that the ecotoxicology of the product cannot be extrapolated from the information on the active substance. The active substance is the most toxic constituent of the product and the only constituent with significant toxicity.</p> <p>The product contains substances that are mostly food-grade materials. There is no evidence of synergistic activity between active substance and coformulants.</p> <p>Please see section A7.4.1.1 – Acute Toxicity to Fish for results of active substance. (note this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active).</p> <p>The active is R50 /R53; very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase.</p> <p>The risk assessment (IIB/C) indicates that there is a risk to non-target mammals and birds from primary and secondary poisoning. The risk is more of a chronic one than acute, although a large single dose could still kill after several days since the active can accumulate in the level.</p> <p>So to summarise, no significant risk to the aquatic environment is indicated based on the DPD whereas to terrestrial organisms (mammals and birds) there is more of a risk.</p> <p>Given the above information, and also to avoid unnecessary animal testing (directive 88/379/EEC (amended as 1999/45/EC)), a derogation to perform studies on the product is requested</p>	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	

Section B7.2 Annex Point IIB VII.7.2	Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance
Evaluation of applicant's justification	<p><i>In addition to the justification provided by the applicant, further evidence is provided.</i></p> <p><i>Coformulants such as Denatonium Benzoate, Triethanolamine and Polyethylene glycol 200 are indeed toxic. However due to both their toxicity thresholds (LD50 oral acute rat, mg/kg bw found in literature*: 584, 4920 28900 for Denatonium Benzoate, Triethanolamine and Polyethylene glycol 200, respectively) and their concentrations in the product, it is likely the toxic effect of brodifacoum to be prevailing. Furthermore, interferences and/or synergistic activity between active substance and coformulants have not been found in literature.</i></p> <p><i>*: Union Carbide (1965) Unpublished data, in "<u>WHO Food Additives Series 14</u>", in http://www.inchem.org/documents/jecfa/jecmono/v14je19.htm ; http://physchem.ox.ac.uk/MSDS/DE/denatonium_benzoate.html; http://physchem.ox.ac.uk/MSDS/TR/triethanolamine.html</i></p>
Conclusion	<i>The applicant's justification is acceptable</i>
Remarks	
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.3	Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern) <i>(Use separate standard format for each substance of concern)</i>	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<p>There are no non-active ingredients present which are substances of concern. Almost all are food-grade materials. The only non-active that is assigned an environmental risk phrase is denatonium benzoate (R52/53). However, this is for the 100% pure compound. According to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53. None of the other non-active ingredients are substances of concern with respect to the aquatic environment. With regards to possible toxicity to non-target organisms the non-active components are far less toxic than the active. According to directive 67/548/EEC, triethanolamine is classed as R36/38 but would not be classified in the product because its concentration is less than 20%(annex II, part B, table III) and propylene glycol 200 is not classified on annex 67/548/EEC therefore won't be a risk at the very low concentrations in the product. There is no evidence that the active has a detrimental synergistic effect with the non-active components.</p> <p>Given the above information, and also to avoid unnecessary animal testing (directive 88/379/EEC (amended as 1999/45/EC)), a derogation to perform studies on the product is requested.</p>	
Undertaking of intended data submission <input type="checkbox"/>	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		

Section B7.3	Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern) <i>(Use separate standard format for each substance of concern)</i>	
	<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		
Section B7.4	Where relevant all the information required in accordance with paragraph A7.1 and A7.2 (data set for the active substance) <i>Annex Point IIIB XII 1</i>	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure []	Other justification [X]	
Detailed justification:	There are no data which are available which are considered to suggest that the ecotoxicity of the product cannot be extrapolated from the information on the active substance. The active substance is the most toxic constituent of the product. The product contains substances that are mostly food-grade materials. There is no evidence of synergistic activity between active substance and co-formulants.	

Section B7.3	<p>Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern)</p> <p><i>(Use separate standard format for each substance of concern)</i></p>
	<p>In addition to the above, with regards to the fate and behaviour of ecotoxicologically relevant components of the product in water and soil (section B7.4, TNsG data requirements), denatonium benzoate has been classified by the manufacturer (see doc X11A) as R 52/53. However, this is for the 100% pure compound. According to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of denatonium benzoate is less than 25%. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53. Likewise for triethanolamine, polyethylene glycol 200 and propylene glycol, none are classified on Annex I of 67/548/EEC as harmful to the environment. Therefore according to the DPD the product will not be classified as harmful to the environment.</p> <p>For all of the above reasons, derogation for studies on fate and behaviour in water and soil for the product is requested.</p>
Undertaking of intended data submission <input type="checkbox"/>	<p><i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i></p>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>

Section B7.3	Available ecotoxicological information relating to ecotoxicological relevant non-active substances (i.e. substances of concern) <i>(Use separate standard format for each substance of concern)</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.5	Testing for distribution and dissipation in the following: (a) Soil (b) Water (c) Air Annex Point IIIB XII 2	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>Although the use-pattern for the wax block bait is restricted to sewers and in and around buildings, it is possible that untreated water could go to surface water and that bait could be dragged from bait stations and rats can excrete in a confined area around the building. In the event that analysis of the active in the aquatic and soil compartment is required, methods for both have been given for the active (see doc IIIA).</p> <p>For air, the vapour pressure of the active is very low ($<<0.001\text{mPa}$ at 20°C, pesticide manual, 13th edition) and the product is not applied by spray. The wax block will mean the absence of respirable particles. On this basis (TNSG) there is no data requirement for a study in air.</p> <p>The only other ecotoxicologically relevant component is denatonium benzoate. However, according to the DPD (Part B, table 1), if a substance is classified as R52/53; harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment, the product does not have to be classified as R52/53 if the concentration of denatonium benzoate is less than 25%. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53.</p> <p>On the grounds that</p> <p>i) analytical methods exist for the active for soil and water and that there is no data requirement for analysis in air due to vapour pressure and use-pattern, a derogation to perform studies for testing the product in soil, air and water is requested.</p> <p>ii) the only other ecotoxicologically relevant component is present below the percentage in the DPD required to classify it as a environmental risk</p>	

Section B7.5	Testing for distribution and dissipation in the following: (a) Soil (b) Water (c) Air Annex Point IIIB XII 2	
	derogation to perform a study on analysis of denatonium benzoate is requested.	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		
Section B7.6.1	Effects on birds – Acute oral toxicity, if not already done in accordance with Annex IIB, section VII Annex Point IIIB XIII. 1	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure []	Other justification []	

Section B7.5	Testing for distribution and dissipation in the following: (a) Soil (b) Water (c) Air Annex Point IIIB XII 2
Detailed justification:	Data on the acute toxicity of the active in birds has already been obtained (see doc IIIA) and could be extrapolated to this end-point. There is no evidence of synergy between the active and the non-active components. None of the other components are classified as toxic on annex I of directive 67/548/EEC. Denatonium benzoate is classed as harmful but according to the DPD the product does not need to be classified as harmful when the R22 is less than 25% in the product. Denatonium Benzoate is 0.001% therefore is not believed to be harmful at this level. Triethanolamine and polyethylene glycol 200 are not classified as either toxic or harmful on Annex I. Therefore in the very dilute concentration in the product will have an insignificant effect compared to the active. On the above grounds a request for derogation of any study for this end-point is requested.
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>

Section B7.5	Testing for distribution and dissipation in the following:
	(a) Soil (b) Water (c) Air
	Annex Point IIIB XII 2
Remarks	

Section B7.7.1.1 -	Effects on aquatic organisms – Particular studies with fish and other aquatic organisms Annex Point IIIB XIII.2.1.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified [X]	
Limited exposure [X]	Other justification []	
Detailed justification:	<p>No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most are food-grade materials. The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is denatonium benzoate, present in the product at a concentration of 0.001% w/w. According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53. Therefore it does not pose a risk to the environment.</p> <p>Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active).</p> <p>The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase.</p> <p>For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that triggers any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.</p>	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	

Section B7.7.1.1 -	Effects on aquatic organisms – Particular studies with fish and other aquatic organisms Annex Point IIIB XIII.2.1.1
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.7.1.2 -	Effects on aquatic organisms – Residue data in fish concerning the active substance and including toxicologically relevant metabolites Annex Point IIIB XIII.2.1.2	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [<input type="checkbox"/>] Limited exposure [<input checked="" type="checkbox"/>]	Technically not feasible [<input checked="" type="checkbox"/>] Scientifically unjustified [<input checked="" type="checkbox"/>] Other justification [<input type="checkbox"/>]	
Detailed justification:	<p>No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most are food-grade materials. The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is denatonium benzoate, present in the product at a concentration of 0.001% w/w. According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53. Therefore it does not pose a risk to the environment.</p> <p>Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active).</p> <p>The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase.</p> <p>For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that triggers any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.</p>	

Section B7.7.1.2 -	Effects on aquatic organisms – Residue data in fish concerning the active substance and including toxicologically relevant metabolites
	Annex Point IIIB XIII.2.1.2
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.7.1.3 -	<p>Effects on aquatic organisms – The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2 and 2.3 may be required for relevant components of the biocidal product</p> <p>Annex Point IIIB XIII.2.1.3</p>	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
<p>Other existing data []</p> <p>Limited exposure [X]</p>	<p>Technically not feasible []</p> <p>Other justification []</p>	Scientifically unjustified [X]
<p>Detailed justification:</p>	<p>No effects are expected which cannot be predicted from the acute toxicity of the active substance, as the ingredients in the product do not enhance the toxicity of the active substance. With one exception, all of the non-active ingredients are not significantly toxic to fish and other aquatic organisms, and most are food-grade materials. The only ingredient in the product, other than the a.i., which is potentially harmful to the environment is denatonium benzoate, present in the product at a concentration of 0.001% w/w. According to the DPD (Annex III, Part B, table 1), if a substance is classified as R52/53, the product does not have to be classified as R52/53 if the concentration of the substance is less than 25% in the product. The concentration of denatonium benzoate in the product is 0.001%, therefore the product is not classified as R52/53 or any other environmental risk phrase. Therefore it does not pose a risk to the environment.</p> <p>Data already exists (A7.4.1.1) for the toxicity of the active to Fish for results of active substance. (note: this summary has been upgraded as a result of recalculated LC50 values using measured concentrations of active).</p> <p>The active is R50 /R53: very toxic to aquatic organisms. Using the DPD (annex III, part B, table 1) this states that at 0.005% the product does not have to be classified as R50/53 or any other environmental risk phrase.</p> <p>For the above reasons that: extrapolation from existing data is possible; that there is no evidence of synergy between the active and non-actives in the literature; that the non-active components are not at concentrations in the product that trigger any environmental risk phrases according to the DPD, a derogation to perform any study for this end-point is requested.</p>	

Section B7.7.1.3 -	Effects on aquatic organisms – The studies referred to in Annex IIIA, section XIII parts 2.1, 2.2 and 2.3 may be required for relevant components of the biocidal product Annex Point IIIB XIII.2.1.3
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.7.2 -	Effects on aquatic organisms – If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms under field conditions	
	Annex Point IIIB XIII.2.2	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible [X] Scientifically unjustified [X]	
Limited exposure [X]	Other justification []	
Detailed justification:	The product is a wax block bait rodenticide. Rodenticide wax blocks are not sprayed. Rodenticide wax blocks are not sprayed near to surface waters	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPOREUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section B7.8.1 -	Effects on other non-target organisms – Toxicity to terrestrial vertebrates other than birds	
	Annex Point IIIB XIII.3.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>The active substance is toxic to all vertebrates and operates by a common and well-known mode of action- reduction in blood coagulation leading to haemorrhage and death from blood loss.</p> <p>All data on brodifacoum and its analogues show a similar effect on all vertebrates. For this reason, possible routes of exposure of non-target organisms are restricted by means of careful siting of baiting points, using bait boxes and other mechanical or engineering systems to prevent access by non-target organisms. Under these circumstances, further experimental studies on live animals are considered an invalid use of experimental animals.</p>	
Undertaking of intended data submission []	<p>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</p>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	November 2006	
Evaluation of applicant's justification	Accepted	
Conclusion	No need of further studies	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Section B7.8.2 -	Effects on other non-target organisms – Acute Toxicity to honeybees	
	Annex Point IIIB XIII.3.2	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>The product is a solid wax block bait, which is unattractive to bees. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200°C. Plants are not sprayed with rodenticides, and bees do not frequent the types of area where the product is used e.g. sewers.</p> <p>On grounds of limited exposure, it is believed that a study on honeybees is unnecessary. Derogation for this study is requested.</p>	
Undertaking of intended data submission []	<p><i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i></p>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section B7.8.3 -	Effects on other non-target organisms – Effects on beneficial arthropods other than bees Annex Point IIIB XIII.3.3	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>The product is a solid wax block bait, which is unattractive to beneficial arthropods. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200°C. Plants are not sprayed with rodenticides, and very few beneficial arthropods frequent the types of area where the product is used e.g. sewers.</p> <p>On grounds of limited exposure, it is believed that a study on beneficial arthropods other than honeybees is unnecessary. Derogation for this study is requested.</p>	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section B7.8.4 -	Effects on other non-target organisms – Effects on earthworms and other soil non-target macro-organisms, believed to be at risk Annex Point IIIB XIII.3.4	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>According to the risk assessment (doc IIB) using the ESD (2003) for PT14, the active does get into the soil-compartment when the wax blocks are used in and around buildings. The calculated value is 0.011mg/kg soil. This is based on direct release (from bits of left-over bait or bait dragged from station by the rodent) and indirect release via excretion from the rodent. It is therefore possible for earthworms and other soil non-target macro-organisms to be exposed.</p> <p>However, a study on the acute toxicity of brodifacoum to earthworms has been performed (see Doc IIIA) which resulted in an LC50 >994mg/kg soil. Using an AF of 1000 (TGD) gives a PNEC for soil organisms of >0.994. Therefore the PEC/PNEC is <0.011mg/kg soil. So, from the risk assessment there is no risk to earthworms or other soil non-target macro-organisms at the low levels of active expected to be present in the soil. Also in the risk assessment the equilibrium partition method was used since we only have one test result with soil-dwelling organisms (see TGD, part II, page 116). The PEC/PNEC from this was lower than the earthworm so the higher value was used.</p> <p>On the above grounds it is believed that a study for this end-point is not necessary. A derogation is requested.</p>	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		

