Product Assessment Report

Derat®

Internal registration/file no: UR.DRB.RBE.4230.0002.2012.AB

Authorisation no: PL/2014/0116

Granting date: 28.02.2014

Biocidal product assessment report related to national authorisation under Biocidal Product Regulation 528/2012

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1 General information about the product application

1.1 Applicant

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1.1.1 Person authorised for communication on behalf of the applicant

Name:	Halina Daraż
Function:	Chairman of the management board
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1.2 Information about the product application

Application received:	27 January 2012
Application reported complete:	25 May 2012
Type of application:	National authorisation
Further information:	No

1.3 Information about the biocidal product

1.3.1 General information

Trade name:	Derat®
Manufacturer's development code number(s), if appropriate:	–
Product type:	14 (Rodenticides)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Brodifacoum 0.005 %
Formulation type:	Wax blocks (rings)
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	No

1.3.2 Information on the intended use

Overall use pattern (manner and area of use):	▪ In and around buildings (e.g. live-stock buildings); ▪ Open areas (e.g. parks, tennis courts, camping sites and other places of the public utility) ▪ Waste dumps ▪ Sewers
Target organisms:	Brown rat *(Rattus norvegicus)* House mouse *(Mus musculus)*
Category of users:	Non-professional Professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	*Rats*: 200 g (14 wax blocks) per bait station spaced at 15 m. Typical treatment time 20 days (according to field trial) *Mice*: 100 g (7 wax blocks) per bait station spaced at 3 – 4 m. Typical treatment time 20 days (according to field trial)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/ feeding stuff (yes/no)	No
Proposed Label:	Annex 8
Use Restrictions:	Please refer to section 2.9

1.3.3 Information on active substance

Active substance chemical name:	Brodifacoum 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]- 4-hydroxycoumarin
CAS No:	56073-10-0
EC No:	259-980-5
Purity (minimum, g/kg or g/l):	950 g/kg
Inclusion directive:	2010/10/EU
Date of inclusion:	01.02.2012

Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes

Manufacturer of active substance used in the biocidal product

Company Name:	PelGar International Limited
Address:	Unit 13 Newman Lane Alton
City:	Hampshire
Postal Code:	GU34 2QR
Country:	UK
Telephone:	+ 44 (0)1420 80744
Fax:	+ 44 (0)1420 80733
E-mail address:	info@pelgar.co.uk

1.3.4 Information on the substance(s) of concern

Substance chemical name	–
CAS No:	–
EC No :	–
Purity (minimum, g/kg or g/l):	–
Typical concentration (minimum and maximum, g/kg, or g/l):	–
Relevant toxicological/ecotoxicological information:	–
Original ingredient (trade name):	–

1.4 Documentation

1.4.1 Data submitted in relation to product application

Please see Annex 1.

1.4.2 Access to documentation

"FREGATA" S.A. has letter of access to data held by PelGar International Limited which was used to support the Annex I listing of the active substance brodifacoum according to Directive 98/8/EC.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product Derat® contains the active substance brodifacoum (0.005%) (purity ≥ 950 g/kg).

The source of active substance used in the biocidal product is identical to the source of the active substance listed in Annex I of 98/8/EC.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Product classification: None

2.2.2 Labelling of the biocidal product

The current Classification of brodifacoum under EC 1272/2008 is:

Acute Toxic, Category 1 H310 Fatal in contact with the skin
H300 Fatal if swallowed

STOT RE, Category 1 H372 Causes damage to organs through prolonged or repeated exposure .

Aquatic Acute, Category 1 H400 Very toxic to aquatic life

Aquatic Chronic, Category 1 H410 Very toxic to aquatic life with long lasting effects

Classification and labelling of the product:

H-phrases
None

P-phrases
P102 - Keep out of reach of children.
P280 - Wear protective gloves.

2.2.3 Packaging of the biocidal product

The packaging details for the biocidal product Derat® are outlined below for non-professional and professional users.

Packing type	Pack sizes for non professional use	Pack sizes for professional use
Welded PET/Al/PE bag made of foil resistant to tearing. On front of the bag clearly warning "*Keep out of the reach of children*"	200 g	200 g
Welded PET/Al/PE bag made of foil resistant to tearing. On front of the bag clearly warning "*Keep out of the reach of children*"	400 g	400 g
Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, protected with an additional seal. Protective gloves inside bucket.	1 kg	1 kg
Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, protected with an additional seal. Protective gloves inside bucket.	–	5 kg
Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, protected with an additional seal. Protective gloves inside bucket.	–	10 kg

2.3 Physical-chemical properties and analytical methods

Product Derat® is ready-to-use, block bait containing brodifacoum active substance The active substance is supplied to the producer, "FREGATA" S.A., by PelGar International Limited company (one of the active substance notifiers) in a form of a concentrate for which full, detailed composition is submitted to the Polish Competent Authority.

Derat® is claret, grain smelling product. Since none of the components is classified as explosive or oxidizing, it can be anticipated that Derat® has neither explosive nor oxidizing

properties (also confirmed by structural analysis of individual ingredients). Moreover, none of the components showed self-ignition up to 400°C (see relevant MSDS) and none is classified as flammable/highly flammable. Due to these facts, it can be anticipated that Derat® is neither highly flammable nor auto-flammable. Additionally, none of the components is known to evolve any flammable gases in contact with water, humid air or to has pyrophoric properties either. Density of the product in the temperature of 20°C is equal to 1.0929 g/cm^3. Water suspension of the product gives light-acetic pH (1%, pH=6.02 to 6.01).

The technical characteristic of a product is documented. Blocks integrity was tested before and after accelerated storage stability test, which also confirms the stability of the product for eight weeks in 40^{o}C. Owing to the physical state and nature of Derat®, no further testing of technical properties is deemed necessary.

The active substance content decreased from 0.0434 g/kg to 0.0416 g/kg after storage stability test. The loss of 4.15% is acceptable taking into consideration formulation type.

The results of the accelerated storage stability test and also stability of technical characteristics proved that the shelf life of the product is acceptable up to two years in ambient conditions.

The UV–VIS detection-HPLC analytical method based on SANCO/3030/99 rev. 4 requirements is fully validated and it is acceptable for determination of the active substance content in the product.

2.3.1 Physical-chemical properties

Physical-chemical properties of the active substance:

The letter of access from PelGar International Limited, granted to "FREGATA" S.A., has been submitted for the active substance therefore no additional information for this point is needed.

Physical-chemical properties of the biocidal product:

	Method	Purity/ Specification	Results	Reference
Physical state and nature	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6302	Derat, batch no (lot No.) 22112011 Specification.: SP-DERAT -01/12 with additional statement	solid, wax block bait (rings)	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2

	Method	Purity/ Specification	Results	Reference
Colour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6303	Derat batch no (lot No.) 22112011 Specification.: SP-DERAT -01/12 with additional statement	claret	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Odour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6304	Derat, batch no (lot No.) 22112011 Specification.: SP-DERAT -01/12 with additional statement	of grain	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Explosive properties	n.a	n.a	Due to the properties of components it can be assumed that Derat® does not possess explosive properties.	n.a
Oxidizing properties	n.a	n.a	Due to the properties of components it can be assumed that Derat® does not possess oxidizing properties.	n.a
Flash point	n.a	n.a	Due to the properties of components it can be assumed that Derat® is not highly flammable.	n.a
Autoflammability	n.a	n.a	The self-ignition none of individual components occurs up to 400 °C so it can be assumed that Derat® is not autoflammable.	n.a
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	CIPAC MT 75.3	Derat batch no (lot No.) 22112011 Specification.: SP –DERAT-01/12 with additional statement	pH of 1% water suspension is 6.02 before and 6.01 after accelerated storage stability test	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Relative density /	PN-C-	Derat, batch no	1.0929 g/cm^3	FRE 05/12

	Method	Purity/ Specification	Results	Reference
bulk density	89035:1980	(lot No.) 1209015 Specification.: SP-DERAT -01/12 with additional statement		
Storage stability – stability and shelf life	CIPAC MT 46 (8 weeks 40 °C)	Derat, batch no (lot No.) 22112011 Specification: SP-DERAT -01/12 with additional statement	Derat® is stable for eight weeks in 40 °C	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Effects of temperature	CIPAC MT 46	Derat, batch no (lot No.) 22112011 Specification.: SP-DERAT -01/12 with additional statement	Derat® is stable for eight weeks in 40 °C	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Reactivity towards container material	CIPAC MT 46	Derat, batch no (lot No.) 22112011 Specification: SP-DERAT -01/12 with additional statement	the weight, colour and shape of container as well as physical-chemical properties of product were not changed during storage stability test	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Technical characteristics in dependence of the formulation type ***Blocks integrity***	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6302 to 830.6304	Derat, batch no (lot No.) 22112011 Specification: SP-DERAT -01/12 with additional statement	integrity and dimensions of blocks were not changed after accelerated storage stability test	EMC 375900019 study codes: BF-39/11-1 and BF-39/11-2
Capability with other products	n.a.	n.a.	Derat® will not be used with other products (especially biocidal products)	n.a.
Surface tension	n.a.	n.a.	n.a.	n.a.
Viscosity	n.a.	n.a.	n.a.	n.a.
Particle size distribution	n.a	n.a	n.a	n.a

2.3.2 Analytical methods

	Principle of method

Technical active substance as manufactured:	–
Impurities in technical active substance:	–
Active substance in the formulation:	Specific analytical method with validation data was established for determination of content of the active substance in the product. The UV–VIS detection-HPLC method is based on SANCO/3030/99 rev. 4 requirements.

2.4 Risk assessment for physical-chemical properties

Based on the physical-chemical data submitted for Derat® it can be concluded that there are no additional, specific, physical-chemical risks for the product. Due to the properties of particular components it can be assumed that Derat® has no explosive nor oxidizing properties and is not highly flammable. Also there are not autoflammability indications. Technical properties characteristics of the product were done before and after accelerated storage stability test. No additional risks are found based on technical characteristics of the product.

2.5 Effectiveness against target organisms

Function

The biocidal product Derat® will be used as rodenticide (PT 14) for the control of commensal rodent species.

The product is intended for use by professional and non-professional users in and around buildings (e.g. live-stock buildings), in open areas (e.g. parks, tennis courts, camping sites and other places of the public utility).

In sewers and in waste dumps product can be used only by professional users.

Organisms to be controlled

Derat® is intended to be used against *Rattus norvegicus* (brown rat) and *Mus musculus* (house mouse).

