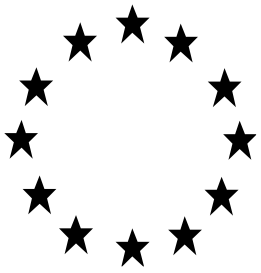
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Neo-Actiblock-Brod

Product type(s) PT14

Brodifacoum

Case Number in R4BP: BC-HU025927-10

Evaluating Competent Authority: Italy

Date:14/11/2018

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1 CONCLUSION

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for granting an authorisation for the NA-MAC of the biocidal product NEO-ACTIBLOCK-BROD, concerning the reduction of the a.s. content.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Activa s.r.l
	Address	via Feltre 32, 20132 Milano, Italy
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer of the product

Name of manufacturer	Activa srl
Address of manufacturer	via Feltre 32, 20132 Milano, Italy
[redacted]	[redacted]

2.1.1.4 Manufacturer of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	Activa srl
Address of manufacturer	via Feltre 32, 20132 Milano, Italy
[redacted]	[redacted]

1 Please fill in here the identifying product name from R4BP.

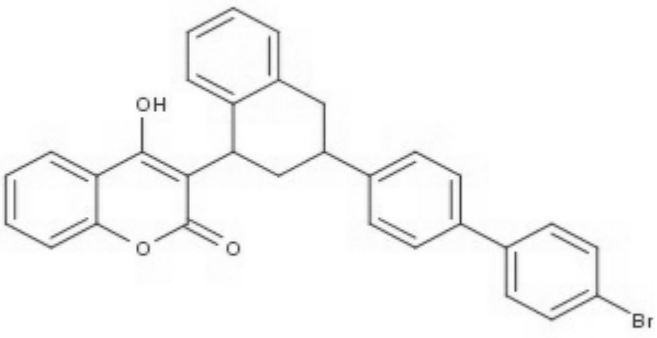
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Brodifacoum
IUPAC or EC name	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]- 4-hydroxycoumarin
EC number	259-980-5
CAS number	56073-10-0
Index number in Annex VI of CLP	607-172-00-1
Minimum purity / content	99.2 % w/w
Structural formula	

2.1.2.2 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	Active substance	56073-10-0	259-980-5	0.0025
Denatonium benzoate	N-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate hydrate	Non-active substance[3]	3734-33-6	223-095-2	0.001
Non-active substances					Up to 100 %

2.1.2.3 Information on technical equivalence

Activa supported Brodifacoum inclusion into Annex I of BPD [redacted]

Information on the substance(s) of concern
Please see the confidential annex for further details.

2.1.2.4 Type of formulation

Block bait [BB]

2 Please delete as appropriate.

3 Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance.

2.1.3 Hazard and precautionary statements[4]

Classification and labelling of the products according to the Regulation (EC) 1272/2008

Classification	
Hazard category	GHS08
Hazard statement	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Labelling	
Signal words	Warning
Hazard statements	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Precautionary statements	P102: Keep out of reach of children (non-professional use only). P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician. P308+313: IF exposed or concerned: Get medical advice. P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations.
Note	None

[4] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

2.1.4 Authorised use(s)

2.1.4.1 Use description[5]

Table 1. Use # 1 –House mice – professional – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice)
Field of use **Application method(s)**	Indoor ready-to-use wax block bait to be used in tamper-resistant bait stations[6].
Application rate(s) and frequency	APPLICATION RATE 20 g - 40 g block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.
Category(ies) of users	Professional use
Pack sizes and packaging material	Please, refers to the section 2.1.7

5 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

6 See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

Table 2. Use # 2 – Rats – professional – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	Ready-to-use wax block bait to be used in tamper-resistant bait stations[6] .
Application rate(s) and frequency	APPLICATION RATE 100 g - 200 g per bait station If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional use
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 3. Use # 3 – House mice and Rats – professionals – around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Around buildings
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[7].
Application rate(s) and frequency	House mice: 20 – 40 g wax block bait per bait point Brown rat: 100 g - 200 g wax block bait per bait point If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professionals
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 4. Use # 4 – House mice – general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[7].
Application rate(s) and frequency	APPLICATION RATE 20 g - 40 g wax block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meter
Category(ies) of users	Professional and general public use
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 5. Use # 5 – Rats – general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[6] .
Application rate(s) and frequency	APPLICATION RATE 100 g - 200 g per bait point If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional and general public
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 6. Use # 6 – Rats – general public – around buildings