Section B7.8.4 -	Effects on other non-target organisms – Effects on earthworms and other soil non-target macro-organisms, believed to be at risk Annex Point IIIB XIII.3.4
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.8.5 -	Effects on other non-target organisms – Effects on soil non-target micro-organisms Annex Point IIIB XIII.3.5	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [] Limited exposure [X]	Technically not feasible [] Other justification []	Scientifically unjustified [X]
Detailed justification:	<p>Although the use pattern does not exclude exposure to soil (via excretion from rat) the water solubility of brodifacoum is very low (<0.1mg/l, see doc IIIA). Therefore it should not affect bacteria in the pore water to any degree. Secondly, data from the ready biodegradation study (A 7.1.1.2.1) provides information on the toxicity of brodifacoum to micro-organisms in sewage sludge. According to the OECD 301B guideline, if the degradation of the reference is greater than 25% after 14 days, then the test substance is not considered to be inhibitory to the micro-organisms. In the study the degradation in the toxicity reference after 14 days was 60 % and therefore significantly more than the guideline required. Also the OECD 301B guideline states that the ready biodegradability study can take inoculum from a variety of places including sewage treatment plants and soil, therefore it seems reasonable that the results from the use of the sewage inoculum can be transferable to the micro-organisms found in the soil (at least in the pore water part of it).</p> <p>The microbial respiration inhibition study (A7.4.1.4) is not believed to be entirely invalid (please see comments from test lab, in the robust summary). A strong argument can be made that if there were no signs of inhibition when 1000mg/l of brodifacoum was present (in whatever form) in the study, it is not likely to be a problem at the predicted level of 0.01 1mg/kg in soil, in whatever form(see doc IIB). Also, it can be argued that in the above study, the brodifacoum was present in solution at its solubility limit of 0.1mg/l and <u>still</u> did not show any inhibition at that level. It is not likely that this concentration would be found in soil-pore water in the soil due to Brodifacoum's very high Koc (50000, pesticide manual) indicating a strong tendency to adhere to soil. In fact the risk assessment calculates a soil pore water value of 1.13E-04mg/l (ESD (2003) PT14 and TGD, 2003).</p> <p>The risk assessment (doc IIB/C) has also shown that there is no risk to the soil compartment with respect to earthworms. The PEC/PNEC obtained was 0.011. This was based on the calculated PEC (using the ESD, 2003) for soil (0.01 1mg/kg) as a result of direct and indirect release (via rat) of the active from bait blocks. The PNEC was based on an EC50 earthworm of >994mg/kg soil with an AF of 1000 giving >0.994mg/kg.</p> <p>Finally the area of use is limited to areas such as sewers and in and around buildings and it is not applied in a widespread fashion to extensive areas.</p>	

Section B7.8.5 -	Effects on other non-target organisms – Effects on soil non-target micro-organisms Annex Point IIIB XIII.3.5
	For all of the above reasons a derogation to perform a study on inhibition to microbial inhibition (terrestrial) is requested.
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>November 2006</i>
Evaluation of applicant's justification	<i>Accepted</i>
Conclusion	<i>No need of further studies</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.8.6 -	Effects on other non-target organisms – Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk	
	Annex Point IIIB XIII.3.6	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>The product is a solid wax block bait, which is unavailable to most non-target flora and fauna. It is not applied by spraying or other dispersive systems, and the active substance is of low vapour pressure and stable at up to 200°C. Plants and soil are not sprayed with rodenticides. The application of rodenticide wax blocks to soil is limited and extensive areas of soil are not treated with such products.</p> <p>From the risk assessment (IIB/C) it is acknowledged that there is some risk of primary and secondary poisoning to Fauna (use of ESD, 2003). It is believed that the best way to reduce this risk is to ensure stringent following of label instructions and that access of fauna to bait and dead rats is minimised. For flora there is no literature evidence that brodifacoum is toxic to plants. None of the other components are as toxic as brodifacoum and are present in very low levels in the product.</p> <p>For the above reasons and for animal welfare reasons (directive 88/379/EEC, amended as 1999/45/EC) a derogation to perform a study is requested.</p>	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		

Section B7.8.6 -	<p>Effects on other non-target organisms – Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk</p> <p>Annex Point IIIB XIII.3.6</p>
<p>Date</p> <p>Evaluation of applicant's justification</p> <p>Conclusion</p> <p>Remarks</p>	<p>COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i></p> <p><i>Give date of comments submitted</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p> <p><i>Discuss if deviating from view of rapporteur member state</i></p>

Section B7.8.7.1 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions	
	Annex Point IIIB XIII.3.7.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:	<p>Product has been in commercial and experimental use for many years. Effects on non-target organisms are well known and well documented. Where necessary, use of bait stations and careful siting of baiting points shows satisfactory control of non-target casualties via primary exposure.</p> <p>Please see the robust summaries 1 to 4 in Section IIIB.7.8.7.1, below, for more detailed information.</p>	
Undertaking of intended data submission <input type="checkbox"/>	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	November 2006	
Evaluation of applicant's justification	See sections IIIB.7.8.7.1(1-4)	
Conclusion	See sections IIIB.7.8.7.1(1-4)	
Remarks	See sections IIIB.7.8.7.1(1-4)	
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section B7.8.7.1 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions
---------------------------	--

Annex Point IIIB XIII.3.7.1

Section B7.8.7.1 (1) Further ecotoxicological studies: Baits/granules – Field trials

Annex Point IIB XII3.7.1

Section B7.8.7.1 - Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions

Annex Point IIIB XIII.3.7.1

47 Reference

47.1 Reference [REDACTED] (1982) „A Review of the Secondary Poisoning Hazard to Wildlife from the Use of Anticoagulant Rodenticides“

47.2 Data protection No, published paper.

47.2.1 Criteria for data protection No data protection claimed

48 Guidelines and Quality Assurance

48.1 Guideline study The guideline study is not stated in the published paper.

48.2 GLP The GLP status of the study is not stated in the published paper

48.3 Deviations No

49 Applicant's Summary and conclusion

**Official
use
only**

Section B7.8.7.1 - Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions

Annex Point IIIB XIII.3.7.1

49.1 Results and discussion

With an LD50 to most rodents of less than 0.5 mg/kg, brodifacoum of a single feed is used in rodent control application. For anticoagulant rodenticides, no significant non-target incidents of non-rodent, wildlife mortality have been subject of any known publication. Over the past 15 years, there has been extensive monitoring of the 400 to 500 tons of anticoagulant bait applied yearly in California for the control of agricultural rodents pests, particularly aerial control of ground squirrels and there has been very few primary and secondary poisoning.

A study was performed on potential tawny owl poisoning from the baiting of squirrels with warfarin. It was concluded that this usage of warfarin did not pose a significant threat to the local owl population. Primary poisoning of most non-target animals with rodenticides such as anticoagulants can frequently be overcome by modification of toxic chemical formulation or application techniques. Modified application techniques may significantly reduce hazard i.e by using bait boxes, bait packs or other bait enclosures or protective applications. Bait boxes can reduce the amount and availability of bait to larger-bodied primary feeders and also reduce consumption and resulting residues in rodents potentially at risk of predation.

The largest study of potential anti-coagulant rodenticide secondary hazard to raptors was completed in 1980 by Denver Wildlife Research Centre of US Fish and Wildlife service. Working with barn owls within a 1100Km² area of Southwestern New Jersey, the study was to determine the effect of brodifacoum farm baiting with the 50ppm pelletised. Talon formulation on the barn owl. Owls moved farther and hunted away from farmsteads, consuming very low levels of commensal rodents. At least 9 and possibly 12 of the radioed birds during the 6-month study were shown to have frequented Talon-treated sites for at least 5 and up to 62 days post treatment. Owls were fledged from at least 8 sites where poisoned rodents were demonstrated to be available on the farmstead for at least a portion of the nesting and feeding period. Brodifacoum did not affect the owls and was allowed unrestricted usage.

49.1.1 Reliability

2

49.1.2 Deficiencies

No

Evaluation by Competent Authorities

Section B7.8.7.1 -	<p>Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions</p> <p>Annex Point IIIB XIII.3.7.1</p>
<p>Date</p> <p>Materials and Methods</p> <p>Results and discussion</p> <p>Conclusion</p> <p>Reliability</p> <p>Acceptability</p> <p>Remarks</p>	<p>42 Evaluation by Rapporteur Member State</p> <p><i>November 2006</i></p> <p><i>Accepted</i></p> <p><i>Accepted</i></p> <p><i>Accepted</i></p> <p><i>4</i></p> <p><i>The monitoring carried out by the Denver Wildlife Research Center in 1980 is reported by Dale E. Kaukeinen (1982) in a review paper on secondary poisoning. This kind of reporting is not arranged as a scientific paper but only describes the main features of the original field trial in the frame of a general review on secondary poisoning by anticoagulant rodenticides. As a result, the information given on the experimental layout, materials and methods and statistics are not useful for risk assessment (no endpoints are derived) rather might be used for general discussion.</i></p> <p><i>Not acceptable</i></p>
Date	<p>43 Comments from ...</p> <p><i>Give date of comments submitted</i></p>

Section B7.8.7.1 -	<p>Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Supervised trials to assess risks to non-target organisms under field conditions</p> <p>Annex Point IIIB XIII.3.7.1</p>
<i>Materials and Methods</i>	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i>
	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Results and discussion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Conclusion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Reliability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Acceptability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Remarks</i>	

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

		50 Reference	Official use only
50.1 Reference		[REDACTED] Effects of New Rodenticides on Owls, [REDACTED] [REDACTED]	
50.2 Data protection		No, published paper.	
50.2.1 Criteria for data protection		No data protection claimed	
		51 Guidelines and Quality Assurance	
51.1 Guideline study		The guideline study is not stated in the published paper.	
51.2 GLP		The GLP status of the study is not stated in the published paper	
51.3 Deviations		No	
		52 materials and methods	
52.1 Test material		Warfarin, difenacoum and brodifacoum	

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

52.1.1	Lot/batch number	Batch numbers not stated in the published paper.
52.1.2	Specification	Warfarin supplied by Ward Blenkinsop Difenacoum and brodifacoum supplied by Sorex Laboratories, Widnes.
52.1.2.1	Description	
52.1.2.2	Purity	
52.1.2.3	Stability	A specific statement on stability is not provided within the paper.
52.1.2.4	Radiolabelling	
52.2	Test Animals	
52.2.1	Species	Barn Owls
52.2.2	Strain	<i>Tyto alba</i>
52.2.3	Source	Not stated in published report
52.2.4	Number of animals per group	6
52.2.5	Volume applied	0.5 ml/kg bodyweight

53 Applicant's Summary and conclusion

53.1	Materials and methods	Laboratory mice, were fed for one day on difenacoum or brodifacoum bait, and died 2-11 days later. Some of these dead mice were analysed to determine their rodenticide contents, and others were fed to captive Barn Owls. Six owls were fed for one day on difenacoum-killed mice (3 per owl) and another six owls were fed for one day on brodifacoum-killed mice (3 per owl). After dosing, blood samples were taken periodically from the owls to monitor coagulation times. This indicated the recovery times. Any owls which survived the one day feeding trial were later fed for three consecutive days on rodenticides-poisoned mice, and those which recovered from this treatment were then fed for six successive days on poisoned mice.
-------------	------------------------------	---

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

53.2	<i>Results and discussion</i>	<p>The six owls fed on difenacoum-poisoned mice all survived the 1,3 and 6 treatments. After the 1-day treatment, all six owls were blood-sampled 5-9 days later, and coagulation times were normal. After the 3-day treatment, the blood of one bird taken three days later did not coagulate, but blood from all birds was normal until day 23. With difenacoum the effects were temporary and were not lethal. No external haemorrhaging was seen.</p> <p>Of the 6 owls fed on brodifacoum, four died 6, 10, 1, and 17 days after the one day treatment. Their livers contained 0.63-1.25ppm in fresh weight of brodifacoum. Some of these owls bled periodically from the mouth, blood taken from two birds would not coagulate 9 days after the end of feeding. Brodifacoum was more toxic to barn owls than difenacoum. The owls had consumed in the one day trial approximately 46.2µg brodifacoum. Of the dead owls, the livers contained an average of 4.6g brodifacoum.</p>
53.3	<i>Conclusion</i>	<p>Owls are exposed to the rodenticides despite its supposed restriction, and it can be concluded that brodifacoum is more toxic to Barn owls than is difenacoum</p>
53.3.1	Reliability	2
53.3.2	Deficiencies	No

Evaluation by Competent Authorities
--

Section B7.8.7.1 (2) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

	45 Evaluation by Rapporteur Member State
<i>Date</i>	<i>November 2006</i>
<i>Materials and Methods</i>	<i>Accepted</i>
<i>Results and discussion</i>	<i>Accepted</i>
<i>Conclusion</i>	<i>Accepted</i>
<i>Reliability</i>	<i>2</i>
<i>Acceptability</i>	<i>acceptable</i>
<i>Remarks</i>	
	46 Comments from ...
<i>Date</i>	<i>Give date of comments submitted</i>
<i>Materials and Methods</i>	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
<i>Results and discussion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Conclusion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Reliability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Acceptability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Remarks</i>	

Section B7.8.7.1 (3) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

	54	Reference		Official use only
54.1	Reference	XXXXXXXXXX 1994) The toxicity of three second-generation rodenticides to Barn Owls		
54.2	Data protection	No, published paper.		
54.2.1	Criteria for data protection	No data protection claimed		
	55	Guidelines and Quality Assurance		
55.1	Guideline study	The guideline study is not stated in the published paper.		
55.2	GLP	The GLP status of the study is not stated in the published paper		
55.3	Deviations	No		
	56	MATERIALS AND MethodS		
56.1	Test material	Flocoumafen difenacoum and brodifacoum		
56.1.1	Lot/Batch number	Batch numbers not stated in the published paper.		
56.1.2	Specification	Flocoumafen, 'Storm' bait (Ref. No. ST90/388) Difenacoum, 'Ratak' bait (Ref. No. ST90/396) Brodifacoum, 'Klerat' bait (Ref.No ST90/395)		
56.1.2.1	Description	Wax baits with 0.05 g kg ⁻¹		
56.1.2.2	Purity	Brodifacoum: 97.9% Difenacoum: 99.5% Flocoumafen: 97.8%		
56.2	Test Animals			
56.2.1	Species	Mice, Barn Owl		
56.2.2	Strain	Mice:Harlan Olac Hsd/Ola: ICR Barn Owl: Tyto alba Scop.		
56.2.3	Source	XXXXXXXXXX		

Section B7.8.7.1 (3) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

56.2.4	Sex	Not determined
56.2.5	Age/weight at study initiation	Age not stated in published report. Mice: Range from 20-25g Owls: 320-455g
56.2.6	Control animals	yes
56.3	Administration/ Exposure	Oral
57.1	Materials and methods	<p data-bbox="528 696 1054 719">57 Applicant's Summary and conclusion</p> <p data-bbox="528 741 1305 1234">To provide dosed mice with a range of rodenticide concentrations for the owl feeding study, batches of mice (5/batch) were allowed to feed on rodenticide wax block bait. First the mice were each fed 2g per mouse of the individual bait for 24h. Further batches were fed larger or smaller amounts of bait to increase or decrease residual rodenticide. Untreated mice from the same batches were used for feeding the owls during acclimatisation. After acclimatisation, batches of mice were either housed singly and allowed to feed on weighed amounts of bait or housed in groups of 20 and fed for either 24 or 48 h. The mice were killed by carbon dioxide euthanasia.</p> <p data-bbox="528 1256 1305 1559">The 12 owls were fed for 15 days in four batches each of three owls, one per rodenticide. The net rodenticide consumption was calculated. Owls surviving the 15-day treatment period were fed on untreated mice for a further 15 days or until death. The dosing of the owls covered a six-month period. Body weight, food consumption and clinical signs were monitored throughout the study.</p> <p data-bbox="528 1581 1305 1662">Post-mortem examinations included looking for signs of external and internal haemorrhage and assessment of general health.</p>