2.5.1 Dose / mode of action

Test organism(s)	Test system	Test conditions	Test results	Reference
House mouse *(Mus*	Field test done according to	The size of rodents population was evaluated	The study indicates that:	IIIB5.10.2/1

musculus)	method FRE/RT-03/2007	by measure of control bait intake at the beginning and the end of the study. 100 g Derat® (6 bait blocks) has been placed into each bait station spaced every 3 – 4 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested: 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait 3) percentage of active holes	1) intake of control bait was reduced 88.2% 2) intake of tested bait was reduced 87.8% 3) percentage of active holes was reduced to 16.0%	
Brown rat *(Rattus norvegicus)*	Field test done according to method FRE/RT-03/2007	The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study. 200 g Derat® (12 bait blocks) has been placed into each bait station located every 15 meters in infested area. Bait stations were refilled 5 times every 3 days. After 20 days three parameters were tested: 1) percentage loss of intake control bait, 2) percentage loss of intake poison bait 3) percentage of active holes	The study indicates that 1) intake of control bait was reduced 87.0% 2) intake of tested bait was reduced 85.2% 3) percentage of active holes was reduced to 9.5%	IIIB5.10.2/1
House mouse *(Mus musculus)*	Palatability test done according to method EPPO 1982 "Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations"	Control group (10 males and 10 females) Tested group (10 males and 10 females) Total time of study 22 days includes pre-treatment period (4 days), treatments period (4 days) and observation period (14 days)	Total mortality of mouse has reached 85% and edibility was at the level 30.8%. Palatability ratio for males was 0.3 and for females 0.8. The average mortality for males has occurred at 7.5 day (5 – 14 days) with average consumption of bait 11.3 mg/kg b.w. For females average	IIIB5.10.2/3

			mortality has occurred at 10.4 day (6 – 13 days) with average consumption of bait 19.1 mg/kg b.w.	
Brown rat *Rattus norvegicus*	Palatability test done according to method EPPO 1982 "Laboratory Tests for Evaluation of the Toxicity and Acceptability of Rodenticides and Rodenticide Preparations"	Control group (10 males and 10 females) Tested group (10 males and 10 females) Total time of study 22 days includes pre-treatment period (4 days), treatments period (4 days) and observation period (14 days)	Total mortality of rats has reached 90% and edibility was at the level 45.2%. Palatability ratio for males was 1.4 and for females 0.9. The average mortality for males has occurred at 8.4 day (5 – 12 days) with average consumption of bait 6.6 mg/kg b.w. For females average mortality has occurred at 10.1 day (7 – 18 days) with average consumption of bait 6.4 mg/kg b.w.	IIIB5.10.2/2

2.5.2 Known limitation

In order to limit risk of poisoning and contamination of environment the following conditions should be ensured:

1) the nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready for use baits shall be authorised;
2) product shall contain an aversive agent and where appropriate a dye;
3) products shall not be used as tracking powder;
4) primary as well as secondary exposure of humans, non-target animals and the environment are minimized, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, setting an upper limit to package size and laying down obligations to use tamper resistant and secured bait boxes.

2.5.3 Resistance

1) The population size of the target rodent should be evaluated before the control campaign.

2) The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
3) A complete elimination of rodents in the infested area should be achieved.
4) The use instructions of products should contain guidance on resistance management for rodenticides.
5) Brodifacoum should not be used in an area where resistance to this substance is suspected.
6) The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

2.6 Exposure assessment

2.6.1 Description of the intended use

Derat® is a rodenticides wax block bait for the effective control of rat and mice species. Derat® takes the form of a ready to use wax block bait containing 0.005% w/w (50 ppm) brodifacoum, second-generation and single-dose anticoagulant, which causes death due to massive internal haemorrhages after several days of ingestion as a consequence of an accumulated lethal dose. Other than the active ingredient, the product is composed of food-grade materials forming a bait base.

2.6.2 Assessment of exposure to humans and the environment

The active substance brodifacoum is the only substance of concern in biocidal product Derat®. New exposure studies have not been submitted and the risk assessment was performed based on the information presented in CAR[1].

2.7 Risk assessment for human health

The biocidal product Derat® is in the form of a ready to use wax block that should be put in tamper resistant bait stations. It contains 0.005% of the active substance brodifacoum. It belongs to PT 14 product group. Derat® is designed for use by professional and non-professional users. Potential exposure to product is possible for people during the product formulation and its use.

[1] Competent Authority Report available at *https://circabc.europa.eu*

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The letter of access form PelGar International Limited, granted to "FREGATA" S.A., has been submitted for the active substance brodifacoum therefore no additional information for this point is needed.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product Derat® does not contain in its composition toxicologically relevant substances (classified as dangerous according to Directive 67/548/EEC and present at concentrations likely to cause harmful effects to humans, animals or the environment), other than the active substance. The only substance important from a toxicological point of view is the active substance brodifacoum.

2.7.1.3 Toxicology of the biocidal product

The toxicological studies for the biocidal product Derat® were not performed. The toxicological evaluation of this product was based on toxicological data for the active substance brodifacoum.

Information on the assessment of the active substance brodifacoum were granted to "FREGATA" S.A. by PelGar International Limited as the brodifacoum manufacturer (based on data from letter of access dated on 14.11.2011) for the registration of the biocidal product Derat®.

Summary of toxicity data for the biocidal product Derat®:

Dermal absorption studies for biocidal product were not performed. The absorption for biocidal product will be comparable to dermal absorption of the active substance. Two values of dermal absorption were taken into account for the calculation of dermal exposure for professional and non-professional users: 0.047% and 3% (values derived from *Assessment Report*[2]).

Oral LD_{50} (mouse):

[2] *Assessment Report* is part of *Competent Authority Report* with is available at *https://circabc.europa.eu*

8 g/kg b.w. (male)

Dermal LD_{50} (rat):

63.2 g/kg b.w. (female)

Inhalation LC_{50} (rat):

61 g/l (female)

Inhalation acute studies for biocidal product were not performed. Due to that brodifacoum has a low vapour pressure (1 x 10^{-6} Pa at room temperature) and the product is not dust releasing and consists of solid particles exposure via inhalation is expected to be negligible.

Irritation to skin

Not irritating to skin

Irritation to eye

Not irritating to eye

Sensitizing to skin

Not a skin sensitizer

2.7.2 Exposure

The calculations of exposure have been performed in accordance with the assumptions of document published by the European Commission, "*The Technical Notes for Guidance: Human Exposure to Biocidal Products" (TNsG June 2007)* implementing the objectives of the Directive 98/8/EC concerning the placing of biocidal products on the market.

Additionally, exposure calculations have been done based on the data from the study by J.G. Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which "FREGATA" S.A. submitted the letter of access.

Main paths of human exposure

Route of exposure	Industrial use	Professional user	Non-professional user	Bystanders
inhalation	Yes	No	No	No
dermal	Yes	Yes	Yes	Yes
oral	No	No	No	Yes

The potential exposure is identified during the formulation of the biocidal product. According to the declaration of the aplicant the packaging and the final preparing of the product is fully automatic process and no direct contact with the product is expected. For this reason the calculation of exposure at this stage was omitted. Exposure during use of the product was calculated according to the recommended scenarios and the specifications of the product were taken into account.

2.7.2.1 Exposure of professional users

2.7.2.1.1 Exposure during the formulation of biocidal product

The results of inhalation exposure measurements and information on dermal exposure during production of the biocidal product are not available. However, data on the manufacturing process, contained in Document IIIB6.6 indicates that the dermal and inhalation exposure for people working in the hall of the product formulation is likely. Data contained in Document IIIB6.6 were used to calculate the exposure according to the EASE model (EUSES 2.1)[3].

EASE – Estimations of exposure to the active substance during the formulation of the biocidal product:

Exposure path	Inhalation exposure	Dermal exposure
Estimations	wax blocks – the product is not volatile – closed system: 0.00000545 mg/kg b.w./day	wax blocks – incidental contact with skin – all hands – direct contact with the skin during handling of the product: 0 mg/kg b.w./day

The packaging of the product is done in a separate hall than the formulation process, using the confection machine and without the involvement of operators. From the confection machine, the product packed in a tightly – closed bags goes to the line of confection and where these bags are labelled and put on the pallet by people working at the confection line.
The inhalation and dermal exposure to the product during its packaging is not expected and therefore the calculation of that has been omitted.

2.7.2.1.2 Exposure during the use of biocidal product

In the estimation of exposure the following elements were taken into consideration:

- Derat® is supplied to the customer in tightly-closed packaging.

[3] The European Union System for the Evaluation of Substance (EUSES). EUSES version 2.1

- The inhalation exposure was not estimated. Derat® is not dust releasing and the active substance brodifacoum is not volatile - the risk of inhalation exposure is considered negligible.
- The dermal exposure was estimated. During the use, the Derat® should be put in tamper resistant bait stations. In that case dermal exposure may be limited only to the surface of the hands.
- The oral exposure was not estimated. It is unlikely that the product will be swallowed by professional users. It is possible, however, that contamination of the skin may indirectly lead to oral exposure.

  However, for professional users is assumed to deliberate and professional use of personal protective equipment, using appropriate personal protective equipment including protective gloves. For this reason, the risk of oral exposure in this way during the use of the product is considered to be insignificant.
- The dermal exposure was estimated at two levels:
  - Level 1 – the application without the use of personal protective equipment PPE (without gloves)
  - Level 2 – application with the use of personal protective equipment PPE (with gloves)
- The question of choosing a suitable value of percutaneous absorption (0.047% and 3%, the data from the *Assessment Report*) for the calculation of dermal exposure for products in vax formulation was discussed by countries at the European Community level, calculations were carried out using both of the above values. The risk characterisation was also made adequately. However, the dermal absorption value equal to 0.047% and associated to this calculations should be considered as appropriate for Derat®.

Estimations according to *TNsG*:

According to *TNsG*, for professional users the application phase (use) and disposal phase of the product should be considered. The calculations were performed according to formulas presented in the *TNsG* June 2007. Detailed calculations are presented in Document IIB.