7 See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Around buildings
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[2].
Application rate(s) and frequency	100 g - 200 g wax block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional and general public
Pack sizes and packaging material	Please, refers to the section 2.1.7

2.1.4.2 Use-specific instructions for use[8]

Uses #1& #4) House mice – professional and general public - indoor

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Uses #2& #5) Rats – professional and general public – indoor

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Use #3) House mice and rats – professionals - around buildings

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- The bait stations should be visited *[for mice* - at least every 2 to 3 days at*] [for rats* - only 5 to 7 days after*]* the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

Use #6) Rats –general public – around buildings

- Place the bait stations in areas not liable to flooding.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

[8] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.3 Use-specific risk mitigation measures

No specific measures for professional and public use indoor.

No specific measures for general public use around buildings.

For **professional use around buildings**:

- Do not apply this product directly in the burrows.

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

For **general public use**: no specific measures.

For professional use:

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

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

-

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

-

2.1.5 General directions for use

2.1.5.1 Instructions for use[9]

Professional use:
- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

- Where possible, bait stations must be fixed to the ground or other structures.

- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.

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

- Bait should be secured so that it cannot be dragged away from the bait station.

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another

[9] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

bait formulation.

- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

- Remove the remaining bait or the bait stations at the end of the treatment period.

General public use:
- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.1.5.2 Risk mitigation measures

For professional use:
- Do not handle until all safety precautions have been read and understood.
- Wear protective gloves.
- Do not eat, drink or smoke when using this product.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any]".
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). [Where relevant, specify if more frequent or daily inspection is required].
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- The product information (i.e. label and/or leaflet) shall clearly show that:
the product shall not be supplied to the general public (e.g. "for professionals only").
the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information

(i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not wash the bait stations with water between applications.
- Dispose dead rodents in accordance with local requirements.

For general public use
- Do not handle until all safety precautions have been read and understood.
- Do not eat, drink or smoke when using this product.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- The product information (i.e. label and/or leaflet) shall clearly show that:
the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Dispose dead rodents in accordance with local requirements.

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

For professional and general public use:

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

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

- In case of:

- Dermal exposure, wash skin with water and then with water and soap.

- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label. Contact a veterinary surgeon in case of ingestion by a pet.

Further instruction fo professional use:

- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre.
- Hazardous to wildlife.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements.

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years

2.1.6 Other information

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

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

- This product contains a bittering agent and a dye.

2.1.7 Packaging of the biocidal product

TYPE OF PACKAGING	SIZE/VOLUME OF THE PACKAGING	MATERIAL OF THE PACKAGING	TYPE AND MATERIAL OF CLOSURE(s)	INTENDED USERS	COMPATIBILITY OF THE PRODUCT WITH THE PRPOSED PACKAGING
Labelled or printed Bag/Sack	from 10 to 100 grams	Plastic Composite	Prefabricated bags or serial production bags both thermal welded	General Public	YES
Labelled Plastic Bucket	from 10 to 100 grams	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	General Public	YES
Labelled Plastic Bucket	From 100 to 300 grams	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	General Public	YES
Labelled Plastic Bucket - with inner plastic liner	from 10 to 100 grams	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	General Public	YES
Labelled Plastic Bucket - with inner plastic liner	From 100 to 300 grams	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	General Public	YES
Labelled or Printed Carton Sachet with plastic inner liner	from 10 to 100 grams	Carton + Plastic Composite	Prefabricated bags or serial production bags both thermal welded	General Public	YES
Labelled or Printed Carton Sachet with plastic inner liner	From 100 to 300 grams	Carton + Plastic Composite	Prefabricated bags or serial production bags both thermal welded	General Public	YES
Labelled or Printed Cardboard with inner plastic liner	from 10 to 100 grams	Carton + Plastic Composite	Prefabricated cardboard	General Public	YES
Labelled or Printed Cardboard with inner plastic liner	From 100 to 300 grams	Carton + Plastic Composite	Prefabricated cardboard	General Public	YES
Labelled or printed Bag/Sack	from 1,5 Kg to 25 Kg	Plastic Composite	Prefabricated bags or serial production bags both thermal welded	Professional	YES
Labelled or printed Bag/Sack- with inner plastic liner	from 1,5 Kg to 10 Kg - max size innel liner 10 Kg	Plastic Composite	Prefabricated bags or serial production bags both thermal welded	Professional	YES
Labelled Plastic Bucket	from 1,5 Kg to 25 Kg	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	Professional	YES
Labelled Plastic Bucket - with inner plastic liner	from 1,5 Kg to 10 Kg - max size innel liner 10 Kg	Labelled Plastic (HDPE) bucket	Rectangular or truncated cone bucket sealed	Professional	YES
Labelled or Printed Carto Sachet with plastic inner liner	from 1,5 Kg to 10 Kg single inner plastic bags of up to 10 Kg each	Carton + Plastic Composite	Prefabricated bags or serial production bags both thermal welded	Professional	YES
Labelled or Printed Cardboard with inner plastic liner	1,5-10 Kg single inner plastic bags of up to 10 Kg each	Carton + Plastic Composite	Prefabricated cardboard	Professional	YES