Section B7.8.7.1 (3) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

57.2	<i>Results and discussion</i>	<p>For each rodenticide, the owls survived a cumulative dose of at least 1.9 mg/kg weight over the 15 days of treatment. Four owls died, with the treatments of brodifacoum and difenacoum and two with flocoumafen, on day 15 of the treatment. These owls had consumed cumulative doses of 5.4, 3.7 and 2.2/2.8 mg/kg of rodenticides.</p> <p>On initial examination, flocoumafen appears slightly more toxic to Barn Owls than the other two rodenticides. However, the toxicity of the three rodenticides was measured over a narrow concentration range, and the number of owls tested was small. All three rodenticides are considered to have approximately the same order of magnitude of toxicity to Barn Owls.</p> <p>The residues of all rodenticides in breast muscle and abdominal fat were low. Liver retained the highest concentration of rodenticide residues. For each rodenticide, the concentration appears largely independent of dose, providing supporting evidence that the owl liver contains saturable binding sites. The residues of difenacoum in the liver are lower than those of the other two rodenticides. All owls that died contained liver residues in excess of brodifacoum 1.7mg/kg, difenacoum 0.25mg/kg and flocoumafen 0.6-0.7 mg/kg.</p>
57.3	<i>Conclusion</i>	<p>The results suggest that although the toxicity to Barn Owls of all three rodenticides is high, the risk of poisoning owls in the wild is low. This is supported by another field study in Eire, which monitored Barn owl roosts and nests in an area where the three rodenticides were being used commercially. No residues of the three rodenticides were found, indicating that over the study period, none of the owls were exposed to residues of the rodenticides in their prey.</p>
57.3.1	Reliability	2
57.3.2	Deficiencies	No

Evaluation by Competent Authorities
--

Section B7.8.7.1 (3) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

	47	Evaluation by Rapporteur Member State
Date		<i>November 2006</i>
Materials and Methods		<i>Accepted</i>
Results and discussion		<i>Accepted</i>
Conclusion		<i>Accepted</i>
Reliability		<i>2</i>
Acceptability		<i>acceptable</i>
Remarks		
	48	Comments from ...
Date		<i>Give date of comments submitted</i>
Materials and Methods		<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion		<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion		<i>Discuss if deviating from view of rapporteur member state</i>
Reliability		<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability		<i>Discuss if deviating from view of rapporteur member state</i>
Remarks		

Section B7.8.7.1 (4) Further ecotoxicological studies: Baits/granules – Field trials
Annex Point IIB XII3.7.1

		58 Reference	Official use only
58.1 Reference		[REDACTED] The toxicity of three second-generation rodenticides to Barn Owls [REDACTED] [REDACTED]	
58.2 Data protection		No, published paper.	
58.2.1 Criteria for data protection		No data protection claimed	
		59 Guidelines and Quality Assurance	
59.1 Guideline study		The guideline study is not stated in the published paper.	
59.2 GLP		The GLP status of the study is not stated in the published paper	
59.3 Deviations		No	
		60 MATERIALS AND MethodS	
		61 Applicant's Summary and conclusion	
61.1 Materials and methods		The aim of the study were to find to what extent Barn Owls Tyto alba in Britain were contaminated with certain rodenticide residues, and whether such residues are likely to represent a significant source of mortality. Carcasses for analysis were obtained by placing advertisements in bird's journal requesting for any Bran Owls found dead. At necropsy, any signs of haemorrhaging were carefully recorded. Typical sites for rodenticides induced haemorrhaging include the muscle on both sides of the breastbone, the leg joints, the mouth and nose, and internal organs. After inspection, part of the liver was removed and examined for second-generation rodenticides, using the method of Hunter (1985). The concentrated samples were analysed by HPLC. When an apparent rodenticide was detected, a recovery test was done form a spiked sample of solvent to validate the identification and to correct the estimate of mass present.	

Section B7.8.7.1 (4) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

61.2	<i>Results and discussion</i>	<p>In 1983-91, a total of 363 (175 of each sex) Barn Owls were received for analysis. The main mortality causes were road accidents, other accidents, and starvation. In each of the main categories, approximately 20% of carcasses had detectable rodenticides residues in the liver. Of 363 birds, 21% contained detectable residues of second-generation rodenticides in liver. 14 birds had residues of 2 or 3 different chemicals. There was a marked increase in the proportion of owls in which residues were present, from 6% in 1983-84, 12% in 1985-86, 13% in 1987-88, and 23% in 1989-90, rising to 34% in 1991. Overall, difenacoum was found in 49 (13%) birds, bromadiolone in 6%, brodifacoum 4% and flocoumafen 1%. Difenacoum was found in liver at concentrations of 0.002-0.135ug/g, bromadiolone at 0.004-0.319 µg/g, brodifacoum at 0.002-0.515µg/g and flocoumafen at 0.003-0.144µg/g.</p>
61.3	<i>Conclusion</i>	<p>It was clear that contamination of Barn Owls with second-generation rodenticides is both widespread and increasing. The residues in most specimens were below lethal levels and less than 1% of all owls examined appeared from their symptoms to have died directly from rodenticide poisoning. There is no evidence that second-generation rodenticides contribute to the overall mortality in British Barn Owls and hence no evidence that they are affecting population levels.</p>
61.3.1	Reliability	2
61.3.2	Deficiencies	No

Evaluation by Competent Authorities
--

Section B7.8.7.1 (4) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

	49 Evaluation by Rapporteur Member State
Date	November 2006
Materials and Methods	acceptable
Results and discussion	acceptable
Conclusion	<p><i>It was clear that contamination of Barn Owls with second-generation rodenticides is both widespread and increasing. The residues in most specimens were below lethal levels and less than 1% of all owls examined appeared from their symptoms to have died directly from rodenticide poisoning. From this study, there is no evidence that second-generation rodenticides contribute to the overall mortality in British Barn Owls and hence no evidence that they are affecting population levels.</i></p> <p><i>Concern however arises since the consumption of three brodifacoum poisoned mice (possibly fewer) by a one barn owl can provide the bird with a lethal dose of anticoagulant. It is highlighted also that results of field trials carried out on owls for the assessment of secondary poisoning might generally be biased on regard of the sample of dead birds found. It is argued in fact, that poisoned birds are most likely to die at their roosts as death from anticoagulants is slow and preceded by lethargy. This would therefore make the carcasses of poisoned owls of difficult finding.</i></p> <p><i>Moreover, studies on captive birds are likely to underestimate the extent of secondary poisoning of wild owls as these are more active than captive animals and therefore sensitivity to haemorrhages is higher too.</i></p>
Reliability	2
Acceptability	acceptable
Remarks	
	50 Comments from ...

Section B7.8.7.1 (4) Further ecotoxicological studies: Baits/granules – Field trials**Annex Point IIB XII3.7.1**

<i>Date</i>	<i>Give date of comments submitted</i>
<i>Materials and Methods</i>	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
<i>Results and discussion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Conclusion</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Reliability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Acceptability</i>	<i>Discuss if deviating from view of rapporteur member state</i>
<i>Remarks</i>	

Section B7.8.7.2 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Studies on acceptance by ingestion the biocidal product is in by any non-target organisms thought to be at risk	
	Annex Point IIIB XIII.3.7.2	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure [X]	Other justification []	
Detailed justification:	<p>Toxicology studies on the biocidal product are not scientifically justified as the ingredients in the product do not enhance the toxicity of the active substance, and the product itself is not classified, so these end points can be satisfied by the dose-response relationship established for the technical active ingredient.</p> <p>In addition, the wax blocks are dyed red or blue to make them unattractive to wildlife, and birds in particular. However, in “old” bait that had been stored under ambient conditions for two years, the formulation remained both palatable and effective in controlling rats. The product is toxic to most mammalian and avian species, including domesticated animals, wildlife and humans.</p>	
Undertaking of intended data submission []	<i>Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>November 2006</i>	
Evaluation of applicant's justification	<i>Accepted</i>	
Conclusion	<i>No need of further studies</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	

Section B7.8.7.2 -	Effects on other non-target organisms – If the biocidal product is in the form of bait or granules – Studies on acceptance by ingestion the biocidal product is in by any non-target organisms thought to be at risk
	Annex Point IIIB XIII.3.7.2
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section B7.9 -	Summary and evaluation of ecotoxicological data
	Annex Point IIIB XIII.4
Detailed justification:	<p>An abiotic degradation study was conducted with the half-life DT_{50} (hours) being greater than 2.5 at pH 4,7 and 9. Based on photolysis in water results of 2.2 K_{PE} and a half-life of 0.083 days, it is concluded that Brodifacoum undergoes rapid photodegradation. The photodegradation in air was calculated using EPIWIN v3.12, it was decided that it had an estimated half-life of approximately 2 hours, therefore it is predicted to have a negligible effect on stratospheric ozone. It is predicted not to be a potential greenhouse gas.</p> <p>During a 28 day biodegradation study there was <3% biodegradation, hence it is not readily biodegradable.</p> <p>Using EPIWIN v3.12, K_{oc} is estimated to be $7.54 \cdot 10^{006}$ ($\log K_{oc} = 6.877$). In addition based on the insolubility of the active substance in water, a $\log Pow >4$ and ionisable groups at environmental pH it is considered that Brodifacoum will not have a high mobility in soil and will absorb to soil particles.</p> <p>Based on the $\log Pow >4$ it is considered that Brodifacoum has a potential for bioaccumulation. The BCF has been estimated using EPIWIN v3.12 as 568.9 ($\log BCF = 2.755$).</p> <p>Brodifacoum is very toxic to aquatic organisms (fish $LC_{50} = 0.09\text{mg/l}$, algae $E_rC_{50} = 0.27\text{mg/l}$). Fish and algae are more sensitive than Daphnia ($LC_{50} = 0.45 \text{ mg/l}$). However, there is no difference in the order of magnitude of toxicity between the three trophic levels.</p> <p>Overall: The active substance is a large aromatic organic compound of low volatility with two polar groups, which can potentially ionise at environmental pH. The active substance has a high $\log Pow (> 4)$, a high predicted BCF of 568.9, is not readily biodegradable and is of low</p>

Section B7.9 -	Summary and evaluation of ecotoxicological data Annex Point IIIB XIII.4
	<p>solubility (<0.1 mg/l). The predicted Log K_{oc} indicates that the active substance would not be mobile in soil and would be expected to adsorb to soil particles. The substance does not undergo hydrolysis ($t_{1/2} > 1$ year). It is however predicted undergo rapid indirect photolysis with OH radicals and ozone ($t_{1/2}$ = approximately 2 hours) and undergoes rapid direct photodegradation ($t_{1/2}$ = 0.217 days). There are no predicted effects on the atmosphere.</p> <p>The active substance is very toxic to aquatic organisms ($E/LC_{50} < 1$ mg/l) and is potentially bioaccumulative.</p>

Section B8

Measures to be adopted to protect man, animals and the environment

**Subsection
(Annex Point)**

**Official
use
only**

Section B8**Measures to be adopted to protect man, animals and the environment**

8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire (IIB8.1)
8.1.0 Methods and precautions concerning placing on the market	Where supplied, bait boxes are lockable and tamper-proof. Bait boxes can be refilled but should then be locked, using the key supplied.
8.1.1 Methods and precautions concerning handling and use	<p>Avoid contact with skin and eyes. Avoid dust formation. Do not smoke eat or drink while handling this product. Always use good personal hygiene procedures when handling chemicals. Wash hands and face before eating, drinking or smoking. Read the label before use. Unlikely to produce dust as the product is a wax block bait.</p> <p>Use Ready for use rodenticide containing 50 ppm brodifacoum.</p> <p>Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, baits should be secured so that they cannot be dragged away.</p>
8.1.2 Methods and precautions concerning storage	<p>Store in original container under cool and dry conditions in a secure (lockable), well ventilated place, inaccessible to children and away from foodstuffs, animal feedstuffs and products which may have an odour</p> <p>Keep away from oxidising agents, sources of ignition.</p>
8.1.3 Methods and precautions concerning transport	Not classified as dangerous for transport.

Section B8**Measures to be adopted to protect man, animals and the environment****8.1.4 Methods and****precautions****concerning fire****Suitable Extinguishing Media**

Keep fire exposed containers cool by spraying with water if exposed to fire. Carbon dioxide (CO₂) alcohol-resistant foam dry powder water spray mist or foam.

Extinguishing media which must not be used for safety reasons

DO NOT USE WATER JETS

Specific hazards

Combustion or thermal decomposition will produce toxic and irritant fumes.

Special protective equipment for fire-fighters

In the event of fire, wear self contained breathing apparatus, suitable gloves and boots

Residues

Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.

8.2

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment (IIB8.2)

Section B8**Measures to be adopted to protect man, animals and the environment**

8.2.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	<p>Skin contact</p> <p>May cause skin irritation in susceptible persons. Remove contaminated clothing. Wash off immediately with soap and plenty of water. If irritation persists obtain medical attention. Contaminated clothing should be washed and dried before re-use.</p> <p>Eye contact</p> <p>May cause eye irritation with susceptible persons. Rinse immediately with plenty of water and seek medical advice.</p> <p>Inhalation</p> <p>Unlikely to present an inhalation hazard unless excessive dust is present. Move to fresh air. Obtain medical advice immediately.</p> <p>Ingestion</p> <p>If swallowed, seek medical advice immediately and show this container or label.</p> <p>General advice</p> <p>In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>ADVICE FOR DOCTORS:</p> <p>Brodifacoum is an indirect anti-coagulant. Vitamin K1 is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.</p>
8.3 Procedures, if any, for cleaning application equipment (IIB8.3)	<p>Other than PPE for professional users, specifically gloves, there is no application equipment. Gloves should be reused or disposed of according to the procedures for waste management in section 8.5 below.</p>
8.4 Identity of relevant	<p>Oxides of carbon, nitrogen and hydrogen. Combustion or thermal decomposition will produce toxic and irritant fumes</p>

Section B8 Measures to be adopted to protect man, animals and the environment

<p>combustion products in cases of fire (IIB8.4)</p>	
<p>8.5 Procedures for waste management of the active substance for industry or professional users</p>	<p>Dispose of packaging, remains of unused product and dead rodents to certified waste disposal operator for incineration and licensed waste disposal site.</p> <p>Clean up promptly by sweeping or vacuum. Transfer to a suitable labelled container. Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.</p>
<p>8.6 Possibility of destruction or decontamination following release in or on the following:</p>	
<p>8.6.1 (a) Air;</p>	<p>Unlikely to present an inhalation hazard unless excessive dust is present. If levels approach the MEL's or OES then suitable approved respiratory protection should be worn.</p>
<p>8.6.2 (b) Water, including drinking water;</p>	<p>Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.</p>
<p>8.6.3 (c) Soil</p>	<p>Direct and/or intentional release to soil is not anticipated for the use of the product as a rodenticide. In the event of a significant accidental release, contaminated soil should be disposed according to local regulations.</p>
<p>8.7 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIB8.7)</p>	<p>Toxic to most mammalian and avian species, including domesticated animals, wildlife and humans. Haemorrhagic diathesis, haematuria, extended prothrombin time, abdominal pain, anaemia, shock.</p>

Section B8**Measures to be adopted to protect man, animals and the environment**

8.8 Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms (IIB8.8)	The wax bock bait is dyed red to make it unattractive to wildlife, and birds in particular. The product contains a human taste deterrent.
---	--