For the calculations the following element were used:

Application phase:

- frequency of events per day: 8 bait stations per day (*TNsG* June 2007)
- the amount of the product per event: 14 wax blocks weighting 14 g ± 3g (Document IIIB5)

Disposal/utilization phase:

- the amount of the removed product per event: 20% of the amount of the product per event i.e. 2.8 g of the one wax block (*TNsG* June 2007)
- frequency of events per day: 1 bait station per day

Two values of dermal absorption were taken into account for the calculation of exposure, that is 0.047% and 3% (*Assessment Report*).
The operator body weight used in the calculation: 60 kg (*TNsG* June 2007)
Product density: 1.0929 g/cm^3 (Document IIIB3)

	Dermal absorption value = 0.047%		**Dermal absorption value = 3%**	
	Level 1 [mg/kg b.w./day]	**Level 2 [mg/kg b.w./day]**	**Level 1 [mg/kg b.w./day]**	**Level 2 [mg/kg b.w./day]**
Application phase	14.39×10^{-6}	14.39×10^{-7}	9.18×10^{-4}	9.18×10^{-5}
Removal of the preparation phase	1.80×10^{-6}	1.80×10^{-7}	1.15×10^{-4}	1.15×10^{-5}
Total exposure	16.19×10^{-6}	16.19×10^{-7}	10.33×10^{-4}	10.33×10^{-5}

The second level includes gloves and 10% uptake.

Estimations based on the data from a study by J.G. Chambers and P.J. Snowdon

The exposure calculations have been done also based on the data from the study by J.G. Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which "FREGATA" S.A. submitted the letter of access. Detailed calculations are presented in Document IIB.

In this study, two phases of use of the product were indicated:

Application phase – loading and placing of the biocidal product in places of rodents' presence

- frequency of events per day: 60
- the amount of the product per event: 14 wax blocks weighting 14 g ± 3 g (Document IIIB5)
- the recommended value of potential exposure: 27.79 mg (for 5 contacs with the wax blocks)

Final phase – including the removal of unused biocidal product

- frequency of events per day: 15
- recommended value to potential exposure: 5.7 mg (for 5 contacs with the wax blocks)

	Dermal absorption value = 0.047%		**Dermal absorption value = 3%**	
	Level 1 [mg/kg b.w./day]	**Level 2 [mg/kg b.w./day]**	**Level 1 [mg/kg b.w./day]**	**Level 2 [mg/kg b.w./day]**
Total exposure	1.92×10^{-6}	1.92×10^{-7}	122.71×10^{-6}	122.71×10^{-7}

The second level includes gloves and 10% uptake.

2.7.2.2 Exposure of non-professional users and the general public

To estimate the exposure for non-professional users the same elements were taken into account as for the professional users (see above).

Estimations to non-professionals according to *TNsG*:

According to *TNsG*, for non-professional users the application phase (use) and disposal phase of the product should be considered.

Application phase:

- frequency of events per day: 1 bait station per day (*TNsG* June 2007)
- the amount of the product per event: 14 wax blocks weighting 14 g ± 3 g (Document IIIB5)

Disposal/utilization phase:

- the amount of the removed product per event: 20% of the amount of the product per event i.e. 2.8 g of the one wax disc (*TNsG* June 2007)
- frequency of events per day: 1 bait station per day

	Dermal absorption value = 0.047%	**Dermal absorption value = 3%**
	Exposure value [mg/kg b.w./day]	**Exposure value [mg/kg b.w./day]**
Application phase	1.80×10^{-6}	114.8×10^{-6}
Removal of the preparation phase	1.80×10^{-6}	114.8×10^{-6}
Total exposure	3.6×10^{-6}	229.6×10^{-6}

Estimations to non-professionals based on the data from a study by J.G. Chambers and P.J. Snowdon

The exposure calculations have been done also based on the data from the study by J.G. Chambers and P.J. Snowdon, "*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*" (2004) to which "FREGATA" S.A. submitted the letter of access. Detailed calculations are presented in Document IIB.

In this study, there are two phases of use of the product:

Application phase – loading and placing of the biocidal product in places of rodents' presence

- frequency of events per day: 5
- the amount of the product per event: 14 wax discs weighting 14 g ± 3g (Document IIIB 5)
- the recommended value of potential exposure: 27.79 mg (for 5 contacts with the wax blocks)

Final phase – including the removal of unused biocidal product

- frequency of events per day: 5
- the recommended value of potential exposure: 5.7 mg (for 5 contacts with the wax blocks)

	Dermal absorption value = 0.047%	**Dermal absorption value = 3%**
Total exposure value [mg/kg b.w./day]	18.37×10^{-8}	11.72×10^{-6}

While use of the biocidal product, bystanders including for example children and infants may come into contact with the biocidal product. For example, putting poison in cardboard bait station can not prevent the child from contact with this poison. There is also likely to eat the poison by the child directly from the container in which the biocidal product is placed. Technical guidelines assume that the child can eat at one time about 5 g. The method of assessing the potential exposure for bystanders were based on default values, contained in the guidelines for Human Exposure to Biocidal Products, Section 5, Anex 4 (*TNsG* June 2007). The assumptions were adopted for the worst-case envisaged scenario – worst case scenario.

There is also potential exposure for the skin after taking the poison by hand. However, it is assumed that the exposure at this type of situation is far less compared to oral exposure and therefore dermal exposure was not calculated.

For the calculations the following element were used:

- the amount of eaten product: 5 g (*TNsG* June 2007)
- it is assumed that dermal absorption value is 100% (*TNsG* June 2007)
- body weight of child: 10 kg (*TNsG* June 2007)

	Exposure value [mg/kg b.w./day]
Exposure for child	0.025

2.7.2.3 Exposure to residues in food

Not applicable.

2.7.3 Risk Characterisation

The risk characterization was performed in accordance with the recommendations of the technical guidelines *TNsG* (Annex I Inclusion Revision of Charter 4.1: Quantitative Human Health Risk Characterisation), based on the determined values of MOE and AEL.

According to information submitted by applicant, the biocidal product Derat® does not contain in its composition any toxicologically relevant substances other than the active substance brodifacoum. For this reason, the assessment of toxicological properties of the biocidal product was based only on the data for the active substance brodifacoum, for which the letter of access was submitted by "FREGATA" S.A.

According to the information placed in the *Assessment Report* for the active substance brodifacoum this substance does not have local toxic effects. For this reason the AEC value was not set and the risk characterization has not been made with regard to local effects.

According to the information placed in the *Assessment Report* brodifacoum has systemic toxicity. This substance is so-called the second generation anticoagulant, which causes death of target organism due to massive internal haemorrhages after several days of ingestion of a lethal dose. Determined on the basis of developmental studies NOAEL value equal to 0.001 mg/kg b.w./day was used to estimation of acceptable level of exposure (AEL).

NOAEL [mg/kg b.w.]	Assessment factor (AF)			Reference doses	
	Intraspecies AF	Interspecies AF	Total AF	Absorption [%]	AEL [mg/kg b.w./day]
Two generations reproduction study (rat) 0.001	10	10	300*	100	3.3×10^{-6}

* This value results from the use of additional factors related to the general factor for anticoagulants (3)

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2.7.3.1 Risk for Professional Users

Formulation of biocidal product

Kind of exposure	Exposure value [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOEL/ exposure)
inhalation exposure	5.45×10^{-6}	3.3×10^{-6}	165.15	183.49

*Safe value ≥300

The applicant provided rather general information about the use of the active substance and contact with it at this level. Therefore EASE model was used as most appropriate in such situations. Please note that this model gives results with a rather large margin of safety. The applicants should be required, in accordance with their declarations to supplied the workers which are in contact with the active substance the personal protective equipment. In addition, it should be noted that safety at job is subject to different legislation, defining the rules of work and provide for the inspection of work safety.

Professional user (dermal absorption value = 0.047%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	16.19×10^{-6}	3.3×10^{-6}	490.61	61.77
Level II	16.19×10^{-7}	3.3×10^{-6}	49.061	617.67
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	1.92×10^{-6}	3.3×10^{-6}	58.2	520.83
Level II	1.92×10^{-7}	3.3×10^{-6}	5.82	5208.33

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which is recommended to determine the exposure to rodenticides is indicating less exposure than the acceptable exposure level.

It can be concluded that there is no real risk associated with use of the product Derat® for professional users (dermal absorption value = 0.047%).

Professional user (dermal absorption value = 3 %)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL × 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	10.33×10^{-4}	3.3×10^{-6}	31 303.03	0.97
Level II	10.33×10^{-5}	3.3×10^{-6}	3 130.30	9.68
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	122.71×10^{-6}	3.3×10^{-6}	3 718.48	8.15
Level II	122.71×10^{-7}	3.3×10^{-6}	371.85	81.49

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which is recommended to determine the exposure to rodenticides is indicating the risk due to use of the product Derat® for professional users (dermal absorption value = 3%).

It can be concluded that there is a real risk associated with use of the product Derat® for professional users. The question of choosing a suitable value of percutaneous absorption (0.047% and 3%, the data from the *Assessment Report*) for the calculation of dermal exposure for products in vax formulation was discussed by countries at the European Community level, calculations were carried out using both of the above values. The risk characterisation was also made adequately. However, the dermal absorption value equal to 0.047% and associated to this calculations should be considered as appropriate for Derat®.

Therefore, it can be concluded there is no real risk associated with use of the product Derat® for professional users.

2.7.3.2 Risk for non-professional users and the general public

Non-professional user (dermal absorption value = 0.047%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL x 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	3.6×10^{-6}	3.3×10^{-6}	109.091	277.78
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	18.37×10^{-8}	3.3×10^{-6}	5.567	5 443.66

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which is recommended to determine the exposure to rodenticides is indicating less exposure than the acceptable exposure level.

It can be concluded that there is no real risk associated with use of the product Derat® for non-professional users.

Non-professional user (dermal absorption value = 3%)

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (exposure/ AEL x 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Level I	229.6×10^{-6}	3.3×10^{-6}	6 957.58	4.36
Estimations according to J.G. Chambers and P.J. Snowdon				
Level I	11.72×10^{-6}	3.3×10^{-6}	355.15	85.32

*Safe value ≥300

The use of the data contained in the publication J.G. Chambers and P.J. Snowdon, which is recommended to determine the exposure to rodenticides is indicating the risk due to use of the product Derat® for non-professional users.

The question of choosing a suitable value of percutaneous absorption (0.047% and 3%, the data from the *Assessment Report*) for the calculation of dermal exposure for products in vax formulation was discussed by countries at the European Community level, calculations were carried out using both of the above values. The risk characterisation was also made adequately. However, the dermal absorption value equal to 0.047% and associated to this calculations should be considered as appropriate for Derat®.

Therefore, it can be concluded there is no real risk associated with use of the product Derat® for non-professional users.