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please, see the relevant sections. New studies on the biocidal product, regarding the efficacy and physicochemical properties have been submitted together with the NA-MAC.

2.1.8.2 Access to documentation

The Applicant is owner of all the data on the active substance as a member of the "Brodifacoum and Difenacoum Task Force".

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 1. Use # 1 –House mice – professional – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[10].
Application rate(s) and frequency	APPLICATION RATE 20 g - 40 g wax block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional use
Pack sizes and packaging material	Please, refers to the section 2.1.7

10 See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

Table 2. Use # 2 – Rats – professional – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[6] .
Application rate(s) and frequency	APPLICATION RATE 100 g - 200 g per bait station If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional use
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 3. Use # 3 – House mice and Rats – professionals – around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field of use	Around buildings
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[2].
Application rate(s) and frequency	House mice: 20 – 40 g wax block bait per bait point Brown rat: 100 g - 200 g wax block bait per bait point If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professionals
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 4. Use # 4 – House mice – general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[11].
Application rate(s) and frequency	APPLICATION RATE 20 g - 40 g wax block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional and general public use
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 5. Use # 5 – Rats –general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Indoor
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[6] .
Application rate(s) and frequency	APPLICATION RATE 100 g - 200 g per bait station If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional and general public
Pack sizes and packaging material	Please, refers to the section 2.1.7

Table 6. Use # 6 – Rats – general public – around buildings

Product Type	14

11 See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat)
Field of use	Around buildings
Application method(s)	ready-to-use wax block bait to be used in tamper-resistant bait stations[2].
Application rate(s) and frequency	100 g - 200 g wax block bait per bait point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professional and general public
Pack sizes and packaging material	Please, refers to the section 2.1.7