Evaluation by Competent Authorities

Section B8**Measures to be adopted to protect man, animals and the environment**

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	<p>51 Evaluation by Rapporteur Member State</p> <p><i>April 2007</i></p> <p>Date</p> <p>Materials and methods Applicants version is acceptable</p> <p>Results and discussion Adopt applicant's version</p> <p>Conclusion Applicants version is acceptable</p> <p>Reliability</p> <p>Acceptability Acceptable</p> <p>Remarks</p>
	<p>52 Comments from ...</p> <p><i>Give date of comments submitted</i></p> <p>Date</p> <p>Results and discussion <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i></p> <p>Conclusion <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Reliability <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Acceptability <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Remarks</p>

Annex IV: List of studies reviewed

List of new data²⁰ submitted in support of the evaluation of the active substance (III A)

Not applicable

²⁰ Data which have not been already submitted for the purpose of the Annex I inclusion.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
B5.10.2(2)	[REDACTED]	2005b	Report: Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Mice. [REDACTED] Report No. 17/2005 GLP, Unpublished	Y	[REDACTED]
B5.10.2 (3)	[REDACTED]	2005c	Palatability and Efficacy of Fresh Vertox Wax Block Bait Formulation in Laboratory Rats [REDACTED] Report No. 18/2005. GLP, Unpublished	Y	[REDACTED]
B5.10.2 (4)	[REDACTED]	2005d	Report: Palatability and Efficacy of Aged Vertox Wax Block Bait Formulation in Laboratory Rats. [REDACTED] Report No. 20/2005. GLP, Unpublished	Y	[REDACTED]
B5.10.2 (5)	[REDACTED]	2004a	Field trial report to determine the efficacy of Vertox Wax Block Bait, containing 0.005% w/w brodifacoum for the control of an infestation of house mice (<i>Mus musculus</i>) in a stable block on a smallholding [REDACTED] [REDACTED] [REDACTED] Report Number: PEL/006/04. Unpublished	Y	[REDACTED]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
B5.10.2 (6)	[REDACTED]	2004b	Field trial report to determine the efficacy of Vertex Wax Block Bait, containing 0.005% w/w brodifacoum for the control of an Infestation of house mice (<i>Mus musculus</i>). [REDACTED] [REDACTED] [REDACTED] Report No. PEL/007/04, Unpublished	Y	[REDACTED]
B5.10.2 (7)	[REDACTED]	1995	Field trial report to determine the efficacy of Vertex Wax Block Bait, containing 0.005% w/w brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (<i>Rattus norvegicus</i>) on an agricultural holding [REDACTED] [REDACTED] [REDACTED] Report No. RFT/95/1905, Unpublished	Y	[REDACTED]
B5.10.2 (8)	[REDACTED]	1996	Field trial report to determine the efficacy of Vertex Wax Block Bait, containing 0.005% w/w brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (<i>Rattus norvegicus</i>) on an agricultural holding [REDACTED] [REDACTED] [REDACTED] Report No. RFT/96/1907, Unpublished	Y	[REDACTED]
B5.10.2 (9)	Wade JO	2005	Determination of Mould Growth on Standard Wax Blocks Stored Under Simulated Sewage Inspection Chamber Conditions PelGar International Ltd., Report No. PEL/01/05. Unpublished	Y	PelGar

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
		2010	An evaluation of bait consumption by <i>Rattus norvegicus</i> of environmentally stressed Oktablok (I) block [REDACTED], Report No. TIL/PI/251110/01. Unpublished	Y	[REDACTED]
B5.11	Buckle AP	2010	Expert Review of the Effectiveness of Brodifacoum for the Control of Rats and Mice Resistant to other Anticoagulants PelGar International Limited Unpublished	Y	PelGar
B6.1.1	[REDACTED]	2007a	Brodifacoum Wax Block: Acute Oral Toxicity in the Rat – Fixed Dose Method [REDACTED] Report No. 2254/0021 GLP, Unpublished	Y	[REDACTED]
B6.1.2	[REDACTED]	2007b	Brodifacoum wax block: Acute Dermal Toxicity (Limit Test) in the Rat [REDACTED] Report No. 2254/0022 GLP, Unpublished	Y	[REDACTED]
B6.2 (1)	[REDACTED]	2007c	Brodifacoum wax block: Acute Dermal Irritation in the Rabbit [REDACTED] Report No. 2254/0023 GLP, Unpublished	Y	[REDACTED]
B6.2 (2)	[REDACTED]	2007d	Brodifacoum wax block : Acute Eye Irritation in the Rabbit [REDACTED] Report No. 2254/0024 GLP, Unpublished	Y	[REDACTED]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
B6.4 (1)	Davies DJ	2007	<i>In vitro</i> absorption of difenacoum from wax block and pasta bait through human epidermis. PelGar International Limited Report No. JV2001 GLP, Unpublished	Y	PelGar
B6.6 (1) IN EU SUBMISSION	Chambers JG and Snowdon PJ	2004	Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished.	Y	PelGar and Activa
B6.6 2(2) IN EU SUBMISSION	Vetter D and Sendor T	2006	Estimation of the Frequency of Dermal Exposure During the Occupational Use of Rodenticides EBPRC Consulting., Unpublished.	Y	PelGar and Activa
B7.8.7.1 (1) IN EU SUBMISSION	[REDACTED]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10 th Vertebrate Pest Conference (1982). Published	N	Public Domain
B7.8.7.1 (2) IN EU SUBMISSION	[REDACTED]	-	Effects of New Rodenticides on Owls, [REDACTED] [REDACTED] [REDACTED] Published	N	Public Domain
B7.8.7.1 (3) IN EU SUBMISSION	[REDACTED]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protectio n Claimed (Yes/No)	Owner
B7.8.7.1 (4) IN EU SUBMISSION	[REDACTED]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, [REDACTED] [REDACTED] PE17 2LS Published	N	Public Domain

ANNEX V: Toxicology Calculations

Insert relevant exposure/effect calculations undertaken, if applicable.

ANNEX VI: Environmental Calculations

VI.1 Environmental exposure assessment

The product contains the anticoagulant active substance brodifacoum (CAS No. 56073-10-0) at a concentration of 0.005% w/w (50 mg/kg). The product is designed to be used by **professionals and amateurs** in and around buildings infested by rats or mice. Furthermore, **professional use** of the product is envisaged in the area of rodent control in sewer systems.

For rat abatement (by amateurs and professionals), bait points containing 60g of bait are established, at distances of 5-10m apart. For mouse control, bait points consist of 20g of bait, placed at distances of 2-5m apart. Bait points are protected to help prevent access to non-target animals. The label gives instruction to place the baits securely, i.e., in a way minimizing the risk of consumption by other animals or children. For amateur use the label prescribes to use tamper resistant bait stations for rat control. For amateur mouse control baits have to be placed into or at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the baits must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Since non-target animals and the general public have no entrance to sewer infrastructure, a risk for primary poisoning does not arise due to rodent control in this compartment. The product can be applied by the 'pulsed-baiting' technique - at heavily infested sites bait points have to be replenished after 3-4 days and after 1 week. Thereafter, bait points should be checked weekly for curative treatment and every month for preventive treatment. Clearance of the rodent infestation should be achieved in 7-35 days.

In accordance with the TGD on Risk Assessment (EC, 2003²¹) and with the aid of the Emission Scenario Document for PT 14 (J. Larsen, 2003²², in the following referred to as ESD PT 14), a quantitative approach is performed in order to estimate potential brodifacoum residues in environmental compartments, arising from its use as rodenticide, and local Predicted Environmental Concentrations (PECs) are calculated. These PECs will be compared with the Predicted No Effect Concentrations (PNEC), i.e., the concentrations below which unacceptable effects on organisms will most likely not occur. The PNEC values are derived from the relevant ecotoxicological studies. In the following environmental exposure assessment the active substance is exclusively taken into consideration as no further environmentally relevant substance is formed in the course of brodifacoum release into environmental compartments (*cf.* CA Report for brodifacoum).

Besides denatonium benzoate (Bitrex®) none of the other ingredients in the product is classified with an environmentally relevant R-phrased (EU 99/45) or Hazard Statement (EU CLP 1272/2008). Bitrex® is classified with R52/R53 or H411. However, due to its significantly lower aquatic toxicity compared to brodifacoum (most sensitive species for Bitrex® is *Daphnia magna* with an EC₅₀ of 13 mg/L, compared to brodifacoum with a lowest LC₅₀/EbC₅₀ of 40 mg/L for fish and algae, respectively), and its very low content in the product (0.001% w/w), Bitrex® does not have to be contemplated in this context.

²¹ Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

²² Larsen, 2003: Emission scenario document for biocides used as rodenticides. EUBEES 2 report ENV.C3/SER/2001/0058.

Regional and continental PECs have not been calculated as they are not considered relevant for rodenticide use because the low consumption of rodenticide products leads to a negligible regional contribution (*cf.* Section 2.2, ESD PT 14).

Emissions to the environment from the use of brodifacoum in the product

Exposure during the production and formulation of brodifacoum should be addressed under other EU legislation (e.g. REACH) and not repeated under Directive 98/8/EC. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for brodifacoum which is an existing biocidal active substance within the EU.

Hence, the environmental exposure assessment focuses on the use and disposal of the rodenticide, which is in line with the scenarios proposed by the ESD.

VI.1.1 *Fate and distribution of brodifacoum in the environment*

Details on the environmental fate and behaviour of brodifacoum are given in the CA Report for the active substance with regard to its inclusion in Annex I of Directive 98/8/EC.

The active substance is hydrolytically stable ($t_{1/2} > 1$ year), of low water solubility, ($5.8 \cdot 10^{-5}$ g/l at pH 7 20°C). It has a low vapour pressure and undergoes indirect photodegradation rapidly ($t_{1/2} =$ approx 2 hours). It is not readily and not inherently biodegradable.

In addition to this, supportive data in the literature (EHC 175 , WHO 1995) showed that a study by Hall and Priestley (1992) indicated that the half-life was 157 days with a mean total of 35.80% of applied radioactivity (as radiolabelled brodifacoum) being recovered as $^{14}\text{CO}_2$ at 52 weeks. The levels of radioactivity accounted for by volatiles other than $^{14}\text{CO}_2$ were less than 2% over the study period of 52 weeks.

The Koc of 50000 (The Pesticide Manual 13th ed) indicate that the active substance would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

The potential for the substance to ionise at environmental pH indicates that *Brodifacoum* is likely to absorb strongly to soil particles or sediment if released to the environment.

VI.1.1.1 **PEC calculations**

The ESD PT 14 categorises scenarios according to the application surrounding (area of use) of the rodenticide and the application type (formulation). The PECs for the scenarios relevant to this product are presented below. It must be noted that the ESD PT 14 does not provide a scenario for the indoor use of rodenticides even though it is possible for a product to reach the sewer system due to cleaning processes following indoor use. However, these environmental emissions are considered negligible compared to emissions from outdoor use around buildings. Therefore, environmental emissions arising from the indoor use can be regarded to be covered by allowance for outdoor applications, as a conservative assumption. Since rat abatement requires higher application amounts compared to mouse control, the exposure assessment includes application amounts and distances for placing the bait for the former target organisms (rat).

Emissions to the environment have been calculated in a two-tiered approach. In a first tier, the default values of the ESD PT 14 regarding application amounts and mode of use are used to calculate the worst-case PECs (first column in the tables). For refinement (Tier 2), product-specific application amounts and mode of use are used to derive PEC values that more closely reflect the realistic usage.

The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.

Sewer system

The product is used in sewer systems solely by professionals. Detailed usage instructions are provided on the label.

The ESD PT 14 proposes the scenario of pulsed baiting as a realistic worst case for rodenticide use in a city having a serious rat problem. A campaign of 21 days is assumed, with control operations at days 7 and 14. The revisit at day 7 requires the highest refill of baits (1/3 of the rodenticide has been consumed and must be replaced) so only the first 7 days of the campaign are observed. This scenario has been taken for the current risk assessment.

As outlined above, a two-tiered approach is conducted, comprising the following assumptions:

Tier 1:

In an area corresponding to 10,000 inhabitants, 300 portions of baits (300 g of bait per portion) are applied to 300 cesspools (in total 90 kg product in the catchment of one STP). During the first 7 days of control operation, 1/3 of the baits being placed are lost. Hence, the amount of product either being consumed by rodents or spilled (Q_{prod}) accounts for 30 kg. The fraction of the active substance released to the sewer system (F_{released}) is set to 0.9 by default.

Tier 2:

The applicant recommends a dosage rate of 200g to be placed at each of the 300 cesspools. This corresponds to a total mass of product of 20kg. In addition the applicant suggested refining the PEC values by including data on the metabolisation of Brodifacoum. However as explained above the evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.

Regarding the fate and behaviour of brodifacoum in a STP, the SimpleTreat model, implemented in EUSES 2.1, was used. Accordingly, the bulk of the active substance when entering a STP is translocated into sewage sludge (80.3%) with the remainder being present in the STP effluent after wastewater treatment.

The input parameters for EUSES 2.1 are summarized in the following table. They have been adopted from the list of endpoints of the CA Report for brodifacoum.

Table 1: Input parameter for EUSES calculation

Parameter	Unit	Value	Condition
Molar mass	g/mol	523.4	
Melting point	°C	232	
Boiling point	°C	Not applicable	
Vapour pressure	Pa	10 ⁻⁶	20°C
Henry's constant	Pa*m ³ *mol	2.18*10 ⁻³	pH 7
Water solubility	mg/L	0.24	pH 7, 20°C
Log P _{ow}		4.92	
DT ₅₀ in soil	d	157	20°C
		298	12°C
K _{oc} (soil)	L/kg	50000	Pesticide Manual 13th ed.
Distribution in STP		80.3% sludge	SimpleTreat distribution

Using these input parameters and the Tier 1 and Tier 2 approaches explained above environmental concentrations have been assessed and are presented in the following table:

Table-2: Brodifacoum concentrations in environmental compartments for the scenario 'sewer system'

		Tier 1 ^a	Tier 2 ^b
Input			
Q _{prod}	Amount of product used in control operation (kg)	30	20
F _{Cproduct}	Fraction of active substance in product	0.00005	0.00005
T _{emission}	Number of emission days	7	7
F _{released}	Fraction of active ingredient released	0.9	0.9
Output			
E _{localwater} ^c	Mean local emission of active substance to waste water during episode (g/d)	0.193	0.129
C _{infi} ^d	Concentration in sewage water to local STP (mg/L)	9.64 x 10 ⁻⁵	6.43 x 10 ⁻⁵
Local concentrations in different compartments after elimination processes in STP according to TGD (2003) calculated by EUSES 2.1			
PEC _{stp}	PEC for microorganisms in the STP (mg/L)	1.93 x 10 ⁻⁵	1.27 x 10 ⁻⁵
PEC _{localwater}	Local PEC in surface water during emission episode (mg/L)	1.77 x 10 ⁻⁶	1.18 x 10 ⁻⁶
PEC _{local} _{sediment}	Local PEC in fresh-water sediment during emission episode (mg/kg)	1.92 x 10 ⁻³	1.28 x 10 ⁻³
PEC _{local} _{soil}	Through application of sewage sludge (mg/kg)	4.86 x 10 ⁻⁴	3.24 x 10 ⁻⁴
PEC _{local} _{soil, porew}	Concentration in porewater/groundwater of agricultural soil (mg/L)	4.66 x 10 ⁻⁷	3.11 x 10 ⁻⁷

^a ESD default application data

^b Product specific application data

^c $E_{localwater} = (Q_{prod} \times F_{Cproduct} / T_{emission}) \times F_{released}$

^d $C_{infiuent} = E_{localwater} / \text{total volume of sewage water per day (related to standard STP scenario in TGD with 200 L per person per day and 10000 inhabitants per STP)}$

In and around buildings

As mentioned above, in the ESD PT14 emissions to the environment from the indoor use of rodenticides are considered to be insignificant compared to those arising from the outdoor use. Hence, the emission pathway: indoor use → disposal or cleaning operation → STP will not be contemplated.