2.7.3.2.1 Incidental ingestion by child

Scenario	Exposure [mg/kg b.w./day]	AEL [mg/kg b.w./day]	%AEL (Exposure /AEL x 100%)	MOE* (NOEL/ exposure)
Estimations according to TNsG				
Incidental ingestion of product	0.025	3.3×10^{-6}	757 575.76	0.04

*Safe value ≥300

The risk of accidental ingestion by the infant was identified. Unfortunately there is no possibility of total elimination of risk for this scenario, for this reason it is recommended to enter as many as possible restrictions to minimize these risks.

For this purpose, it is recommended to:

- limit the size of the packaging of the product for the non-professional user to reduce the likelihood of product storage;
- use of the packaging that will prevent or significantly impede the opening by the children;
- reduce the attractiveness of the packaging and the product for a child;
- use of the special substances, limiting intake;
- use only closed bait stations made of durable material.

2.7.3.3 Risk for consumers via residues

Not applicable.

2.8 Risk assessment for the environment

Biocidal product Derat® containing 0.05g/kg brodifacoum and is intended to be used as a rodenticide for the control of commensal rodent species – rats and mice in the following use situations: in sewers system, in and around buildings, open areas and waste dumps.
The product is in the form of wax blocks of a weight 14 ± 3 g.
The amount of used product per application is 14 wax blocks (200 g) per bait station for rats and 7 wax blocks (100 g) per bait station for mice.
In and around buildings, in open areas and waste dumps biocidal product must be placed only in tamper resistant bait stations. The bait station should be fixed to the ground.

The product is intended to be used by non-professional users in and around buildings and in open areas. Biocidal product must be placed only in tamper resistant bait stations. The bait station should be fixed to the ground.

The product is intended to be used by professional users in and around buildings, in open areas, waste dumps and sewers. In sewers blocks are fixed with a metal rod or cable ties. Blocks can not have direct contact with the surface of the water. In other areas of use application in tamper resistant bait stations is recommended.

Baiting points must be inspected frequently and replenished when bait has been eaten. Dead rodents, uneaten bait, contaminated and found outside the bait station should be removed for disposal in order to prevent them being eaten by non-target animals. When no more bait is eaten and rodent activity stops, the remains of all bait must be removed for disposal.

The risk assessment was carried out for the case when the target organism is a rat (assuming that this is the worst case – bait station contains 200 g of bait). The risk assessment for mouse was not performed. It was assumed that during control of mice the environmental risk will not be greater than during the control of rats.

Brodifacoum contamination in environment will occur both from direct contamination when bait are deployed outside the bait station and from indirect contamination via dead bodies, urine and faeces of the target organisms.

Environmental assessment was performed based on scenarios outlined in *ESD*[4] and *TGD*[5] taking into consideration possible scenarios for the use of the product Derat®.

The risk assessment was performed by comparing the Predicted Environmental Concentration (PEC) with the Predicted No Effect Concentration (PNEC). The PNEC values have been derived from the *Assessment Report* for which company "FREGATA" S.A. submitted a letter of access. The PEC values have been derived through calculation presented in detail in Document IIB.

[4] Larsen J. (2003) *Emission Scenario Document for Biocides used as Rodenticides. Supplement to the methodology for risk evaluation of biocides* CA -Jun03-Doc.8.2-PT14. (EUBBES 2).

[5] *Technical Guidance Document on Risk Assessment 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. Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.* Part II. Published.

Regional and continental PEC concentrations were not calculated due to the low consumption and the anticipated very local emission patterns of the use of rodenticides with soil as the main receiving compartment (in accordance with point 2.2 *ESD*).

Considering the composition of the product Derat® only the active substance brodifacoum should be considered as substance of concern for environment and the risk characterisation was therefore only performed for brodifacoum.

2.8.1 Aquatic environment

2.8.1.1 Sewers

The use of Derat® as a rodenticides in the sewer system may pose a potential risk to surface waters, groundwater, sediments and microorganisms in sewage treatment plants (hereafter STP).

The Predicted No Effect Concentrations for aquatic organisms ($PNEC_{water}$), for sediment ($PNEC_{sed}$) and for microorganisms ($PNEC_{microorganisms}$) was derived from *Assessment report*.

The Predicted Effect Concentration (PEC) value was presented in details in Document IIB.

The PEC/PNEC ratios for the aquatic compartment from the use of Derat® in sewers are summarised in Table below.

Due to the lack of measured data for both $PEC_{sediment}$ and $PNEC_{sediment}$ the risk characterization of sediment was performed based on the PEC/PNEC ratio for the aquatic compartment. According to the *TGD*, the risk for sediment can be calculated by increasing the PEC/PNEC ratio for the aquatic compartment by a factor of 10.

Aquatic PEC/PNEC ratios assuming worst case PECs as a result of Derat® use in sewers

Exposure scenario		PEC [mg/l]	PNEC [mg/l]	PEC/PNEC
Sewage treatment plant				
PEC_{stp}	Worst case use	9.64×10^{-5}	3.8×10^{-3}	0.0254
	Normal use	6.43×10^{-5}	3.8×10^{-3}	0.0169
Surface water				
Sewer – during emission from STP	Worst case use	3.71×10^{-6}	4×10^{-5}	0.093
	Normal use	2.47×10^{-6}	4×10^{-5}	0.062
Sediment				

Sediment – during emission from STP	Worst case use	–	–	0.93
	Normal use	–	–	0.62

All the PEC/PNEC ratios are below 1 and showing no risk to organisms in the surface water, sediment or involved in the biological processes of the sewage treatment during use biocidal product Derat® in sewers.

2.8.1.2 In and around buildings

Exposure of surface water arising from the use Derat® in and around buildings is not expected to be significant (detailed explanation in Document IIB). Therefore PECs in surface water have not been calculated and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

2.8.1.3 Open areas

Exposure of surface water arising from the use Derat® in open areas is not expected to be significant (detailed explanation in Document IIB). Therefore calculations of PECs in surface water have not been performed and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

2.8.1.4 Waste dumps

Exposure of surface water arising from the use Derat® in waste dumps is not expected to be significant (detailed explanation in Document IIB). Therefore calculations of PECs in surface water have not been performed and aquatic PEC/PNEC quotients are not presented. Risk assessment was performed only for groundwater since this is the only water compartment that can be contaminated.

2.8.2 Atmosphere

Brodifacoum has a low vapour pressure (1×10^{-6} Pa), Henry's Law constant (2.18×10^{-3} Pa m^3 mol^{-1}) and low water solubility (2.4×10^{-4} g/l). The active substance hydrolyzed relatively slowly under environmentally relevant conditions (DT_{50} = 300 days) and undergoes rapid direct photodegradation (t½ = 6.5 h). The active substance is not readily

and not inherently biodegradable. Therefore it is expected that brodifacoum is not volatile and release to air during use of Derat® is considered to be negligible.

Taking in to account above, it is concluded that during use of biocidal product Derat® in sewers, in and around buildings, open areas and in waste dumps, is highly unlikely that significant amount of brodifacoum will be released into the atmosphere. Therefore, PEC for that substance in the air was not determined. It is not expected that brodifacoum contribute to global warming, ozone depletion in the stratosphere or acidification.

2.8.3 Soil

2.8.3.1 Sewers

Contamination of soil following the use of bait blocks in sewers is highly unlikely during application and use of Derat®. However, soil may contain low concentrations of brodifacoum from the spreading on land the sludge derived from STP receiving water after the baiting of sewer systems. The sewage sludge can be applied to soil as a source of nutrients or as a soil improver.

The PEC values for the use of sewage sludge was performed in Document IIB, section 3.3.4.1. The $PNEC_{soil}$ value (0.88 $mg_{brodifacoum}/kg_{wwt}$) was derived from *Assessment report.*

The resulting terrestrial PEC/PNEC ratios are indicated below:

PEC/PNEC ratios for soil organisms as a result of Derat® use in sewers

Exposure scenario	PEC [mg/kg_{wwt}]	PNEC [mg/kg_{wwt}]	PEC/PNEC
Worst case use	3.68×10^{-4}	0.88	4.18×10^{-4}
Normal use	2.45×10^{-4}	0.88	2.78×10^{-4}

Estimated PEC/PNEC ratios are less than one indicating that there should be no risk to soil organisms during use of biocidal product Derat® in sewers.

2.8.3.2 In and around buildings

Exposure of soil to Derat® may also occur when bait blocks are deployed in and around buildings. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.

Predicted Environmental Concentration for soil (PEC_{soil}) for the biocidal product Derat® was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.88 $mg_{brodifacoum}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

Terrestrial PEC/PNEC ratio as a result of Derat® use in and around buildings

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case use	0.034	0.88	0.039
Normal use	0.010	0.88	0.012

In both cases the calculated PEC/PNEC values indicate that there is no concern for the terrestrial compartment as a result of use of Derat® in this specific emission scenario.

2.8.3.3 Open areas

Exposure of soil organisms to biocidal product Derat® may occur when bait blocks are deployed in open areas. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.
Predicted Environmental Concentration for soil (PEC_{soil}) was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.88 $mg_{brodifacoum}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

Terrestrial PEC/PNEC ratio as a result of Derat® use in open areas

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case use	0.346	0.88	0.393
Normal use (+ bait stations)*	0.138	0.88	0.157

*According to *ESD* in open areas the bait is placed into rat holes. Biocidal product Derat® in open areas are placed only into tamper resistant bait station, therefore this scenario was modified.

Estimated PEC/PNEC ratios are less than one indicating that there should be no risk to soil organisms during use of biocidal product Derat® in open areas.

2.8.3.4 Waste dumps

Exposure of soil organisms to biocidal product Derat® may occur when bait blocks are deployed on waste dumps. It is assumed that exposure of soil organisms arise through a direct and indirect (via dead bodies, urine and faeces of the target organisms) contamination of soil.

Predicted Environmental Concentration for soil (PEC_{soil}) was calculated in Document IIB and compared to $PNEC_{soil}$ – 0.88 $mg_{brodifacoum}/kg_{wwt}$ value. The calculated PEC/PNEC ratios for soil summarised in Table below.

Terrestrial PEC/PNEC ratio as a result of Derat® use on waste dumps

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
Worst case scenario	0.007	0.88	0.008

The calculated PEC/PNEC values indicate that there is no concern for the terrestrial compartment from use of Derat ® in this specific emission scenario.