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual examination OPPTS 830.6303	Nominal active ingredient: Brodifacoum 0.0025 % w/w	Solid	Brioschi. (2016a)
Colour at 20 °C and 101.3 kPa	Visual examination OPPTS 830.6302	Nominal active ingredient: Brodifacoum 0.0025 % w/w	Dark Blue	Brioschi. (2016a)
Odour at 20 °C and 101.3 kPa	Olfactory test OPPTS 830.6304	Nominal active ingredient: Brodifacoum 0.0025 % w/w	Characteristic odour	Brioschi. (2016a)
Acidity / alkalinity	CIPAC MT 75.3	Nominal active ingredient: Brodifacoum 0.0025 % w/w The tested product is an aqueous solution of 1%w/v.	pH 7.2 at 20°C	Brioschi. (2016a)
Relative density / bulk density	EC Regulation No. 440/2008 A.3	Nominal active ingredient: Brodifacoum 0.0025 % w/w	1.0855	Brioschi. (2016a)
Storage stability test – **accelerated**	Internal method No.	Nominal active ingredient:	Physical state, colour and	Brioschi. (2016b)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
storage	804/2015 OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3 Council Regulation (EC) No 440/2008 A.3 (hydrostatic balance) Visual examination of both external and internal packaging By technical balance	Brodifacoum 0.0025 % w/w	odour – no changes in comparison with the initial value No significant change in active ingredient content was found compared to the value obtained in the repeatability test of the method validation. For details see table below.	
Storage stability test – **long term storage at ambient temperature**	GIFAP Monograph No. 17, 2nd edition, June 2009: Guidelines for Specifying the Shelf Life of Plant Protection Products - EPA Guidelines OPPTS 830.6302 (1996) ; OPPTS 830.6303 (1996) ; OPPTS 830.6304 (1996) - CIPAC (Collaborative International	Nominal active ingredient: Brodifacoum 0.0025 % w/w	After two years the product is stable. For details see the table below.	Brioschi. (2016c)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Pesticides Analytical Council), Physico-chemical Methods for Technical and Formulated Pesticides: MT 75.3 "Determination of pH values			
Storage stability test – **low temperature stability test for liquids**			Not required since the product is not a liquid. The conduction of the storage stability study at low temperature technically not feasible.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The product will be stored and transported in the packaging, not allowing for the direct exposition to the light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The container did not present any deformation in bottom or lateral layers or loss of sample or evident corrosion phenomena.	Brioschi. (2016b)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Wettability			Not relevant to be measured since the product is not going to be dispersed in water (study technically not feasible).	
Suspensibility, spontaneity and dispersion stability			Not relevant to be measured since the product is not a liquid formulation (Study technically not feasible)	
Wet sieve analysis and dry sieve test			Wet sieve test: Not relevant to be measured since the product is not a liquid formulation (Study technically not feasible). Dry sieve test: Not relevant to be measured since the test item is a ready to use biocidal product (blockbait), the study on dry sieve test is only relevant for dusts and granular formulation to determine the size distribution of dustable powders and granules for direct application (study	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			scientifically not necessary).	
Emulsifiability, re-emulsifiability and emulsion stability			Not relevant to be measured since the product is not a liquid formulation (study technically not feasible).	
Disintegration time			Not relevant to be measured since the test item is a ready to use biocidal product (block bait), the study on disintegration time is only applicable to products that are tablets (study scientifically not necessary).	
Particle size distribution, content of dust/fines, attrition, friability			Not relevant to be measured since the test item is a ready to use biocidal product (block bait), the study particle size distribution, content of dust, attrition and friability is only applicable to powder biocidal products and granules (study scientifically not necessary).	
Persistent foaming			Not relevant to be measured since the product is not a liquid formulation	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(study technically not feasible).	
Flowability/Pourability/Dustability			Flowability: Not relevant to be measured since the test item is a ready to use biocidal product (blockbait), the study on flowability to granular formulation (study scientifically not necessary). Pourability: Not relevant to be measured since the test item is a ready to use biocidal product (blockbait), the study on pourability applies only to liquid formulations as suspension concentrates (study scientifically not necessary).	
Burning rate — smoke generators			Not relevant to be measured since the test item is a ready to use biocidal product (block bait)	
Burning completeness — smoke generators			Not relevant to be measured since the test item is a ready to use biocidal product (bloc kbait)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators			Not relevant to be measured since the test item is a ready to use biocidal product (block bait)	
Spraying pattern — aerosols			Not relevant to be measured since the test item is a ready to use biocidal product (block bait),	
Physical compatibility			Not relevant to be measured since the product is not going to be mixed or applied with other biocidal products.	
Chemical compatibility			Not relevant to be measured since the product is not going to be mixed or applied with other biocidal products.	
Degree of dissolution and dilution stability			Not relevant to be measured since the product is not a liquid formulation (study technically not feasible).	
Surface tension			Not relevant to be measured since the product is not a liquid formulation (study technically not feasible).	
Viscosity			Not relevant to	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			be measured since the product is not a liquid formulation (study technically not feasible).	