The current risk assessment focuses on rat control because rat abatement with the product requires higher application amounts related to an area compared to mice control. The product can be applied by amateurs and professionals with the same maximum application amounts (60g bait maximum per bait point with a minimum distance of 5m between points) however the modes of application may be slightly different for the two user groups. **Amateurs are instructed to always use tamper resistant bait stations**, reducing the risk for unintended uptake by humans and non-target vertebrates as well as leading to a decrease in exposure of soils if applied around buildings. **The use of tamper resistant bait stations is not obligatory for professionals.** However, if professionals do not employ tamper resistant bait stations they are instructed to secure baits by strings or wire in order to limit access to the baits, and dispersal.

In conjunction with rodenticide applications **in and around buildings** the main exposed environmental compartment is soil contaminated by spills during the application, refilling and disposal (1% direct release) as well as from indirect release via urine and faeces (90% per default).

The environmental risk assessment for brodifacoum, a.s. of the product, is performed in a two steps approach:

Tier 1:

Tier 1 comprises the ESD PT 14 default values regarding dosages and emissions to the environment. Ten bait stations, each containing 250 g, are assumed to be placed within an area 55m long and 10m wide (550m²). The distance between the bait stations is 5m. The ESD PT 14 assumes that during a campaign (21 days) a complete refill of each bait station 5 times is necessary (day 1, 3, 7, 14 and 21).

Tier 2:

Tier 2 comprises the product specific application mode and the ESD PT14 default values regarding emissions to the environment (*cf.* Tier 1). In this case 60g bait is placed at each bait point. The placement of the bait is as described under Tier 1. The ESD recommends a total of 2.6 replenishments (as opposed to 5 for Tier 1). This is to reflect the fact that as the campaign proceeds less and less bait is eaten.

Table-3: Brodifacoum concentrations in environmental compartments for the scenario 'in and around buildings'

Input		Tier 1 ^a	Tier 2 ^b
Q_{prod}	Amount of product used in control operation (g) per site	250	60
F_{Cproduct}	Fraction of active substance in product	0.00005	0.00005
N_{sites}	Number of application sites	10	10
N_{refill}	Number of refilling times	5	2.6
$F_{\text{releaseD, soil}}$	Fraction of product released directly to soil	0.01	0.01
$F_{\text{releaseID, soil}}$	Fraction of unmetabolised active ingredient released indirectly to soil	0.9	0.9
Output			
$E_{\text{localsoil-D-campaign}}$	Local direct emission of active substance to soil from a campaign (g/camp)	0.006	0.0008
$E_{\text{localsoil-ID-campaign}}$	Local indirect emission of active substance to soil from a campaign (g/camp)	0.557	0.069
$E_{\text{localsoilcampaign}}$	Local emission of active substance to soil from a campaign (g/camp)	0.563	0.070
$C_{\text{localsoil-D}}^{\text{c}}$	Local concentration in soil due to direct release after a campaign (mg/kg)	0.041	0.005
$C_{\text{localsoil-ID}}^{\text{d}}$	Concentration in soil due to indirect release after a campaign (mg/kg)	0.006	0.0007
$C_{\text{localsoil}} = C_{\text{localsoil-D}} + C_{\text{localsoil-ID}}$	Total concentration in soil (mg/kg)	0.047	0.006
$PE_{\text{Clocal soil, porew}}$ (acc. to TGD, eq.67)	Concentration in porewater resulting from total concentration in soil (mg/L)	5.3×10^{-5}	6.62×10^{-6}

^a Default application data and values for release

^b Product specific application data

^c $C_{local\ soil-D} = (E_{local\ soil-D-campaign} \times 1000) / (AREA_{exposed-D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ according to ESD: $AREA_{exposed-D} = 0.09 \text{ m}^2$, $DEPTH_{soil} = 0.1 \text{ m}$, $RHO_{soil} = 1700 \text{ kg/m}^3 \text{ soil}$,

$$E_{local\ soil-D-campaign} = Q_{prod} \times FC_{prod} \times N_{sites} \times N_{refil} \times F_{release-D,soil}$$

^d $C_{local\ soil-ID} = (Q_{prod} \times FC_{prod} \times N_{sites} \times N_{refil} \times 1000 \times F_{releaseID,soil} \times (1 - F_{releaseD,soil})) / (AREA_{exposed-ID} \times DEPTH_{soil} \times RHO_{soil})$, according to the ESD $AREA_{exposed-ID} = 550 \text{ m}^2$, $DEPTH_{soil} = 0.1 \text{ m}$, $RHO_{soil} = 1700 \text{ kg/m}^3 \text{ soil}$.

$$E_{local\ soil-ID-campaign} = Q_{prod} \times FC_{prod} \times N_{sites} \times N_{refil} \times F_{releaseID,soil} \times (1 - F_{releaseD,soil})$$

VI.1.2 PEC in surface water, sewage treatment plant, groundwater and sediment

Using the relevant scenarios outlined in the ESD PT14, the modes of calculation of the TGD, and the assumptions laid down above, the following PEC_{local} have been derived for aquatic compartments.

Table-1: Summary of brodifacoum PEC values obtained in the aquatic environment

Compartment/Scenario	Tier 1 ^a	Tier 2 ^b
SEWER SYSTEM		
PEC _{stp} (mg/L)	1.93 x 10 ⁻⁵	1.27 x 10 ⁻⁵
PEC _{local water} (mg/L)	1.77 x 10 ⁻⁶	1.18 x 10 ⁻⁶
PEC _{local sediment} (mg/kg)	1.92 x 10 ⁻³	1.28 x 10 ⁻³
PEC _{local soil, porewater} (mg/L)	4.66 x 10 ⁻⁷	3.11 x 10 ⁻⁷
IN AND AROUND BUILDINGS		
PEC _{local soil, porewater} (mg/L)	5.3 x 10 ⁻⁵	6.62 x 10 ⁻⁶

^a ESD default application data and values for release

^b Product specific application data

VI.1.3 PEC in air

Brodifacoum has a vapour pressure of less than 10⁻⁶ Pa at 20°C and a Henry's Law constant of less than 2.18 x 10⁻³ Pa x m³ x mol⁻¹ at pH 7. In the Assessment Report for brodifacoum it has been

concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

VI.1.4 PEC in soil

The following table contains a summary of the PEC_{localsoil} derived from the different exposure scenarios.

Table-1: Summary of brodifacoum PEC values for soils

Compartment/Scenario	Tier 1 ^a	Tier 2 ^b
SEWER SYSTEM		
PEC _{localsoil} (mg/kg) (via sewage sludge)	4.86 x 10 ⁻⁴	3.24 x 10 ⁻⁴
IN AND AROUND BUILDINGS		
PEC _{localsoil} (mg/kg)	0.047	0.006

^a ESD default application data and values for release

^b Product specific application data

VI.1.5 Summary of calculated PECs

See tables 2, 3, 4 & 5

VI.1.6 Primary and Secondary Poisoning

Basically the same set of physiological processes is responsible for maintaining life for warmblooded animals, i.e. mammals and birds. Therefore, the use of rodenticides meant **for killing selected pest mammals** has to be considered a general hazard to non-target mammals and birds as well.

Non-target animals are potentially at risk in two ways: 1) from direct consumption of the baits (primary poisoning) and 2) through eating rodents that have taken up/accumulated the poison (secondary poisoning). Though similarities exist there are differences as to the susceptibility to or tolerance of the different rodenticides among mammals and birds. These differences may be due to differences in their normal diets, feeding habits, ecological or other factors.

The exposure scenarios and assessments give a basis for evaluating the primary and secondary poisoning risk to non-target animals according to the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning. These are not described in the TGD (2003) but are described in the ESD PT14 (CA-Jun03-Doc.8.2-PT14).

VI.1.6.1 Primary Poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (*cf.* ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, the label claim of the product contains precautionary measures to be undertaken in order to minimise the risk for bait uptake by non-target vertebrates. Amateurs are given instruction to use tamper resistant bait boxes for bait application. Professionals are directed to place the baits so that the baits are inaccessible for non-target animals and children. Accordingly, baits have to be put in tamper resistant stations, or fixed by strings or wire.

The ESD PT14 proposes several non-target species to be assessed for primary poisoning risk assessments. Several bird and mammalian species are proposed (tree sparrow, chaffinch, woodpigeon and pheasant pigs and dogs), all these species will be taken into account in the current risk assessment.

Acute and Long-Term risk assessment for primary poisoning of a non-target organism:

Tier 1:

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and PNEC_{oral}. PEC_{oral} is the concentration of the rodenticide in the food of a non-target organism. PNEC_{oral} is the No Effect Concentration for oral intake.

This evaluation can be used for both short- and long-term exposure. According to the TGD (2003), the PNEC_{oral} is based on; LC50_{bird}, NOEC_{bird} or NOEC_{mammal}, which is divided by a specific assessment factor mentioned in the TGD (2003) Table 23.

The acute and long-term PNEC_{oral} values for birds and mammals are calculated from toxicity data in the CAR and reported in following table.

Organism group	Species / test	Results ¹	Assessment factor	PNEC (concentration in food, mg/kg) ³	PNEC (dose, mg/kg b.w./d) ³
Acute					
Birds	Laughing Gull	-	3 000	0.72 mg/kg food	0.09
Mammals	Rat (teratogenicity)	3.33E-06 mg/kg bw	300	0.000067 mg/kg	0.00000335
Long-term					
Birds	Mallard Duck (Difenacoum read-across)	1.28E-05 mg/kg bw/d.	30	0.00013 mg/kg diet	0.00001625
Mammals	Rat (2-gen)	1.1 E-05 mg/kg bw	90	2.22E-04 mg/kg food	0.000111

¹ CAR Brodifacoum

² According to TGD, the PNEC_{mammal} can be calculated from toxicity studies of 28 days, 90 days or chronic. Therefore, the acute PNEC_{mammal} is based on NOAEL from 28-d toxicity study.

³ Calculated using conversion factor from Table 22 in the TGD: 8 for birds, 20 for rats and 33.3 for rabbit.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and has access to the product. The PEC_{oral} is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

	PEC _{oral} (concentration in food, mg/kg)	PNEC _{oral} (concentration in food, mg/kg)	PEC / PNEC
Acute			
Bird	50	0.72	69.44
Mammal	50	0.000067	746
Long-term			
Bird	50	0.00013	384
Mammal	50	0.000222	225

The ratios PEC/PNEC are above 1 indicating a potential risk, which must be refined.

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. The body weights, daily food intakes and estimates of the product ingestion, based on sufficient bait being accessible to satisfy a day's food intake requirement, are presented below for a representative non-target mammal.

The values for the estimated daily intake (ETE) are calculated for non-target birds and mammals consuming the product. The calculation is a first step conducted according to the following equation, using the default values given in the ESD:

$$\text{ETE} = (\text{FIR}/\text{BW}) * \text{C} * \text{AV} * \text{PT} * \text{PD} \text{ (mg/kg bw/d) (eq 19, ESD)}$$

Where:

ETE is the Estimated Theoretical Exposure to the active substance,

FIR is the non-target animal's daily food intake (fresh weight),

b.w. is bodyweight,

C is the concentration of active substance in the fresh diet (bait),

AV is the avoidance factor (default 1.0 = no avoidance),

PT is the fraction of diet obtained in the treated area (default 1.0)

PD is the fraction of food type in the diet (default 1.0).

In a second step, the avoidance factor (AV) is set to 0.9 and the fraction of the diet obtained in the treated area (PT) is set to 0.8. In a third step expected concentrations are calculated, assuming a default excretion factor of 0.3.

Table-1 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	Body weight (g)	Daily food intake (FIR) (g/d) ^a	Conc. of a.i. after single meal (mg/kg bw/d) (ETE)	Expected conc. after elimination ^b (mg/kg bw/d) (EC)
Tree sparrow	22	7.6	17.27	12.09
Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456 ^d	2.28	1.64
Pig	80 000	600 ^e	0.375	0.270
Pig, young	25 000	600 ^e	1.20	0.864

^a cf. Table 3.1 of ESD PT 14

^b Default excretion factor = 0.3

^c AV = 0.9, PT = 0.8

^d From EUBEES 2, Section 3.2.1, Table 3.1,

^e From EUBEES 2, Section 3.2.1, page 50: for mammals: $\log(\text{FIR}) = 0.822 * \log(\text{BW}) - 0.629$,

^f From EUBEES 2, it seems reasonable to consider a portion of 600 g bait as the normal upper limit for what is available to non-target animals in several EU countries. The 600 g portion is the largest one permitted for use by non-professionals in several countries.

The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: PEC_{oral}/PNEC_{oral} for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		PNEC _{oral} (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.09	0.00013	132846	93000
Chaffinch	15.00	10.50	0.00013	115384	80769
Wood pigeon	5.42	3.79	0.00013	41692	29153
Pheasant	5.39	3.77	0.00013	41461	29000
Dog	2.28	1.596	0.000222	10270	7254
Pig	0.375	0.2625	0.000222	1689	1182
Pig, young	1.20	0.864	0.000222	5405	3927

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-term risk assessment for primary poisoning of a non-target organism:

Tier 1:

In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides. The EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated as follows:

$$EC = ETE \times (1 - EI)$$

EC values are based on the calculations for ETE above but an elimination factor has to be taken into account. The default value for an elimination factor of (*EI*) = 0.3 per day, stated in the EUBEES 2, has been used. This is a reasonable average default value for elimination, as anticoagulant rodenticides are eliminated from the body mainly through faeces.

Expected concentration of Brodifacoum in the animal after one meal followed by a 24-hour elimination period

Species	Estimated daily uptake of a compound (ETE) (mg/kg b.w./d)		Fraction of daily uptake eliminated (number between 0 and 1) (EI)	Expected concentration of active substance in the animal (EC) (mg/kg b.w./d)	
	Step 1	Step 2		Step 1	Step 2

Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

Tier 2 long-term risk assessment: EC_{oral}/PNEC_{oral} ratio after 1-day elimination of Brodifacoum

Species	EC _{oral} (mg/kg b.w./d) after 1 day		PNEC _{oral} (mg/kg b.w./d)	Ratio PEC _{oral} /PNEC _{oral}	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.00013	93000	67000
Chaffinch	10.5	7.56	0.00013	80769	58154
Wood pigeon	3.79	2.73	0.00013	29154	21000
Pheasant	3.77	2.72	0.00013	29000	20923
Dog	1.596	1.149	0.00022	7189	5176
Pig	0.2625	0.189	0.00022	1182	851
Pig, young	0.864	0.6048	0.00022	3892	2724

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC₅ values are used for quantitative risk assessment of primary poisoning in the long-term situation. Calculations of the expected concentrations (EC) for 5-days exposure considering elimination are calculated.