2.8.4 Risk characterisation for groundwater used as drinking water

The exposure of groundwater to the active substance derived from the product Derat® was calculated using equations No. 67 and 68 from the *TGD,* where concentration in porewater of agricultural soil is taken as an indicator for potential groundwater level. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. Exposure of soil via sludge application is possible as result of use in sewers. Thus calculated concentrations for normal use in sewers, in and around buildings, in open areas and waste dumps are respectively 0.0013 µg /L; 0.04 µg /L, 0.53 µg/L and 0.03 µg/L (detailed information in Document IIB). In accordance with Directive 98/83/EC maximum permissible concentration of pesticides (which, according to the legislation, also include rodenticides) cannot exceed 0.1 µg/L.

The comparison above indicates a slight risk of groundwater contamination during use of the product Derat® in open areas. However, it should be noted that, in accordance with the guidelines of the *TGD*, it is assumed that the concentration in the water in the pores of the soil is an indicator of the concentration of active substance in groundwater. This is the unrealistic worst possible assumption, which ignores the possibility of degradation of the substance and dilution in the deeper layers of the soil. It should be underlined that only small amount of soil close to bait station is exposed. Moreover use of risk mitigation measures, including prudent use of the product Derat®, can significantly reduce concentration of active substance brodifacoum in soil, and thus reduce the risk to groundwater.

2.8.5 Non compartment specific effects relevant to the food chain (primary and secondary poisoning)

Non-target vertebrates may be exposed to the biocidal product Derat® either directly by ingestion of exposed bait (primary poisoning) or indirectly by consumption of poisoned rodents and other aquatic and terrestrial organisms that contain residues of the brodifacoum (secondary poisoning).

Considering the composition of the biocidal product Derat® only the active substance brodifacoum should be considered as substance of concern for environment. Therefore the risk characterisation was performed only for brodifacoum. The $PNEC_{oral}$ values for birds and mammals were taken from the *Assessment report*. The $PNEC_{oral}$ values are presented in Table below.

$PNEC_{oral}$ value expressed as the concentration in food and as the daily dose for birds and mammals

	PNEC [mg/kg$_{food}$]	**PNEC [mg/kg bw/d]**
Birds	1.30×10^{-4}	1.28×10^{-5}
Mammals	2.22×10^{-4}	1.10×10^{-5}

2.8.5.1 Primary poisoning

The biocidal product Derat® will be placed only in special tamper resistant bait station. Non – target birds and mammals may be exposed to product if they are small enough to get inside the bait station, when bait station is not property secured or damaged. It is also possible taking out the bait outside bait station by target rodent.

Tier 1

The Tier 1 assessment of primary poisoning is based on the comparison of the concentration of rodenticide in the bait and the $PNEC_{oral}$ related to the concentration in food.

In the Tier 1 assessment of primary poisoning it is assumed that the whole day's food requirement is satisfied by consumption of wax blocks, and therefore the concentration in food will be the same as the concentration of active substance in the bait, 50 mg/kg. This is then compared to the PNECs for birds and mammals.

Concentration of the bait is compared to the $PNEC_{oral}$ expressed as the concentration in food

	PEC_{oral} [mg/kg$_{food}$]	**PNEC [mg/kg$_{food}$]**	**PEC/PNEC**

Birds	50	1.30×10^{-4}	384 615
Mammals	50	2.22×10^{-4}	225 000

The resulting PEC/PNEC ratios in the Table above reveal a high risk for both birds and mammals of long-term primary poisoning.

Tier 2

According to the *ESD* the comparison of concentration in the non-target animals and the $PNEC_{oral}$ describes the long-term risk for primary poisoning. The expected concentration in the non-target animals are calculated after five days intake and elimination. The elimination is assumed to be 30%. The calculations show that mammals and birds would suffer long-term effects of brodifacoum if they would ingest Derat®. Due to high food intake in relation to the body weight the birds are at considerably higher risk than mammals.

Tier 2 risk characterisation of primary poisoning. The expected concentrations (EC) in the non-target animals after five days exposure have been calculated with the Step 2 assumptions, i.e, PT=0.8 and AV=0.9. The $PNEC_{oral}$ is expressed as the daily dose

Species		**PEC EC_5 [mg/kg b.w.]**	**$PNEC_{oral}$ [mg/kg b.w./d]**	**PEC/PNEC**
Dog	*Canis familiaris*	5.32	1.10×10^{-5}	483 573
Pig	*Sus scrofa*	0.66	1.10×10^{-5}	60 447
Pig, young	*Sus scrofa*	2.13	1.10×10^{-5}	193 429
Tree sparrow	*Passer montanus*	30.63	1.28×10^{-5}	2 392 678
Chaffinch	*Fringilla coelebs*	26.60	1.28×10^{-5}	2 077 852
Wood pigeon	*Columba palumbus*	9.61	1.28×10^{-5}	750 571
Pheasant	*Phasianus colchicus*	9.55	1.28×10^{-5}	746 399

Qualitative assessment of acute primary poisoning

There is high risk to non-target mammals and birds. The assumption based on the comparison of expected concentration in animals after one day exposure with and without elimination. In assessment assumed that PT and AV values are 0.8 and 0.9, respectively. The species specific sensitivity differences are not taken into account in this assumption and hence this description must not be considered as a risk characterisation.

Qualitative assessment of acute primary poisoning

Species		**ETE after one day exposure without elimination [mg/kg b.w./d]**	**EC after one day exposure and elimination [mg/kg· b.w.]**	**LD_{50} [mg/kg b.w.]**
Dog	*Canis familiaris*	2.16	1.51	0.4
Pig	*Sus scrofa*	0.27	0.19	0.4
Pig, young	*Sus scrofa*	0.86	0.60	0.4
Tree sparrow	*Passer montanus*	12.44	8.71	0.31
Chaffinch	*Fringilla coelebs*	10.80	7.56	0.31
Wood pigeon	*Columba palumbus*	3.90	2.73	0.31
Pheasant	*Phasianus colchicus*	3.88	2.72	0.31

Conclusion on primary poisoning

The risk characterisation indicates a very high risk to non-target vertebrates, mammals and birds feeding on bait. Primary poisoning incidents can be minimised by preventing the access of non-target animals to the bait.

According to *ESD* if the baits are used in accordance with the label instructions, the risk for primary poisoning is negligible. The risk of primary poisoning is likely to be overestimated because the direct exposure to brodifacoum is mitigated by the use of bait station. Nevertheless, the risk cannot be excluded. It may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals and birds of equal or smaller size than the target rodents.

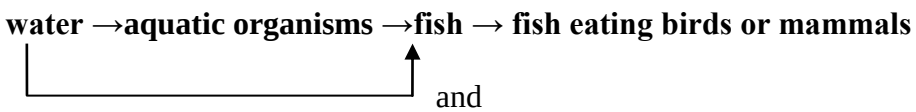
Non-target mammals and birds are unlikely to enter sewers and feed on bait blocks in sewage system. Therefore, there will be no significant exposure following the use of bait blocks in sewers. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target living above sewers. In conclusion, the risk to non-target mammals and birds following the use of biocidal product Derat® containing brodifacoum in sewers is considered to be very low.

2.8.5.2 Secondary poisoning

Secondary poisoning via aquatic and terrestrial food chains

In case of the use Derat® in and around buildings, in open areas and waste dumps exposure of surface water to active substance brodifacoum is negligible (detailed explanation in Document IIB). Therefore risk of poisoning via the aquatic food chain is also considered to be negligible. Secondary poisoning of fish eating birds and mammals is theoretically possible only during use of Derat® in sewers.

Animals living in soil and water contaminated with brodifacoum accumulate this substance. Therefore birds and mammals feeding on these animals are at risk of secondary poisoning. Secondary poisoning is possible in chains given below:



and

soil → earthworms → earthworms eating birds or mammals,

However the Polish Competent Authority considers that the secondary poisoning via earthworms is less important than secondary poisoning via the food chain given below:

bait → rodent → rodent-eating birds or mammals.

Result of risk assessment of secondary poisoning via aquatic and terrestrial food chain presented in Table below.

Secondary poisoning via aquatic food chain

	$PEC_{oral,\ predators}$ [$mg/kg_{wet\ fish}$]	$PNEC_{oral}$ [mg/kg_{food}]	PEC/PNEC
Birds	0.0075	1.30×10^{-4}	58
Mammals	0.0075	2.22×10^{-4}	34

Secondary poisoning via terrestrial food chain

	$PEC_{oral,\ predators}$ [$mg/kg_{wet\ earthworm}$]	$PNEC_{oral}$ [mg/kg_{food}]	PEC/PNEC
Birds	0.2453	1.30×10^{-4}	1 887
Mammals	0.2453	2.22×10^{-4}	1 104

The calculated PEC/PNEC ratios exceed 1 for both fish eating birds and mammals. Despite of this calculation, the risk of secondary poisoning via the aquatic food chain is considered insignificant due to low water solubility and high adsorption tendency of brodifacoum. Based on this information it is expected that the substance brodifacoum would preferably partition into sediments. It is also assumed that mechanical screening of sewage water (screens and grids) reduces the concentration in the recipient water (retain rodent carcasses, uneaten bait and some bait fragments), although this reduction cannot be quantified.

In contrast to the aquatic environment, the calculation shows a considerable risk for secondary poisoning of birds and mammals in the terrestrial environment. The risk is due to feeding on contaminated soil dwelling invertebrates. The scenario is regarded as an extreme worst case and at larger area, the risk is considerably lower.

Tier 1

The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food, i.e. poisoned rodents. The rodents are assumed to consume entirely the bait (PD = 1), while half of the predator's or scavenger's daily food intake are poisoned rodents (F_{rodent} = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days, whereas the predator or the scavenger is assumed to eat the poisoned rodents during one

day. The predator is assumed to caught the rodent after last meal on day 5 or day 14. Only resistant rodents are assumed to eat bait for 14 days. The $PNEC_{oral}$ is based on the highest concentration causing no effects in the test with long-term exposure.

Calculations indicate that there is a risk for both birds and mammals. The risk exists for predators or scavengers eating the rats susceptible to brodifacoum (eating bait for 5 days) and resistant (eating the bait for 14 days).