Stability at 35°C for 12 weeks (accelerated storage stability)

Test	Initial	After 12 weeks at 35°C
Brodifacoum active ingredient content	0.0026% ± 0.0001 % w/w	0.0026% ± 0.0001 % w/w
Appearance (colour, odour and physical state)	Dark blue solid block, with characteristic odour	Dark blue solid block, with characteristic odour
pH (1% acqueous dilution)	7.2	6.8
Relative density	1.0855 at 20°C	1.1077 at 20°C
Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)	----	The container did not present any deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena.
Packaging	---	Aluminium bag from "A1" to "A4" and from "B1" to "B4"
Weight variation (%)	-----	A1:-0.55 A2:-0.60 A3:-0.64 A4:-0.60 B1:-0.57 B2:-0.55 B3:-0.61 B4:-0.55

Stability at ambient temperature for two years (shelf life)

Test	Initial	After 24 months
Brodifacoum active ingredient content	0.0026% ± 0.0001 % w/w	0.0025% ± 0.0001 % w/w
Appearance (colour, odour and physical state)	Dark blue solid block, with characteristic odour (shortcode BL4)	Dark blue solid block, with characteristic odour (shortcode BL4)
pH (1% acqueous dilution)	7.2	7.0
Relative density	1.0855 at 20°C	1.0831 at 20°C
Compatibility (resistance) of the packaging material (Visual examination of	----	The container did not present any deformation in either bottom or lateral

packaging both externally and internally)		layers, or loss of sample or evident corrosion phenomena.
Packaging	------	Plastic composite (triple layer: polyester/ PET met/polyethylene) bag "F1", "F2", "F3", "F4" and G1", "G2", "G3", "G4"
Weight variation (%)	-----	"F1": -0.30 % "F2": -0.31 % "F3": -0.34 % "F4": -0.21% "G1": -0.18 % "G2": -0.17 % "G3": -0.19 % "G4": -0.15%

Conclusion on the physical, chemical and technical properties of the product
Neo-Actiblock-Brod is a ready to use block bait biocidal product. The pH of the product was determined to be 7.2 at 20°C. The relative density was measured to be 1.0855. The product is stable during storage for 12 weeks at 35°C. No changes in the sample appearance, colour, odour, content of the active ingredient, weight variation and packaging was found after storage in three different packaging materials. The shelf life study indicate that the product is stable when stored at Ambient temperature for two years.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Not relevant, because according to Annex I, part 2, paragraphs 2.1.4.2 and 2.1.4.3 of the CLP Regulation, a substance or mixture shall not be classified as explosive if there are no chemical groups associated with explosive properties present in the molecule. The Biocide product does not contain any of the groups which may indicate explosive properties, listed in table A6.1 in Appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual or Tests and Criteria.	
Flammable gases			Not relevant to be conducted since the test item is ready to use solid product (study technically not	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			feasible)	
Flammable aerosols			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Oxidising gases			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Gases under pressure			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Flammable liquids			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Flammable solids	EU Method A.10 (Flammability of Solids)	Not stated	The rate of burning over 200 mm was more than 4 minutes, therefore the product is not highly flammable	(Younis, 2011)
Self-reactive substances and mixtures			Not relevant, because according to Annex I, part 2, paragraph 2.8.4.2 of the CLP Regulation, the classification	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			procedures for self-reactive substances and mixtures need not be applied if there are no chemical groups present in the molecule associated with explosives or self reactive properties. The Biocide product does not contain any such groups, as given in Tables A6.1 and A6.2 in Appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria	
Pyrophoric liquids			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Pyrophoric solids			Not relevant to be conducted since the test item is ready to use solid. None of the components contain metals or metalloids and hence the classification procedure does not need to be applied.	
Self-heating			Not relevant to	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
substances and mixtures			be conducted since none of the coformulants present in the formulation contain metals or metalloids and hence the classification procedure does not need to be applied.	
Substances and mixtures which in contact with water emit flammable gases			Not relevant to be conducted since the product is ready to use solid product which is not going to have any contact to water.	
Oxidising liquids			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Oxidising solids			Not relevant, since for organic substances or mixtures the classification procedure for this hazard class need not to be applied if the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			hydrogen. In the product the oxygen, fluorine or chlorine atoms are chemically bonded only to carbon or hydrogen atoms.	
Organic peroxides			Not relevant to be conducted since the test item does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	
Corrosive to metals			Not relevant to be conducted since based on the chemical evaluation none of the components contain chemical groups, which could initiate an an irreversible electrochemical reaction with metals leading to significant damage or destruction.	
Auto-ignition temperatures of products (liquids and gases)			Not relevant to be conducted since the test item is ready to use solid product (study technically not feasible)	
Relative self-ignition temperature for	EU Method A.16	Not stated	The self-ignition	(Younis, 2011)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
solids	(Relative Self-Ignition Temperatur e for Solids)		temperature was determined as 313ºC	
Dust explosion hazard			Not relevant to be measured since the test item is a ready to use product. The property dust explosion hazard applies only to formulations containing dust or able to produce it, that can ignite or explode when exposed to an ignition source when dispersed in air (study scientifically not necessary)	

Conclusion on the physical hazards and respective characteristics of the product
Neo-Actiblock-Brod is a ready to use block bait biocidal product. The product is not oxidising, explosive or pyrophoric. Furthemore, the self-ignition temperature was determined as 313ºC. The product is not a flammable solid.