The EC_n (expected concentration of active substance in the animal after n days) can be calculated by use of **ESD equation 21**:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

All parameters AV, PT and PD are set to 1 as a worst-case scenario.

The principle in the calculations is for the first 5 days that the animal eats the same daily amount and eliminates 30% of its content of residues. EC₃ is the concentration of residues in the animal before a

new meal on Day 3 and so forth. Therefore, the concentration of residues on Day 5 is calculated stepwise this way:

$$EC_3 = (EC_2 + ETE) * (1 - 0.3)$$

$$EC_4 = (EC_3 + ETE) * (1 - 0.3)$$

$$EC_5 = (EC_4 + ETE) * (1 - 0.3)$$

EC_{oral} for different relevant species

Days	EC _{oral} (mg/kg b.w./d)						
Species	Tree sparrow	Chaffinch	Wood pigeon	Pheasant	Dog	Pig	Young pig
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Tier 2 long-term risk assessment: EC_{oral}/PNEC_{oral} ratio after 5-day elimination

Species	EC _{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw) ^a	EC _{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw) ^a	PNEC _{oral} (mg/kg b.w./d)	Ratio EC _{oral} /PNEC _{oral}
Tree sparrow	30.7	22	0.00013	170031
Chaffinch	26.6	19	0.00013	147323
Wood pigeon	9.61	7	0.00013	53225
Pheasant	9.56	7	0.00013	52948
Dog	4.05	3	0.000222	13135
Pig	0.666	0.480	0.000222	2160
Pig, young	2.13	2	0.000222	6908

^a calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term PEC_{oral}/PNEC_{oral} ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

VI.1.7 Non compartment specific exposure relevant to the food chain (secondary poisoning)

According to the ESD PT 14, the secondary poisoning hazard following sewage system applications is relevant only if poisoned rats or cockroaches move to the surface. However, since cockroaches are predominately nocturnal and the species found in sewers will remain underground, they are not significant prey for birds.

Secondary poisoning hazard can also be ruled out when the rodenticide is used in fully enclosed spaces. If buildings are not fully closed, predators may occur inside buildings or hunt in the vicinity of a building, and are potential targets for secondary poisoning.

Consideration is required for **predators eating fish** which have been exposed to the active substance.

Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for **predators eating the rodent carcasses** and **earthworms** which have ingested the active substance absorbed to soil.

VI.1.7.1 Calculation of concentration in rodents

The following assumption is followed: a rodent of a size occurring in EU countries consumes an average daily amount of food equivalent to about 10% of its body weight.

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been **set to a default value of 5-days**, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation).

Anticoagulant rodenticides are eliminated from the body mainly through faeces. A worst-case scenario assumes that the target rodent will eat continuously during the whole period and that the elimination of active substance is 30% per day during the whole period. Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted.

The concentrations in rodents have been assessed according to **equation 19 of the ESD**. This equation for ETE (see primary poisoning) is used for calculating the amount of active substance being consumed by the target rodent. A reasonable value for factor PD in the equation is necessary for the full scenario.

ETE = (FIR/BW)*C*AV*PT*PD (mg/kg bw/d) (eq. 19, ESD)

The value for FIR/BW is set to a default of 0.1, i.e., the food intake is 10% of the body weight.

The calculation of the concentration in rodents after 5 days of bait consumption, immediately after the last meal, follows the procedure:

Total daily consumption is 100% (PD = 1.0, worst case situation). After the first meal on day 1 the rodenticide in the rat accounts for:

$$\text{ETE} = 0.1 * 50 * 1 * 1 * 1 = 5 \text{ mg/kg}$$

The concentration for day 2 just before the second meal is assessed, using a value of 0.3 for elimination (EI).

$$\text{EC}_2 = 5 * (1 - 0.3) = 3.5 \text{ mg/kg (eq. 20, ESD)}$$

For the following days the concentrations are:

$$\text{EC}_3 = (\text{EC}_2 + \text{ETE}) * (1 - 0.3) = (3.5 + 5) * 0.7 = 5.95 \text{ mg/kg}$$

$$\text{EC}_4 = (\text{EC}_3 + \text{ETE}) * (1 - 0.3) = (5.95 + 5) * 0.7 = 7.665 \text{ mg/kg}$$

$$\text{EC}_5 = (\text{EC}_4 + \text{ETE}) * (1 - 0.3) = (7.665 + 5) * 0.7 = 8.866 \text{ mg/kg}$$

$$\text{EC}_6 = (\text{EC}_5 + \text{ETE}) * (1 - 0.3)$$

For considering the elements in a secondary poisoning scenario for resistant rodents, the concentration of active substance that may be present after a 14-day control operation should be included in the calculations. However, this is considered as a special type of a worst-case scenario, which should only be considered in cases of resistance problems.

For the resistant rodent the calculations have been continued until Day 14 after the meal.

So the concentration in the rat before its last meal on the 5th day is 8.866 mg/kg. Once the ETE is added this results in **13.87 mg/kg**, i.e., this is the concentration **after** the last meal on the 5th day. The following table gives a summary of the expected active substance concentrations in the rodents, using PD values of 1.0, 0.5 and 0.2.

Residues of Brodifacoum in target rodent in mg a.s./kg b.w. at different times during a control operation (concentration of active substance in rodenticide bait 0.005%)

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	0.5	1.0
A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00
Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 <u>after</u> the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

* Equation for ETE is used for calculation of rodenticide in target animal on Day 1 immediately after first meal.

**Equation for EC (primary poisoning) is used for calculating the value for Day 2 before new meal.

The assessment indicates an increased concentration in resistant rodents. The users should be aware of resistance problems and thereby avoid this risk by checking the resistance status of the rodent population in the area to be controlled and by considering the choice of the rodenticide to be used.

Regarding a control operation against normal susceptible rodents, it is seen that the highest concentration of active substance is found in rodents that have just taken their last meal on the fifth day before they are going to die. The realistic worst case is considered best described when the target rodent has consumed an amount of rodenticide making up 100% of its daily food intake.

Table-1: Brodifacoum concentrations in rodents after 5 days of product uptake, immediately after the last meal (PD = fraction of food type in diet)

	PD = 1.0	PD = 0.5	PD = 0.2
Expected concentration in rodents immediately after a last meal on day 5 (mg a.i./kg rat, value corresponds to PEC _{oral} mg/kg food)	13.87	6.93	2.77

Tier 1 risk assessment:

For the first tier exposure assessment of secondary poisoning, the maximum residue levels in target rodents arise on day-5 after the last meal (ETE_{oral, predator}). The Estimated Theoretical Exposure to an active substance in food of a rodent-eating predator is calculated as follows:

$$ETE_{oral, predator} = (EC_n + ETE_{rodent}) \times F_{rodent}$$

where:

ETE_{oral, predator}: Estimated Theoretical Exposure to an active substance in food of a predator per day

EC_n: Expected concentration of active substance in the rodent on day "n" before the last meal

ETE_{rodent}: Estimated uptake of active substance by rodent on day "n" (i.e. intake of rodenticide in the last meal, no elimination)

F_{rodent}: Fraction of poisoned rodents in predator's diet

The first tier assessment also assumes the three levels of bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide (i.e. 100%, PD = 1) and that the non-target animals consume 50% of their daily intake on poisoned rodents (F_{rodent} = 0.5).

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	PNEC _{oral} (mg a.s./kg b.w.)	ETE _{oral, predator} (mg a.s./kg b.w.)			PEC _{oral} /PNEC _{oral} – day 5		
		0.2	0.5	1.0	0.2	0.5	1.0
PD values		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	0.000067				41343	103432	207014
Long-term							
Birds	0.00013	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000222				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	PNEC _{oral} (mg a.s./kg b.w.)	ETE _{oral, predator} (mg a.s./kg b.w.)			PEC _{oral} /PNEC _{oral} – day 14		
		0.2	0.5	1.0	0.2	0.5	1.0
PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.31	5.79	11.58	3.20	8.04	16.08
Mammals	0.000067				34477	86417	172835
Long-term							
Birds	0.00013	1.15	2.31	5.79	8846	17769	44538
Mammals	0.000222				5227	10500	26318

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned is very high as indicated by the above the trigger value of 1 is exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

Tier 2 exposure and risk assessment:

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. Several bird and mammal species are chosen to refine the risk assessment:

Birds: barn owl, kestrel, little owl and tawny owl.

Mammals: fox, polecat, stoat and weasel.

The bodyweights and food intake are drawn from the EUBEEES 2 guidance and on documents referred to in SANCO/4145/2000²³.

In the following table, the expected values for uptake of active substance by a bird of prey or a mammal predator after a single day of exposure are presented and the expected concentration in the non-target animals as a second tier exposure estimation of secondary poisoning. In the following table, concentrations in weasel, kestrel, and some other birds and mammals have been calculated after a single day of exposure for PD = 1 (rodents diet consisted entirely of the product). The parameter F_{rodent} (fraction of poisoned rodents in predator's diet) is set to 0.5.

Table-2: Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

Species		Body weight*)	Daily mean food intake*)	Normal susceptible rodents caught on day 5, before their last meal.		Normal susceptible rodents caught on day 5 just after their last meal		Resistant rodents caught on day 14 just after their last meal	
				Amount a.s. consumed by the non-target animal**	Concentration in non-target animal	Amount a.s. consumed by the non-target animal***	Concentration in non-target animal	Amount a.s. consumed by the non-target animals****	Concentration in non-target animal
		(g)	(g)	(mg)	(mg a.s./kg b.w.)	(mg)	(mg a.s./kg b.w.)	(mg)	(mg a.s./kg b.w.)
Barn Owl	<i>Tyto alba</i>	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	<i>Falco tinnuncul.</i>	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	<i>Athene noctua</i>	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	<i>Strix aluco</i>	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89
Fox	<i>Vulpes vulpes</i>	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76
Polecat	<i>Mustela putorius</i>	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58

Stoat	<i>Mustela erminea</i>	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	<i>Mustela nivalis</i>	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Like for the first tier risk assessment, the ETE_{oral predator} is compared to the PNEC_{oral}.

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE _{oral predators} (mg a.s./kg/d)	PNEC _{oral} (mg a.s./kg/d)	Ratio ETE _{oral predators} / PNEC _{oral}
Barn owl	Day 5 before the last meal	1.10	0.00013	8461
	Day 5 after the last meal	1.72		13230
	Day 14 after the last meal	2.06		15850
Kestrel	Day 5 before the last meal	1.68	0.00013	12920
	Day 5 after the last meal	2.62		20150
	Day 14 after the last meal	3.13		24080
Little owl	Day 5 before the last meal	1.26	0.00013	9690
	Day 5 after the last meal	1.97		15150
	Day 14 after the last meal	2.35		18080
Tawny owl	Day 5 before the last meal	1.01	0.00013	7770
	Day 5 after the last meal	1.58		12150
	Day 14 after the last meal	1.89		14540
Fox	Day 5 before the last meal	0.41	0.000222	1846
	Day 5 after the last meal	0.63		2837
	Day 14 after the last meal	0.76		3423
Polecat	Day 5 before the last meal	0.85	0.000222	3828
	Day 5 after the last meal	1.32		5945
	Day 14 after the last meal	1.58		7117
Stoat	Day 5 before the last meal	1.21	0.000222	5450
	Day 5 after the last meal	1.89		8513
	Day 14 after the last meal	2.26		10180
Weasel	Day 5 before the last meal	1.74	0.000222	7837
	Day 5 after the last meal	2.72		12252
	Day 14 after the last meal	3.25		14639

All ratios $ETE_{\text{oral predators}} / PNEC_{\text{oral}}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

VI.1.7.2 Calculation of the concentration in fish

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{\text{oral, predator}}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP). The $PEC_{\text{oral, predator}}$ (mg/kg wet fish) is calculated from the annual average PEC for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (*cf.* TGD, 2003).

$$PEC_{\text{oral, predator}} = PEC_{\text{water}} * BCF_{\text{fish}} * BMF \quad (\text{eq. 76, TGD, 2003})$$

The bioconcentration factor (BCF_{fish}) is calculated with the aid of **equation 75 of the TGD**, using a log P_{ow} of 6.12. The biomagnification factor is set to 10 according to the TGD.

The following table summarises the $PEC_{\text{oral, fish}}$ for the scenario 'sewage system'.

Predicted concentrations in fish

		Tier 1 ^a	Tier 2 ^b
Input			
PEC_{water}	Annual average local PEC in surface (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{\text{oral, fish}}$	Predicted environmental concentration in fish (mg/kg wet fish)	3.19×10^{-1}	2.13×10^{-1}

^a Product specific application data and default value for release

^b Product specific application data and refined for metabolism

VI.1.6.3 Calculation of concentration in earthworms

The $PEC_{\text{oral, predator}}$ is calculated according to the TGD:

$$PEC_{\text{oral, predator}} = C_{\text{earthworm}} \quad (\text{eq 80, TGD, 2003})$$

$$C_{\text{earthworm}} = (BCF_{\text{earthworm}} * C_{\text{porewater}} + C_{\text{soil}} * F_{\text{gut}} * CONV_{\text{soil}}) / (1 + F_{\text{gut}} * CONV_{\text{soil}}) \quad (\text{eq 82c, TGD 2003})$$

$$BCF_{\text{earthworm}} = (0.84 + 0.012Kow) / RHO_{\text{earthworm}} \quad (\text{eq 82d, TGD, 2003})$$

Where $RHO_{\text{earthworm}}$ is 1 by default

$$\text{So, } BCF_{\text{earthworm}} = (0.84 + 0.012 * 1318257) / 1 = 15820 \text{ l/kg}_{\text{wwt earthworm}}$$

For PEC_{soil} the PEC_{local} is used with respect to sludge applications. The concentration in soil is averaged over a period of 180 days. As for the aquatic food chain it is assumed, that just 50% of the diet comes from the affected region. Hence, the PEC_{soil} averaged over 180 days as well as the $PEC_{porewater}$ are divided by 2.

According to the TGD soil concentrations due to sewage sludge (indirect emissions) are the basis for calculating potential concentrations in earthworms. However, in the current risk assessment a direct intake of the active substance in soils is applicable for the scenario 'in and around buildings'. **EUSES 2.1.1** does not give a result for potential concentrations in earthworms for this scenario and it becomes acknowledged, that the required input parameter for calculating the $PEC_{oral, earthworm}$ according to equation 81 of the TGD cannot be assessed for the respective scenarios. An attempt, nonetheless, is made to calculate $PEC_{oral, earthworm}$ for the direct soil intake. Soil concentrations taken for the calculation represents an active substance intake within a soil mixing depth of just 10 cm. Degradation has not been considered. However, concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm is to original soil from the contaminated area.

The parameter F_{gut} is set to 0.1 (kg dwt/kg wwt) and the conversion factor for soil concentration wet-dry weight ($CONV_{soil}$) is set to 1.13 kg wwt/kg dwt.