Tier 1 risk characterisation of secondary poisoning

	PEC EC in rodent [mg/kg]	**$PNEC_{oral}$ [mg/kg_{food}]**	**PEC/PNEC**
Rodent caught on day 5 after meal			
Bird	6.93	1.3×10^{-4}	53 329
Mammal	6.93	2.2×10^{-4}	31 197
Rodent caught on day 14 after meal			
Bird	8.28	1.3×10^{-4}	63 668
Mammal	8.28	2.2×10^{-4}	37 246

Tier 2

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators is compared to $PNEC_{oral}$ expressed as a daily dose. The predators accumulate brodifacoum by feeding on poisoned target rodents during one day. The rodents are assumed to eat entirely the bait (PD = 1), whereas half of the predator's or scavenger's daily food intake are poisoned rodents (F_{rodent} = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days.

Tier 2 risk characterisation of secondary poisoning

Species		**PEC EC in predator [mg/kg b.w.]**		**$PNEC_{oral}$ [mg/kg b.w./d]**	**PEC/PNEC**	
		rodent caught on day 5	**rodent caught on day 14**		**rodent caught on day 5**	**rodent caught on day 14**
Barn owl	*Tyto alba*	1.72	2.05	1.28×10^{-5}	134 300	160 337
Kestrel	*Falco tinnunculus*	1.96	2.34	1.28×10^{-5}	153 239	182 948
Little owl	*Athene noctua*	1.58	1.89	1.28×10^{-5}	123 454	147 388
Tawny owl	*Strix aluco*	2.61	3.12	1.28×10^{-5}	203 950	243 490
Fox	*Vulpes vulpes*	0.63	0.76	1.10×10^{-5}	57 519	68 670

Polecat	*Mustela putorius*	1.32	1.57	$1{,}10 \times 10^{-5}$	119 738	142 952
Stoat	*Mustela erminea*	1.88	2.25	1.10×10^{-5}	171 244	204 443
Weasel	*Mustela nivalis*	2.72	3.25	1.10×10^{-5}	247 098	295 003

Also the Tier 2 risk characterisation shows a high risk for secondary poisoning. The $PNEC_{oral}$ expressed as a dose is approximately equal for birds and mammals, and the sensitivity of the species used in calculations is determined predominantly by the ratio of daily food consumption to body weight. Only one day exposure of predators is assumed in the *ESD*, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators, because daily elimination of brodifacoum from the predators is assumed to be less than the ingested amount.

Qualitative assessment of acute secondary poisoning

A qualitative assessment of the acute secondary poisoning is made by comparing the concentration in the rodents to LD_{50} values from acute oral studies. Rodents are assumed to eat entirely on bait containing brodifacoum and the non-target animals are assumed to consume entirely poisoned rodents. The calculations of PECs are explained in Document IIB. The qualitative assessment indicates that both birds and mammals are likely to die if they eat poisoned rats. The species specific sensitivity differences or other factors normally covered by the assessment factors are not taken into account in the qualitative assessment.

Qualitative assessment of acute secondary poisoning

Fraction of food type in diet (PD)	EC in rat on day 5 after last meal [mg/kg b.w.]	Birds LD_{50} [mg/kg b.w.]	Mammals LD_{50} [mg/kg b.w.]
1	13,87	0,31	0,4
0,5	6,93	0,31	0,4
0,2	2,77	0,31	0,4

2.8.5.3 Monitoring data

The company "FREGATA" S.A. has access to the documentation of the active substance brodifacoum, which contains a three studies of secondary poisoning in owls.

In the first study reported a comparative trial on the potential for secondary poisoning of difenacoum and brodifacoum. 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 while others were used to feed 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 one day of feeing trial were later fed for three consecutive days on rodenticides-poisoned mice and those which recovered from this treatment were fed for six successive days on poisoned mice. The six owls fed on difenacoum–poisoned mice all survived the 1,3 and 6 days treatments. The effects were temporary and not lethal. No external haemorrhaging was seen. 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 – 1.25 ppm 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. It was concluded that brodifacoum is more toxic to barn owls than difenacoum.

In second study performed comparative trial on the potential for secondary poisoning of flocoumafen, difenacoum and brodifacoum, where to provide mice dosed 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 mice were fed on bait (2 g per mouse) for 24 h. Further, batches of mice were fed on larger or smaller amounts of bait to increase or decrease residual rodenticide. Owls were fed for 15 days in four batches each of three owls, one per rodenticide. 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. 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. 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 residues of anticoagulants in livers: brodifacoum 1.7 mg/kg, difenacoum 0.25 mg/kg and flocoumafen 0.6 – 0.7 mg/kg.

Third study was aimed 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. 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 – 0.135 μg/g, bromadiolone at 0.004 – 0.319 μg/g, brodifacoum at 0.002 – 0.515 μg/g and flocoumafen at 0.003 – 0.144 μg/g. 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. However, concern 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 also highlighted 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. In fact, it is argued, 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 difficult to find.

Moreover documentation contains one monitoring study conducted in Britain to investigate the contamination of barn owls with rodenticides. Brodifacoum was found in 4 % of dead birds and its concentration in liver was 0.002 – 0 .515 μg/g. No evidence of contribution to the overall mortality of owls was concluded. Anyhow it can be argued that the mode of action of anticoagulants (death is slow and preceded by lethargy) makes the carcasses of poisoned owls difficult to find.

Results of secondary poisoning trials with brodifacoum

Endpoint / type of test	Exposure	Results	Remark	Reference
Potential for secondary poisoning /comparative secondary poisoning of captive owls	Laboratory mice fed on difenacoum and brodifacoum baits	Only temporary and not lethal effects on the six owls fed on difenacoum-poisoned mice. No external haemorrhaging was seen. 4 out of the 6 owls fed on brodifacoum, died 6, 10, 1, and 17 days after treatment. Evidence of anticoagulant effects	-	Newton I, Wyllie I. *Effects of New Rodenticides on Owls,* Institute of Terresterial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Camba PE17 2LS

Potential for secondary poisoning /comparative secondary poisoning of captive owls	6 months laboratory mice fed on flocoumafen, difenacoum and brodifacoum wax block baits	Flocoumafen, difenacoum and brodifacoum showed the same degree of toxicity to barn owls. 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 1.7 mg/kg, difenacoum 0.25mg/kg and flocoumafen 0.6 – 0.7 mg/kg	The toxicity of the three rodenticides was measured over a narrow concentration range, and the number of owls tested was small	Gray A, Eadsforth C V, Dutton A J (1994) *The toxicity of three second-generation rodenticides to barn owls*
Difenacoum, bromadiolone, brodifacoum and flocoumafen residues in wild barn owls carcasses/field monitoring	Ambient exposure	Contamination of barn owls with second-generation rodenticides is widespread and increasing but residues in most specimens were below lethal levels. There is no evidence that second-generation rodenticides contribute to the overall mortality in British barn owls and no evidence that they are affecting population levels	-	Wyllie I, Newton I, Freestone P. *Rodenticide Residues in British Barn Owls* Environmental Pollution, 68, 101-117

Conclusion on secondary poisoning

Both theoretical calculations and monitoring data clearly show that brodifacoum poses a risk for secondary poisoning. While all available information indicates risk, it does not tell the frequency of secondary poisoning incidents among wildlife.

During use of Derat® in sewers 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.

2.8.6 PBT assessment

PBT assessment has to be done according to the *TGD* especially for substances which can be shown both to persist for long periods and bioaccumulate in biota, and can give rise to toxic effects after a greater time and greater distances than chemicals without these properties. As brodifacoum is not readily biodegradable, have a relatively high bioconcentration factors and is very toxic to both aquatic organisms and mammals thus a PBT assessment is important.

Persistence

According to the PTB assessment in the *TGD*, a criterion for substance to be persistent is fulfilled when halflife is:

- > 60 days in marine water
- > 40 days in freshwater
- > 180 days in marine sediment
- > 120 days in freshwater sediment;

for substance being very persistent (*vP*) persistent is fulfilled when a half-life is:

- > 60 days in marine- and freshwater
- >180 days in marine or freshwater sediment.

Available experimental data indicate that brodifacoum is not readily, inherently or anaerobically biodegradable. In addition, brodifacoum resulted hydrolytically stable, but undergoes rapid photolysis in water.

As no data on degradation in marine water, freshwater or sediment are available. The DT_{50} in soil is 157 days at 20°C (DT_{50} = 298 days at 12°C), the P-criterion is fulfilled.

Bioaccumulation

According to the *TGD* a substance is considered to fulfil the *B* criterion when measured BCF exceeds the value of 2 000 and if BCF exceeds 5 000 a substance is considered very bioaccumulative (*vB*). If measured BCF values are not available, a substance is considered to potentially fulfil the *B* criterion if log K_{ow} exceeds a value of 4.5.

There is not enough information available to finally be able to clarify the B-criterion. However, for the substance brodifacoum the screening B-criterion is fulfilled as the log K_{ow} is above 4.5. Formally bioconcentration test on fish would be required in order to be able to clarify if brodifacoum meets the B-criterion. However, in case of second generation anticoagulant substances, BCF fish testing might not provide meaningful results.
A bioconcentration test on fish might be technically difficult to conduct as brodifacoum is highly toxic to fish. Furthermore, second generation anticoagulant substances, which are predominantly released to the terrestrial environment, are designed to accumulate in the liver of target rodents and it can be assumed that they also accumulate in the livers of non-target mammals and birds. This is confirmed by the fact that the second generation anticoagulant substances are found in livers of wildlife. However, as no criteria exist for bioaccumulation via the terrestrial food chain and standardised test methods for bioaccumulation in other non-

target animals than earthworms are not available these findings are merely an indication that brodifacoum may have B-properties.

In particular, the experimental determination of BCF_{fish} failed due to high mortality of fish. A BCF_{fish} of 3 034 $l/kg_{wet\ fish}$ was therefore estimated from the experimental Log P_{ow} value of 4.92, using the *TGD* equation 74.

The estimated values of bioaccumulation in fish (BCF_{fish} = 3 034) and earthworm ($BCF_{earthworm}$ = 999), high K_{ow} value (4.92) and the presence of brodifacoum residues in non-target organisms provides sufficient evidence that brodifacoum fulfil the B criterion.

Toxicity

A substance is considered to fulfil the T criterion if long-term NOEC for marine or freshwater organisms is less than 0.01 mg/l or long-term avian NOEC less than 30 mg/kg food (*TGD*). If no long-term data is available a substance is considered potentially toxic when the $L(E)C_{50}$ to aquatic organisms is less than 0.1 mg/l.

Brodifacoum is very toxic to aquatic organisms (LC_{50} = 0.040 mg/l for algae and 0.042 mg/l for the rainbow trout). No long-term data for aquatic organisms are available, moreover due to the lack of reliable long-term study on birds, a NOEC= 0.012 $mg_{brodifacoum}/kg_{diet}$ was estimated by extrapolation from the reference anticoagulant difenacoum.