The $PEC_{oral, earthworm}$ are summarised in the following table:

Table 0-1: Brodifacoum concentrations in earthworms

		Tier 1 ^a	Tier 2 ^b
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820

$C_{\text{porewater sewer}}$	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{\text{porewater building}}$	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$\text{CONV}_{\text{soil}}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$\text{PEC}_{\text{oral, earthworm sewer}}$	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326
$\text{PEC}_{\text{oral, earthworm building}}$	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

^a Product specific application data and default value for release

^b Product specific application data and refined metabolism

Environmental effects assessment***Aquatic compartment***

Ecotoxicological studies with the product on aquatic organisms are not required as the toxicity of the product is expected to be entirely driven by that of the active substance.

As no substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

The PNEC_{sediment} calculation is as follows:

$$\begin{aligned} \text{PNEC}_{\text{soil}} &= K_{\text{susp-water}}/\text{RHO}_{\text{susp}} \times \text{PNEC}_{\text{water}} \times 1000 \text{ (TGD Eq 70)} \\ &= 1250/1150 \times 0.00004 \text{ mg/l} \times 1000 \\ &= 4.348 \times 10^{-2} \text{ mg/kg} \end{aligned}$$

Atmosphere

Not applicable.

Terrestrial compartment

According to the TNsG on data requirements (Ch. 2.5, Part B), additional data is required with the formulation if this is intended for outdoor use in form of baits, granulates or powder. However, as no additional substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

Non compartment specific effects relevant to the food chain (secondary poisoning)

In the frame of the Annex I inclusion of brodifacoum, the applicant had submitted several studies, dealing with secondary poisoning of non target vertebrates. The studies have been discussed in detail in Section 4.2.4 of Doc. IIA of the CA Report. The studies indicate that secondary toxicity is dependent on a variety of factors, related to exposure (like dose and treatment levels, habitat of the non-targets) and effect (species and condition of the animal).

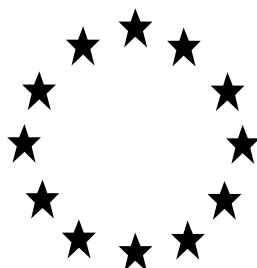
ANNEX VII: Residue Calculations

No residue calculations are required as Vertox Oktablok is a ready to use bait, which is used to kill rats and mice. Vertox Oktablok will not come into contact with the human food chain. The bait may be used indoors, outdoors around buildings and in sewers (professional only). The bait will be placed at protected bait points in dry locations, protected from the weather to help prevent access by non target animals.

Annex 2 - MAC PAR – January 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE MAJOR CHANGE
OF A NATIONAL AUTHORISATION (NA-MAC)**



Product identifier in R4BP	Vertox 25 Oktablok
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-YL028939-03
Asset No. in R4BP	IE-0016001-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	IE/BPA 70505
Date	09.01.18 (NA-MAC Major Change)

Table of contents

1	Conclusion	551
2	Summary of the product assessment	552
2.1	Administrative information	552
2.2	Product composition and formulation	553
2.3	Classification and Labelling according to the Regulation (EC) No 1272/2008.....	554
2.4	Use(s) appropriate after major change to the authorisation.....	555
2.5	General directions for use	584
3	Assessment of the product	588
3.1	Proposed Uses	588
3.2	Physical, chemical and technical properties.....	602
3.3	Physical hazards and respective characteristics	602
3.4	Methods for detection and identification	602
3.5	Efficacy against target organisms	602
3.6	Risk assessment for human health	604
3.7	Risk assessment for animal health.....	608
3.8	Risk assessment for the environment	608
3.9	Assessment of a combination of biocidal products	612
3.10	Comparative assessment	612
4	General Annexes	613
4.1	List of studies for the biocidal product (family)	613
4.2	Output tables from exposure assessment tools	614
4.3	New information on the active substance.....	614
4.4	Residue behaviour.....	614
4.5	Summaries of the efficacy studies (B.5.10.1-xx).....	615
4.6	Other.....	617
5	Confidential annex (Access level: “Restricted” to applicant and authority).....	618
5.1	Full composition of the product	618

1 Conclusion

Implementing Regulation 354/2013 outlines the procedure for making changes/amendments under the Biocidal Products Regulation (EU) 528/2012. According to Implementing Regulation 354/2013, this application for change requires a Major Change evaluation. The change involves a reduction of active substance content in the product from 50 ppm to 25 ppm. The reduction in active substance content has been necessary due to the application of new CLP requirements for certain AVK rodenticides according to the 9th ATP (Commission Regulation (EU) 2016/1179).

The product has been evaluated using the reduced active ingredient concentration. New efficacy trials have been provided by the applicant in order to address the reduced content of active ingredient. The 25ppm assessment report also considers new dermal absorption risk assessment and ground water risk assessments.

Effectiveness data has confirmed that Vertox 25 Oktablok is effective in the proposed areas for use, at the recommended dose rate when used as per label recommendations. An evaluation of the field trials provided demonstrated that the block bait formulation proved to be both palatable to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*).

Vertox 25 Oktablok is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been established previously.

The conclusion of the evaluation is that the product may be authorised.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Vertox 25 Oktablok

2.1.2 Authorisation holder

Name and address of the authorisation holder	Name	PelGar International Limited
	Address	Unit 13, Newman Lane Alton Hampshire GU34 2QR UK
Authorisation number	IE/BPA 70505	
Date of the authorisation	09.01.18	
Expiry date of the authorisation	09.01.23	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	PelGar International Ltd,
Address of manufacturer	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	Unit 13, Newman Lane Newman Lane Alton Hampshire GU34 2QR UK or Promedivet SRL 545500 SOVATA , str. Lunga nr. 46/G jud. Mures, Romania

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Alton Hampshire GU34 2QR UK
Location of manufacturing sites	PelGar International Limited Prazska 54 280 02 Kolin Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl]tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0025

- The product contains a bittering agent and a dye.
 - Information on the full composition is provided in the confidential²⁴ annex (see section 5).
- According to the information provided, the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

²⁴ Access level: "Restricted" to applicant and authority

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use bait: block (RB)


2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008²⁵

Table 3

Classification	
Hazard classes, Hazard categories	Hazard statements
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
	EUH208: Contains 1, 2- Benzisothiazolin-3-one. May produce an allergic reaction.

Table 4

²⁵ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Labelling		
	Code	Pictogram / Wording
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	EUH208	EUH208: Contains 1, 2- Benzisothiazolin-3-one. May produce an allergic reaction.
Supplemental label elements		
Precautionary statements	P260	Do not breath dust.
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% w/w Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after major change to the authorisation

Table 5: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor
8	House mice and/or rats – trained professionals – outdoor around buildings
9	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after major change to the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice up to 20g in bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 100g Refill packs of multiple blocks (maximum pack sizes 100g): 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer - Up to 80g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard

	<p>sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 80g</p> <p>1 - 5 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. – Up to 100g.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 100g.</p>
--	---

2.4.1.1 Use-specific instructions for use

- For mice use up to 20g in bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

None

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after major change to the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use up to 60g in bait stations. Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public

Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>
-----------------------------------	---

2.4.2.1 Use-specific instructions for use

- For rats use up to 60g in bait stations.
- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Do not use this product for permanent or pulse-baiting.

2.4.2.2 Use-specific risk mitigation measures

None

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after major change to the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use up to 60g in bait stations.

	Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer-</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>

2.4.3.1 Use-specific instructions for use

- For rats use up to 60g in bait stations.
- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped.. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait.
- If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait

by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

None

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after major change to the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g 1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p>

<p>10g – 250 15g – 125 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof mouse bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p>

2.4.4.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped.
- Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.4.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).

Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after major change to the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation). Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 2.5 kg. Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg 1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g

50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g
 Bait station packs described above are sold for professional use in larger multi-packs:
 20g – 96, 120, 144
 40g – 72, 96, 120
 50g - 48, 60, 72, 96
 60g – 48, 60, 72, 96
 80g – 32, 48, 60, 72, 96
 100g - 32, 48, 60, 72, 96
 120g - 32, 48, 60, 72, 96
 200g – 16, 32, 48, 60, 72, 96
 240g – 16, 32, 48, 60, 72, 96
 1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:
 80g – 32, 48, 60, 72, 96
 100g - 32, 48, 60, 72, 96
 200g – 16, 32, 48, 60, 72, 96
 400g – 8, 16, 32, 48, 60, 72, 96
 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
 80g – 32, 48, 60, 72, 96
 100g - 32, 48, 60, 72, 96
 200g – 16, 32, 48, 60, 72, 96
 400g – 8, 16, 32, 48, 60, 72, 96

2.4.5.1 Use-specific instructions for use

- For rat infestations use 10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).

Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.6 Use 6 appropriate after major change to the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations. Secure 10-60g of blocks in tamper resistant baiting spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Professionals

Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p> <p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper- Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g - 250</p> <p>20g – 96, 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p>
-----------------------------------	--

100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

2.4.6.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations.
- Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves during product handling phase (EN374).

Do not apply this product directly in the burrows.

Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks</p>

	or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p> <p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer.- Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g - 250 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 240g – 16, 32, 48, 60, 72, 96</p>

<p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96 Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack: 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p>

2.4.7.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations.
- Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.

- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Remove the remaining product at the end of treatment period.
- Do not use this product for permanent baiting.
- If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the

	<p>bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p> <p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs: 10g - 250</p>

20g – 96, 120, 144
30g – 96, 120, 144
40g – 72, 96, 120
50g - 48, 60, 72, 96
60g – 48, 60, 72, 96
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
120g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
240g – 16, 32, 48, 60, 72, 96
1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96
Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:
80g – 32, 48, 60, 72, 96
100g - 32, 48, 60, 72, 96
200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

2.4.8.1 Use-specific instructions for use

- For mice use up to 20g in tamper-resistant bait stations.
- Secure 5-20g of blocks in tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.
- For rats up to 60g in tamper-resistant bait stations or covered bait points.
- Secure 10-60g of blocks in tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near

the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size.

- Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after major change to the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole). Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>20g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p>

200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96

2.4.9.1 Use-specific instructions for use

- In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole).
- Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.
- [If national policy or legislation requires it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Wear protective chemical resistant gloves during product handling phase (EN374).
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Do not open the sachets containing the bait (only for individually wrapped blocks authorised for use by the General Public).
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.

- Where possible, bait stations must be fixed to the ground or other structures.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Do not use brodifacoum containing products as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only").
- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.

Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

Keep only in original container.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant supported the evaluation of the active substance at EU level and has full access to the documents submitted by the taskforce for the EU review programme.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice up to 20g in bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 100g Refill packs of multiple blocks (maximum pack sizes 100g): 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box 5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer 2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g 1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer - Up to 80g

	<p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 80g</p> <p>1 - 5 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. – Up to 100g.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 100g.</p>
--	--

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For rats use up to 60g in bait stations. Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoiled bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	General Public
Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.</p> <p>Additional blocks may be included as refills in the outer. - Up to 240g</p>

	<p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>
--	---

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	<p>For rats use up to 60g in bait stations.</p> <p>Secure 10-60g of blocks in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	General Public
Pack sizes and packaging material	<p>Maximum quantity of bait per pack 300g</p> <p>Refill packs of multiple blocks (maximum pack sizes 300g):</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE within a PE or PP tub or pail</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in PE lined cardboard outers or PE bags in cardboard box</p> <p>5g, 10g, 20g, 28g, 50g and 60g blocks loose or wrapped in PP or PE packed in paper/PE/PE/AL, PP, PET/PE or laminated PP pouches – sold as they are or in cardboard outer-</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.</p> <p>Additional blocks may be included as refills in the outer - Up to 240g</p>

	<p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer - Up to 200g</p> <p>1 -15 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station.</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 300g.</p>
--	--

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p>

	<p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g – 250 15g – 125 20g – 96, 120, 144 30g – 96, 120, 144 40g – 72, 96, 120 50g - 48, 60, 72, 96 60g – 48, 60, 72, 96 80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 120g - 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof mouse bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96 100g - 32, 48, 60, 72, 96 200g – 16, 32, 48, 60, 72, 96 400g – 8, 16, 32, 48, 60, 72, 96</p>
--	--

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	10-60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).

	Regularly check bait consumption and replace consumed or spoiled bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>20g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p>

3.1.6 Use 6 - House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations. Secure 5-20g of blocks in tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations. Secure 10-60g of blocks in tamper resistant baiting spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p>

	<p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper- Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g - 250</p> <p>20g – 96, 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p>
--	---

3.1.7 Use 7 - House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p> <p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or</p>

	<p>cardboard sleeve. Additional blocks may be included as refills in the outer.- Up to 120g</p> <p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g - 250</p> <p>20g – 96, 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p>
--	---

3.1.8 Use 8 - House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	House mouse (<i>Mus musculus</i>) – adults and juveniles Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	<p>For mice use up to 20g in tamper-resistant bait stations or covered bait points. Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p> <p>For rats up to 60g in tamper-resistant bait stations or covered bait points. Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.</p>
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>2, 3 or 4 x 5g blocks packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 80g</p> <p>1 or 2 x 10g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve. Additional blocks may be included as refills in the outer. - Up to 120g</p>

	<p>1 x 20g blocks packed in a single or multi-use tamper-proof mouse PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2, 3, 4, 5 or 6 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 120g</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>10g - 250</p> <p>20g – 96, 120, 144</p> <p>30g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rodent bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p>
--	---

3.1.9 Use 9 - Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide

Target organism(s) (including development stage)	Brown rats (<i>Rattus norvegicus</i>) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	In sewers, place 200 g to 300 g of blocks every 30-50m (never more than 300 g at each manhole). Secure the blocks to available structures to ensure they are not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	<p>Minimum pack size of 2.5 kg.</p> <p>Loose 5g, 10g, 20g, 28g, 50g and 60g blocks within a PE or PP tub or pail - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g, 60g, 100g or 200g blocks either unlined or within a PP or wire-tied PE bag within a double-walled or fibreboard carton - Up to 20kg</p> <p>Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with pop-out blocks) - Up to 12 kg</p> <p>1, 2 or 3 x 20g blocks packed in a single or multi-use tamper-proof rat PET, HIPS, PVC, PE, HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Additional blocks may be included as refills in the outer. - Up to 240g</p> <p>50g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper - Up to 200g</p> <p>Bait station packs described above are sold for professional use in larger multi-packs:</p> <p>20g – 96, 120, 144</p> <p>40g – 72, 96, 120</p> <p>50g - 48, 60, 72, 96</p> <p>60g – 48, 60, 72, 96</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>120g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>240g – 16, 32, 48, 60, 72, 96</p> <p>1 -20 x 20g in a PE sachet or PE, PVC or HIPS clamshell/blister packed in an outer with a multi-use PE, PP, PET, HIPS, PVC tamperproof rat bait station. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p> <p>200g – 16, 32, 48, 60, 72, 96</p> <p>400g – 8, 16, 32, 48, 60, 72, 96</p> <p>Refill pack - Blister pack, pouch or sachet (paper/PE, AL/PE, paper/Al/PE, PE, PP, PET, HIPS, PVC) in a cardboard outer (10g or 20g blocks) – Up to 400g. Multiple units within a pack:</p> <p>80g – 32, 48, 60, 72, 96</p> <p>100g - 32, 48, 60, 72, 96</p>

200g – 16, 32, 48, 60, 72, 96
400g – 8, 16, 32, 48, 60, 72, 96

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Vertox 25 Oktablok (red) is a ready-to-use, grain based cast block bait formulation for the control of mice and brown rats in a number of proposed use scenarios (section 3.1.1). The product is intended for use by amateurs, professionals and trained professionals for the control of house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*).