Regarding mammalian toxicity a substance fulfils T criterion when it is classified as Carcinogenic, Mutagenic or Toxic for reproduction or when there is evidence of chronic toxicity (Classification T, R45, R46; R48, R60 and R61, or Xn, R48, R62, R63 and R64) and also when substance is classified as Very Toxic or Toxic after oral dosing (LD50<200 mg/kg bw/day).

Brodifacoum is very toxic and proposed to be classified as R27/28, R48/24/25, R50/53. This classification indicates that substance brodifacoum fulfils the T criterion**.**

Conclusion: The *P* criterion, the *B* criterion and *T* criterion are fulfilled, therefore active substance brodifacoum should be considered as potential PBT.

2.9 Measures to protect man, animals and the environment

Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying the following appropriate and available risk mitigation measures:

1. The bait in bait station must be protected from weather, accidental ingestion by children or non-target animals and environmental dispersion.
2. Always read the label before use and follow the instructions.
3. The size of the target rodent population should be evaluated before the control campaign.
4. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.
5. When the product is being used in and around buildings, tamper resistant bait stations should be placed along walls and in places where there are signs of rodent activity.
6. The biocidal product must never be placed indiscriminately.
7. Tamper resistant bait stations should be clearly marked to show that they contain rodenticides and that they must not be disturbed.
8. Biocidal product should not be used where food, feeding stuffs or drinking water could be contaminated
9. Places where the biocidal product is being used should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
10. For use only in areas that are inaccessible to children and non-target animals (particularly dogs, cats, pigs, poultry and wild birds).
11. Keep out of the reach of children.
12. Avoid release to the environment.

13. Avoid contamination of soil, surface water or sanitary sewer system with the product or packaging the product.

14. In case of accidental release into the environment, the product should be collected avoiding direct contact with the skin and must be delivered to authorised companies which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

15. In case of contamination of the surface with the product, collect product thoroughly into suitable containers and delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste. In case of an extensive environmental contamination, inform the authorities.

16. If all bait is consumed quickly in a particular area, increase the number of baiting points in that area.

17. Search for and remove dead rodents and bait which is contaminated, bait found outside the bait station, at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances. It is recommended to wear protective gloves. All residues and dead rodent must be delivered to authorised company which are empowered to utilization for hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

18. After the campaign remove dead rodents, the bait damaged by water or contaminated by dirt, bait found outside the bait station, bait stations and package. It is recommended to wear protective gloves. These residues must be delivered to authorised companies which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

19. Packaging of the product, any contaminated materials, the remains of the product after use (closed in a labeled container) and dead rodents must be delivered to authorised company which are empowered for utilization of hazardous wastes and their disposal (e.g. incineration). Do not mix with municipal solid waste.

20. The product must not be used to protect plants and plant products.

21. Avoid contact with eye and skin.

22. Wash hands and exposed skin before eating, drinking smoking and after use.

23. Product is not intended for mixing with other products.

24. If swallowed, seek medical advice immediately – show packaging and the label.

25. It is recommended to wear protective gloves.

26. When using do not eat, drink or smoke.

27. Keep away from food, drink and animal foodstuffs.

28. Product should be stored in original, labelled and closed containers at temperature below 30ºC, in place inaccessible to children and pets.

29. Keep away from children and non-target organisms (particularly dogs, cats, pigs, poultry and wild birds). Protect from direct light.

30. Reduce the attractiveness of the packaging and the product for children.

31. The product must be packed in such a way as to prevent or significantly impede opening by children.

32. Product placed in bait station and uneaten by rodent cannot be reused. Packaging should not be used for any other purpose.

33. The label should include information that the product contains an aversive agent – substance limiting the risk of consumption of the product.

34. The authorisation holder shall report any observed resistance incidents to appropriate sanitary authorities.

35. As a condition, the authorisation holder needs to address the preservative issue on renewal of the authorisation.

Additional restriction for non-professional users:

1. The biocidal product is intended to be used in and around buildings (e.g. livestock buildings) and in open areas (e.g. parks, tennis courts, camping sites and other places of the public utility).

2. Bait must be placed in commercially available tamper resistant bait stations. The bait station should be fixed to the ground.

3. Do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. If after this period rodent activity persists, consult a qualified pest control.

4. Limit to 1.5 kg the size of the packaging of the product in order to reduce likelihood of storage the open product.

Additional restriction for professional users:

1. The product is intended to be used in and around buildings (e.g. livestock buildings), in open areas (e.g. parks, tennis courts, camping sites and other places of the public utility), in waste dumps and in sewers.

2. The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. The biocidal product Derat® should not be used in an area where resistance to brodifacoum is suspected.

5. Bait should be placed in commercially available tamper resistant bait stations (unless used in sewers). The bait station should be fixed to the ground.

3. In sewers wax blocks must be fixed with a metal rod or cable ties. Moreover blocks must not have direct contact with the surface of water.

4. Do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. If after this period rodent activity persists determine the cause of the lack of effectiveness.

5. 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.

6. Read carefully the information contained in the safety data sheet.

3 Proposal for decision

1. Product Formulation - active substance content	% w/w	Manufacturer of active substance
concentrate of brodifacoum (pure brodifacoum content)	0.2% (0.005%)	PelGar International Limited Unit 13 Newman Lane Alton Hampshire GU34 2QR, United Kingdom

2. Formulation type	wax blocks (rings)
3. Product type	PT14
4. User	non-professional and professional
5. Packaging	please refere to PAR section 2.2.3
6. Application	▪ in and around buildings (e.g. live stock buildings) ▪ open areas (e.g. parks, tennis courts, camping sites and other places of the public utility). ▪ waste dumps ▪ sewers
7. Application Method	<u>non-professional user:</u> ▪ in and around buildings – bait must be placed only in tamper resistance bait station ▪ open areas – bait must be placed only in tamper resistance bait station <u>professional user:</u> ▪ in and around buildings – bait should be placed in tamper resistance bait station ▪ open areas – bait should be placed in tamper resistance bait station ▪ waste dumps – bait should be placed in tamper resistance bait station ▪ sewers – wax blocks fixed by using a metal rods or ties. Blocks must not have direct contact with the surface of the water
8. Application Rate	<u>mice</u>: 100 g (7 wax blocks) per bait station spaced at 3 – 4 m. Typical treatment time 20 days (according to field trial) <u>rats:</u> 200 g (14 wax blocks) per bait station spaced at 15 m. Typical treatment time 20 days (according to field trial)
9. Organism controlled	*Rattus norvegicus* (brown rat) *Mus musculus* (house mouse)

10. Shelf life	up to 2 years
11. Expiry data of the authorisation	5 years after the date of authorisation granting
12. Any other specific conditions:	please refer to PAR section 2.9 additionaly: – Methylparaben as non-notified in PT6 active substance should be exchanged on preservative contained in list of approved substance during the process of authorisation renewal – In the case 200 g and 400 g package types the big visible warning "*Keep Out of Reach of Children*" should be placed in the front of label.

Annex 1: List of studies reviewed

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIB	3.1.1 3.1.2 3.1.3 3.5 3.7 3.8	Al Amin Idris	2012	Derat Badania właściwości fizykochemicznych preparatu wyjściowego Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-39/11-1	„FREGATA” S.A.	☐	☒	☒	☐
IIIB	3.1.1 3.1.2 3.1.3 3.5 3.7 3.8	Al Amin Idris	2012	Derat Badania właściwości fizykochemicznych po przyśpieszonym starzeniu Instytut Przemysłu Organicznego (Warszawa) Kod badania: BF-39/11-2	„FREGATA” S.A.	☐	☒	☒	☐
IIIB	3.6	„FREGATA” S.A.	2012	Raport z badań. Oznaczanie gęstości preparatu Derat Numer raportu: FRE 05/12	„FREGATA” S.A.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	4.1	Gwóźdź Ewa Jolanta	2012	Walidacja metody i oznaczanie substancji aktywnej brodifakum, w preparacie Derat Instytut Przemysłu Organicznego (Warszawa) Kod badania: BA – 02/12	„FREGATA" S.A.	☐	☒	☒	☐
IIIB	5.10.2 /1	Ignatowicz Stanisław	2011	Badanie skuteczności preparatu Derat przeznaczonego do zwalczania gryzoni zgodnie z „Metodyką badań skuteczności preparatu przeznaczonego do zwalczania gryzoni", FRE/RT-03/2007 Szkoła Główna Gospodarstwa Wiejskiego (Warszawa)	„FREGATA" S.A.	☐	☒	☒	☐
IIIB	5.10.2/2	Gruszka Katarzyna	2012	Derat. Badanie skuteczności i akceptacji rodentycydów na szczurach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-3/12	„FREGATA" S.A.	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	5.10.2/3	Gruszka Katarzyna	2012	Derat. Badanie skuteczności i akceptacji rodentycydów na myszach laboratoryjnych Instytut Przemyslu Organicznego Oddział w Pszczynie Kod badania: SK-4/12	„FREGATA" S.A.	☐	☒	☒	☐
IIIB	6.6/1 6.6/2	„FREGATA" S.A.	2012	Derat. Oszacowanie ekspozycji oraz ryzyka	„FREGATA" S.A.	☐	☒	☒	☐

Annex 2: Analytical methods residues – active substance

< Brodifacoum >

No new data for the active substance residues was submitted. For datailed information please see the CAR for active substance brodifacoum.

Annex 3: Toxicology and metabolism –active substance

< Brodifacoum >

No new data for the active substance was submitted. For datailed information please see the CAR for active substance brodifacoum.

Annex 4: Toxicology – biocidal product

< Derat® >

General information

Formulation Type:	wax block
Active substance(s) (incl. content)	0.005% brodifacoum
Category	PT 14- rodenticides

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD_{50} oral (OECD 420)	8 g/kg bw (male mouse)
Rat LD_{50} dermal (OECD 402)	63.2 g/kg bw (female rat)
Rat LC_{50} inhalation (OECD 403)	61 g/l (female rat)
Skin irritation (OECD 404)	Not irritating
Eye irritation (OECD 405)	Not irritating
Skin sensitisation (OECD 429; LLNA)	Not a skin sensitizer

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	Not required
Toxicological data on active substance(s) (not tested with the preparation)	For datailed information please see the CAR for active substance brodifacoum.
Toxicological data on non-active substance(s) (not tested with the preparation)	The biocidal produkt does not contain any toxicologically relevant substances other then the active substance brodifacoum
Further toxicological information	Not required

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
EC 1272/2008	Product classification: NONE

Annex 5: Safety for professional operators

<Derat®>

See point 2.7.3.1 above

Annex 6: Safety for non-professional operators and the general public

< Derat®>

See Tables 2.7.3.2.1 and 2.7.3.2.2 above

Annex 7: Residue behaviour

<Brodifacoum>

No new data for the active substance was submitted. For datailed information please see the CAR for active substance brodifacoum.