The applicant provided a comprehensive and valid justification not to repeat the laboratory palatability studies. Their case for extrapolation of the dose from 50ppm to 25ppm (ref: Regulatory Case in support of Vertox 25 Oktablok) took into account the minor changes to the composition of the product and also used worst-case data from palatability choice tests. Minor changes in the preservative and solvents used are not deemed to present any adverse effect the palatability of the product, nor are the inclusion of two additional components in the formulation tested for efficacy which are not present in the current version:

Using the previously evaluated laboratory palatability study data, the likely toxicity of the 25ppm product was predicted. Taking the worst-case data in choice testing, house mouse diet consisted of 36% of bait and rat diet consisted of 35.1% of bait. Using predictions that a rat eats 10% of its bodyweight per day and a mouse eats 20% of its bodyweight per day (i.e. 1g/kg for a rat and 2 g/kg for a mouse) it was estimated that a brown rat would consume a lethal dose and 0.32 days and a mouse would consume a lethal dose in 0.22 days.

The results of two field trials demonstrated that the 25ppm product is both palatable to, and effective in controlling target populations of brown rats and house mice when applied according to the label advice. The block bait formulation proved to be both attractive to and effective against infestations of brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*) in the trials and provided complete (100%) control of the infestations treated based upon census baiting and tracking data.

Potential for the development for resistance owing to the reduction in active content in the product:

The applicant claims that that a 25ppm Brodifacoum bait presentation would suffer no lack in control in regards to resistance for the following reasons.

- Out of all the gene loci so far identified which have been shown to confer resistance to the Second and First Generation Anticoagulants (SGAR/FGAR), none have shown a practical resistance to Brodifacoum.
- The average lethal dose for Brodifacoum at 25ppm is around 3grams for a 250gram rat. Even if a resistance loci were to occur which showed a x10 resistance to Brodifacoum (considered to be the threshold of practical resistance in SGAR's where resistance has already been identified) this would translate to a consumption of an average lethal dose of 30 grams. This level of bait would easily be consumed over a 2-3 day period even with food competition being a factor.
- At present the maximum identified tolerance to Brodifacoum is a resistance factor of 1.8 in rats showing the Y139C gene variant.
- Therefore if proper integrated pest management is observed there is no reason that a rat or a mouse population would be repeatedly exposed to chronic partial dosing, meaning there should be little if not any population bias towards animals which are showing any partial resistances.

The applicant's defence of the reduced active substance not being a factor in the development of resistance are regarded as robust by the IE CA and the points outlined above are discussed in greater detail in the Rodenticide Resistance Action Committee resistance guidelines (RRAC guidelines on Anticoagulant Rodenticide Resistance Management, September 2015)

No efficacy data using the wax block formulation was provided for the black rat (*Rattus rattus*) therefore only claims relating to control of the brown rat (*Rattus norvegicus*) and house mice (*Mus musculus*) are authorised. References to UK specialist agencies on the proposed product label should be amended in line to reflect Irish local/national waste disposal regulations.

The label reference to permanent baiting must be removed in accordance with the BPC opinion. The use of pulse baiting techniques is authorised for trained professional users only.

Data previously evaluated demonstrated that Vertox 25 Oktablok is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been demonstrated. These findings remain valid for the 25ppm product.

3.6 Risk assessment for human health

Similarly to the previous evaluation, a dermal absorption value of 0.047% was used for brodifacoum for the wax block product. The dermal absorption value for brodifacoum was obtained by way of read across from studies on a wax block product containing difenacoum.

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:

A read across from difenacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance (EFSA Journal 2012; 10(4):2665).

Re-assessment of the relevant data:

The product has been evaluated using the reduced active ingredient concentration and new dermal absorption.

3.6.3 Exposure assessment

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products. The dermal absorption value used previously for difenacoum of 0.047% was used for brodifacoum by way of read across for the wax block product.

Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE.

The AELs considered in the risk characterization for *Brodifacoum* were:

AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)

AEL_{medium term} of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day

AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 8 Kg based on HEEG opinion endorsed at TM II 2013.

Biocidal Exposure Risk assessment for Vertox 25 Oktablok Brodifacoum rodenticide (25 ppm) using read across values for dermal absorption obtained from difenacoum of 0.047% (block).

Professional user

	Block
Without PPE	19.9% of AEL (0.001 µg/kg bw/day)
With PPE	1.9% of AEL (0.0001 µg/kg bw/day)

Non-trained professional user (farmer)

	Block
Without PPE	0.896% of AEL (0.00006 µg/kg bw/day)
With PPE	0.0896% of AEL (0.000001 µg/kg bw/day)

Exposure to children (Infant)

	Block

Oral exposure -treated with repellent	947% of AEL (0.00003125 mg/kg bw/day)
Oral exposure - without repellent	473484% of AEL (0.015625 mg/kg bw/day)
<p>Derived values indicated safe usage scenarios for professional users handling the brodifacoum block product, both with and without PPE. Derived values for professional users handling the block product without PPE were 0.001 µg/kg bw/day (19.9% AEL). Derived values for professional users handling the block product with PPE were 0.0001 µg/kg bw/day (1.9% AEL).</p> <p>Derived values indicated safe usage for non-trained professional users handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.00006 µg/kg bw/day (0.896% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.000006 µg/kg bw/day (0.0896% AEL).</p> <p>The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.00006 µg/kg bw/day (0.896% AEL).</p> <p>Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.</p>	

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product²⁶

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated safe usage scenarios for professional users handling the brodifacoum block product, both with and without PPE. Derived values for professional users handling the block product without PPE were 0.001 µg/kg bw/day (19.9% AEL). Derived values for professional users handling the block product with PPE were 0.0001 µg/kg bw/day (1.9% AEL).

Derived values indicated safe usage for non-trained professional users (farmer) handling the block product with and without PPE. Derived values for non-trained professional users handling the block product without PPE were 0.00006 µg/kg bw/day (0.896% AEL). Derived values for non-trained professional users handling the block product with PPE were 0.000006 µg/kg bw/day (0.0896% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.00006 µg/kg bw/day (0.896% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the infant found transient mounting of a block not containing a repellent to result in a dose of 0.0156 mg (473484% AEL). Derived values for oral exposures in the infant found transient mounting of a block containing a repellent to result in a dose of 0.00003125 mg (947% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

the risk in case of exposure to several active substances or substances of concern within a product]

3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the major change. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The change in active substance concentration from 0.005% to 0.0025% will result in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides

As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:

- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

As the major change will lead to a lower PECgw a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0025% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios $PEC/PNEC$ are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	$PEC/PNEC$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	8.64	6.22	0.00013	66462	47846
Chaffinch	7.5	5.4	0.00013	57692	41538
Wood pigeon	2.71	1.95	0.00013	20846	15000
Pheasant	2.69	1.94	0.00013	20692	14923
Dog	1.5	1.08	0.000222	6757	4865
Pig	0.188	0.135	0.000222	847	608
Pig, young	0.6	0.432	0.000222	2703	1946

The ratios $PEC/PNEC$ are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral}/PNEC_{ratio}$ after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral}/PNEC_{ratio}$ are above 1 after 1-day elimination of

Brodifacoum indicating a potential risk (data not shown). The $EC_{oral}/PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw) ^a	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw) ^a	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	15.31	11.02	0.00013	84836
Chaffinch	13.3	9.58	0.00013	73662
Wood pigeon	4.8	3.46	0.00013	26585
Pheasant	4.77	3.43	0.00013	26418
Dog	2.66	1.92	0.000222	8627
Pig	0.333	0.240	0.000222	1080
Pig, young	1.06	0.76	0.000222	3438

^a calculation according to equation 21 in the ESD

The ratios $PEC/PNEC$ are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The $PEC_{oral}/PNEC_{oral}$ values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated ($ETE_{oral\ predators}$) and compared to the $PNEC_{oral}$

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	ETE _{oral} predators (mg a.s./kg/d)	PNEC _{oral} (mg a.s./kg/d)	Ratio ETE _{oral} predators / PNEC _{oral}
Barn owl	Day 5 before the last meal	0.549	0.00013	4224
	Day 5 after the last meal	0.895		6885
	Day 14 after the last meal	1.02		7892
Kestrel	Day 5 before the last meal	0.83	0.00013	6415
	Day 5 after the last meal	1.35		10456
	Day 14 after the last meal	1.55		11896
Little owl	Day 5 before the last meal	0.62	0.00013	4820
	Day 5 after the last meal	1.02		7856
	Day 14 after the last meal	1.17		9005
Tawny owl	Day 5 before the last meal	0.50	0.00013	3883
	Day 5 after the last meal	0.82		6329
	Day 14 after the last meal	0.94		7255
Fox	Day 5 before the last meal	0.20	0.000222	910
	Day 5 after the last meal	0.32		1484
	Day 14 after the last meal	0.37		1701
Polecat	Day 5 before the last meal	0.42	0.000222	1895
	Day 5 after the last meal	0.68		3089
	Day 14 after the last meal	0.78		3541
Stoat	Day 5 before the last meal	0.60	0.000222	2710
	Day 5 after the last meal	0.98		4418
	Day 14 after the last meal	1.12		5064
Weasel	Day 5 before the last meal	0.86	0.000222	3911
	Day 5 after the last meal	1.41		6375
	Day 14 after the last meal	1.62		7307

All ratios ETE_{oral} predators / PNEC_{oral} are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk assessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As brodifacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The Opinion states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Opinion forms the basis of the Commission Implementing Decision addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

On the basis of this comparative assessment, the authorisation of rodenticide products containing brodifacoum is justified.

4 General Annexes

4.1 List of studies for the biocidal product (family)

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
██████████	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Wax Block against the house mouse (<i>Mus musculus</i>)	unpublished	PEL-BCM25WBB0615-Mm01-0216	██████████ ██████████	29/2/2016	Non-GLP	Y
██████████	2016	A field trial to establish the efficacy of a 25ppm Brodifacoum Wax Block against the brown rat (<i>Rattus norvegicus</i>)	unpublished	PEL-BCM25WBB1015-Rn01-0416	██████████ ██████████	13/4/2016	Non-GLP	Y

4.2 Output tables from exposure assessment tools

None


4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Summaries of the efficacy studies (B.5.10.1-xx)²⁷

Function and field of use envisaged	Test substance	Test organism(s)	Test method, test system/concentrations applied/ exposure time	Test results; effects	Reference																												
Vertox 25 Oktablok (PT14)	A wax block bait containing 25 ppm Brodifacoum	Brown Rat (<i>Rattus norvegicus</i>) Wild population located on a poultry farm in Chelmsford, UK (resistance status unknown)	Field trial conducted on a poultry farm. Activity noted from rat prints, faeces, rat runs and rats seen running around water tanks and into drainage pipes. Five locations used for; pre-treatment census, treated bait and post-treatment census points. A pre-treatment census using untreated whole grain and sand trays employed for 4 days. One day lag period. 25ppm Wax block Bait was placed into commercially available tamper proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.	<table border="1"> <thead> <tr> <th>Bait consumption</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> </thead> <tbody> <tr> <td>Total bait consumption (g)</td> <td>509</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily bait consumption (g)</td> <td>94</td> <td>0</td> <td>100</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <th>Activity over sand patches</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> <tr> <td>Total activity score</td> <td>7</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily activity score</td> <td>3</td> <td>0</td> <td>100</td> </tr> </tbody> </table> <p>Extended baiting period was observed and explained as being due to some of the population exhibiting a</p>	Bait consumption	Pre-treatment census	Post-treatment census	% control	Total bait consumption (g)	509	0	100	Maximum daily bait consumption (g)	94	0	100					Activity over sand patches	Pre-treatment census	Post-treatment census	% control	Total activity score	7	0	100	Maximum daily activity score	3	0	100	 (2016)
Bait consumption	Pre-treatment census	Post-treatment census	% control																														
Total bait consumption (g)	509	0	100																														
Maximum daily bait consumption (g)	94	0	100																														
Activity over sand patches	Pre-treatment census	Post-treatment census	% control																														
Total activity score	7	0	100																														
Maximum daily activity score	3	0	100																														

²⁷ If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

			<p>The trial was ended after 26 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</p>	<p>neophobic response to the bait placement, this may have been compounded by movement of farm material on site at the beginning of the trial. 942g of treated bait was consumed during the 26 day baiting phase. No evidence was found during the trial that the use of 25ppm Brodifacoum Wax block Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. Complete (100%) control of <i>Rattus norvegicus</i> achieved based on census baiting and tracking.</p>																													
Vertox 25 Oktablok (PT14)	A wax block bait containing 25 ppm Brodifacoum	House mouse (<i>Mus musculus</i>) Wild population located on a poultry farm in Chelmsford, UK (resistance status unknown)	<p>A pre-treatment census using untreated whole grain and sand trays was employed to measure rodent populations both quantitatively and qualitatively for a period of 4 days prior to commencement of the test.</p> <p>The pre-treatment census showed a population of rodents primarily established inside a grain silo. Droppings established these rodents to be mice.</p> <p>A lag period of three days between the census data and the trial was observed.</p> <p>The trial was then undertaken using the product as per the proposed label instructions.</p> <p>25ppm Wax Block Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken every two days. Bait points which dropped below 20g or that had been spoilt</p>	<table border="1"> <thead> <tr> <th>Bait consumption</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> </thead> <tbody> <tr> <td>Total bait consumption (g)</td> <td>53</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily bait consumption (g)</td> <td>16</td> <td>0</td> <td>100</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <th>Activity over sand patches</th> <th>Pre-treatment census</th> <th>Post-treatment census</th> <th>% control</th> </tr> <tr> <td>Total activity score</td> <td>10</td> <td>0</td> <td>100</td> </tr> <tr> <td>Maximum daily activity score</td> <td>4</td> <td>0</td> <td>100</td> </tr> </tbody> </table> <p>30g of treated bait was consumed during the 6 day baiting phase.</p>	Bait consumption	Pre-treatment census	Post-treatment census	% control	Total bait consumption (g)	53	0	100	Maximum daily bait consumption (g)	16	0	100					Activity over sand patches	Pre-treatment census	Post-treatment census	% control	Total activity score	10	0	100	Maximum daily activity score	4	0	100	<p>██████████ 2016)</p>
Bait consumption	Pre-treatment census	Post-treatment census	% control																														
Total bait consumption (g)	53	0	100																														
Maximum daily bait consumption (g)	16	0	100																														
Activity over sand patches	Pre-treatment census	Post-treatment census	% control																														
Total activity score	10	0	100																														
Maximum daily activity score	4	0	100																														

			<p>were either topped up or swapped with fresh bait.</p> <p>The trial was ended after 6 days, when activity on the site had dropped to zero and further variances in bait point weight were deemed to be environmental rather than through rodent activity. At this point a post-treatment census was undertaken.</p>	<p>No evidence was found during the trial that the use of 25ppm Brodifacoum Wax block Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. Complete (100%) control of <i>Mus musculus</i> achieved based on census baiting and tracking.</p>	
--	--	--	---	---	--

4.6 Other

None

5 Confidential annex (Access level: "Restricted" to applicant and authority)