Annex 8: Proposed Label

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Derat®

Gotowa do wyłożenia przynęta w postaci woskowych krążków przeznaczona do zwalczania myszy i szczurów. Do stosowania wewnątrz i wokół budynków, na terenach otwartych (parki, korty tenisowe, kempingi, itp.) Preparat do użytku powszechnego.

Pozwolenie Prezesa Urzędu nr:

Substancja czynna:

- brodifakum 0,005 % (0,05 g/kg) - substancja czynna z grupy antykoagulantów jednodawkowych II generacji.

Zawiera:

- benzoesan denatonium - gorzka substancja zniechęcająca do spożycia przez ludzi.

Derat® jest preparatem przeznaczonym do zwalczania szczurów i myszy w obiektach o dużej wilgotności podłoża i powietrza (np. w piwnicy).

Sposób użycia:

Derat® musi być wykładany do dostępnych w sprzedaży, odpornych na manipulację i zabezpieczonych przed niepożądanym otwarciem karmników deratyzacyjnych w porcjach po 14 krążków (200g) – przy zwalczaniu szczurów (w odstępach co 15 m) i po 7 krążków (100 g) – przy zwalczaniu myszy (w odstępach co 3 - 4 m). Karmniki deratyzacyjne powinny być rozmieszczone wzdłuż ścian budynków oraz w miejscach aktywności gryzoni. Powinny być one przytwierdzone do podłoża, odpowiednio oznaczone i zawierać informację, że zawierają rodentycyd, który nie może być roznoszony. W przypadku stosowania produktu w miejscach ogólnodostępnych, miejsca te powinny być w trakcie zabiegu odpowiednio oznaczone. W pobliżu wyłożonej przynęty, w miejscu dostępnym, powinna znaleźć się informacja o ryzyku pierwotnego i wtórnego zatrucia oraz działaniach, które należy podjąć w przypadku zatrucia. Nigdy nie rozmieszczać produktu w sposób przypadkowy.

Spożyty preparat systematycznie uzupełniać do momentu całkowitego wytępienia gryzoni (okres 6-10 dni). **Gryzonie zaczynają padać po 4-6 dniach**. Typowy okres stosowania przynęty wynosi 20 dni.
Karmniki muszą być zabezpieczone przed niepożądanym otwarciem, działaniem czynników atmosferycznych, dostępem dzieci oraz organizmów niebędących przedmiotem zwalczania.
W czasie trwania akcji deratyzacyjnej pomieszczenie może być użytkowane z zachowaniem wymienionych środków ostrożności. Zabieg powtórzyć w razie ponownego pojawienia się gryzoni.

Przeprowadzać regularne inspekcje punktów wykładania przynęty – uzupełniać przynętę zjedzoną oraz wymieniać przynętę uszkodzoną przez wodę lub zanieczyszczoną. Jeżeli przynęta została całkowicie zjedzona należy zwiększyć liczbę punktów w tym obszarze. Przynętę znalezioną poza karmnikiem deratyzacyjnym oraz padłe gryzonie zaleca się usuwać stosując rękawice ochronne.

Nie należy długoterminowo stosować na danym terenie produktów gryzoniobójczych zawierających antykoagulanty. W przypadku tego typu produktów gryzonie powinny zostać zwalczone w ciągu 35 dni. Jeśli po tym okresie aktywność gryzoni nadal się utrzymuje należy skonsultować się z wykwalifikowanym pracownikiem deratyzacji. Tam gdzie stwierdzono lub podejrzewa się zjawisko oporności na brodifakum należy zastosować produkt zawierający inną alternatywną substancję czynną z grupy rodentycydów.

Środki ostrożności:

Preparat może być szkodliwy dla ludzi i organizmów niebędących przedmiotem zwalczania w przypadku spożycia dużych ilości. Preparat zabezpieczyć przed kontaktem z dziećmi, ptakami i innymi organizmami niepodlegającymi zwalczaniu (psy, koty, świnie, drób itp.). Przed i po wyłożeniu preparatu umyć ręce wodą z mydłem. Unikać kontaktu z ustami (bardzo gorzki smak). Unikać kontaktu produktu z oczami i skórą. Nie jeść, nie pić i nie palić podczas stosowania produktu.

P102 Chronić przed dziećmi.
P280 Stosować rękawice ochronne.

Uwaga:

Postępowanie z odpadami produktu, odpadami opakowaniowymi i padłymi gryzoniami:
Padłe gryzonie, zawilgoconą i zanieczyszczoną przynętę oraz przynętę znalezioną poza karmnikiem deratyzacyjnym należy systematycznie usuwać w sposób bezpieczny i zgodny z

aktualnymi przepisami (np. unieszkodliwiać w autoryzowanych firmach). Pozostałości produktu i jego opakowanie po zakończonym zabiegu usuwać w sposób bezpieczny (np. unieszkodliwiać przez spalanie w autoryzowanych firmach), ale zawsze zgodny z aktualnymi przepisami. Nie wykorzystywać powtórnie zużytych opakowań. Nie mieszać ze strumieniem odpadów komunalnych.

Produkt przechowywać w oryginalnym, oznakowanym i szczelnie zamkniętym opakowaniu, w temperaturze poniżej 30ºC, poza zasięgiem dzieci i zwierząt. Nie przechowywać razem z żywnością, napojami i paszami dla zwierząt. Preparatu nie przechowywać razem z substancjami chemicznymi, które mogłyby zmienić atrakcyjny dla gryzoni zapach środka. Preparat chronić przed bezpośrednim nasłonecznieniem. Zapobiegać przedostawaniu się do środowiska.

Masa jednego krążka – 14 g

Pierwsza pomoc:

W razie połknięcia lub wystąpienia niepokojących objawów (np. osłabienie lub krwawienia) zasięgnąć porady lekarza. **Antidotum: Witamina K_1** podawana pod nadzorem lekarza.
W razie zanieczyszczenia skóry, miejsce zabrudzenia dokładnie umyć wodą z mydłem.
W razie zanieczyszczenia oczu przemyć je dużą ilością wody.
W razie narażenia inhalacyjnego, w przypadku wystąpienia niepokojących objawów - zasięgnąć porady lekarza.

- W nagłych wypadkach kontaktować się z ośrodkami toksykologicznymi w Polsce:
  Gdańsk – (58) 682 04 04 Kraków – (12) 411 99 99
  Poznań – (61) 847 69 46 Warszawa – (22) 619 66 54

Zawartość netto: …

Data ważności i nr serii na opakowaniu.

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Derat®

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Preparat do stosowania wyłącznie przez profesjonalistów.

Pozwolenie Prezesa Urzędu nr:

Substancja czynna:

- brodifakum 0,005 % (0,05 g/kg) - substancja czynna z grupy antykoagulantów jednodawkowych II generacji.

Zawiera:

- benzoesan denatonium - gorzka substancja zniechęcająca do spożycia przez ludzi.

Derat® jest preparatem przeznaczonym do zwalczania szczurów i myszy w obiektach o dużej wilgotności podłoża i powietrza, w instalacjach kanalizacyjnych.

Sposób użycia:

Derat® należy wykładać do dostępnych w sprzedaży, odpornych na manipulację i zabezpieczonych przed niepożądanym otwarciem karmników deratyzacyjnych (z wyjątkiem instalacji kanalizacyjnych). Karmniki deratyzacyjne powinny być rozmieszczone wzdłuż ścian budynków oraz w miejscach aktywności gryzoni. Przy zwalczaniu gryzoni w kanalizacji krążki Derat® należy mocować przy użyciu metalowych prętów lub opasek zaciskowych, które pozwolą w sposób bezpieczny i stabilny umieścić produkt w miejscu jego wykładania (np. na występach, krawędziach lub uskokach ścian). Wyłożony preparat nie powinien mieć bezpośredniego kontaktu z bieżącą wodą.

Derat® wykładać w ilości:

- po 14 krążków (200 g) w odstępach co 15 metrów przy zwalczaniu szczurów
- po 7 krążków (100 g) w odstępach co 3-4 metry przy zwalczaniu myszy.

Karmniki deratyzacyjne powinny być przytwierdzone do podłoża, odpowiednio oznaczone i zawierać informację, że zawierają rodentycyd, który nie może być roznoszony. W przypadku stosowania produktu w miejscach ogólnodostępnych, miejsca te powinny być w trakcie zabiegu odpowiednio oznaczone. W pobliżu wyłożonej przynęty, w miejscu dostępnym,

powinna znaleźć się informacja o ryzyku pierwotnego i wtórnego zatrucia oraz działaniach, które należy podjąć w przypadku zatrucia. Nigdy nie rozmieszczać produktu w sposób przypadkowy.
Spożyty preparat systematycznie uzupełniać do momentu całkowitego wytępienia gryzoni (okres 6-10 dni). **Gryzonie zaczynają padać po 4-6 dniach**. Typowy okres stosowania przynęty wynosi 20 dni.
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W czasie trwania akcji deratyzacyjnej pomieszczenie może być użytkowane z zachowaniem wymienionych środków ostrożności. Zabieg powtórzyć w razie ponownego pojawienia się gryzoni.

Przeprowadzać regularne inspekcje punktów wykładania przynęty – uzupełniać przynętę zjedzoną oraz wymieniać przynętę uszkodzoną przez wodę lub zanieczyszczoną. Jeżeli przynęta została całkowicie zjedzona należy zwiększyć liczbę punktów w tym obszarze.

Nie należy długoterminowo stosować na danym terenie produktów gryzoniobójczych zawierających antykoagulanty. W przypadku tego typu produktów gryzonie powinny zostać zwalczone w ciągu 35 dni. Jeśli po tym okresie aktywność gryzoni nadal się utrzymuje należy ustalić przyczynę braku skuteczności ich działania. Tam gdzie stwierdzono lub podejrzewa się zjawisko oporności na brodifakum należy zastosować produkt zawierający inną alternatywną substancję czynną z grupy rodentycydów.

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