2.2.4 Methods for detection and identification

Analysis of the active substance as manufactured

Acceptable methods for the determination of Brodifacoum and the only impurity present at quantity >0.1% w/w in the technical grade material manufactured by PelGar are available in the Competent Authority Report (CAR) on Brodifacoum (PT 14) prepared according to Art. 11(2) of Directive 98/8/EC by the RMS-IT.

Information on purity, isomeric composition and impurities is now available from both Members of the *Task Force* based on their respective 5-batch analysis. The technical equivalence assessment of the two sources concluded that Activa's Brodifacoum and PelGar's Brodifacoum are technically equivalent.

Formulation Analysis

A method by HPLC with UV detection at 270 nm for the determination of Brodifacoum in [redacted] has been developed and validated according to SANCO/3030/99 rev. 4. The Brodifacoum content proved to be 0.0026 ± 0.0001 % w/w in the investigated test item (from batch 2511, internal number 2925383-001). The method is sufficiently specific, linear (correlation coefficient > .99), accurate (with the mean recovery rate of 104.1% in the acceptable range 80-120%) and precise (being %RSDn = 1.1, below the limit proposed by the modified Horowitz equation, which is 6.55 at a.i. concentration of 0.0026 ± 0.0001 % w/w.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Brodifacoum	HPLC - UV	0.00490 - 0.01497 / 5	y = 116347 R = 0.99970	Specific	-	104.1 %	Not stated	Not relevant	Brioschi (2016d)

Residues Analysis

As regards the detection and identification of Brodifacoum residues in air, water, animal and human body fluids and tissues and in treated food or feeding stuff, acceptable analytical methods for the determination of Brodifacoum residues in all relevant matrices are already available in the CAR of the active substance.

Some co-formulants are classified as dangerous substances, but exist in extremely small concentrations that none of them lead to the classification of [redacted] as a hazardous preparation. No analytical method for the determination of residues in soil, water, animal and body fluid and tissues, treated food or feeding stuff is deemed necessary for co-formulants. As regards residues in air some components are volatile. Nevertheless, their occurrence in air is deemed negligible owing to the nature of the product (solid wax block-baits) and its use pattern and to the low content of volatile components dispersed in the wax block. No analytical method for the determination of residues in air is necessary for co-formulants, either.

For the identification/quantification of Brodifacoum residues in soil, no fully-acceptable analytical method for Brodifacoum residues in soil was available in the relevant CAR. A new study for the determination of Brodifacoum residues in soil was presented by the Applicant post Annex I inclusion and evaluated by the IT-CA only at product authorization. The submitted LC-MS/MS method for the analysis of Brodifacoum residues down to 0.01 mg/kg in both sandy loam and clay meets the requirements provided for by SANCO/825/00 and the Additional Guidance to TNsG on Data Requirements on analytical methods and supports the residue definition. The method is highly specific (LC-MS/MS, with two mass transitions validated), linear over the range 0.005–0.250 mg brodifacoum/kg in soil, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70–110%) and precise (%RSDn = 5 < 20% for each fortification level). The LOQ (as the lowest validated fortification level) complies with the relevant end-point (Eisenia fetida 14-d LC50 > 994 mg/kg dwt, corresponding to > 879.6 mg/kg wwt). For further details, please refer to the PAR of the product [redacted], containing 50 ppm Brodifacoum.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

NEO-ACTIBLOCK -BROD is a rodenticide formulated as wax bait, based on the active substance Brodifacoum. It is intended to be used for control of rodent pests in and around buildings (professional and general public use).

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The target species of NEO-ACTIBLOCK -BROD are brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*).

NEO-ACTIBLOCK-BROD is used for control of rodent pests in and around buildings, in cellars, garages, closets and gardens of property, farms and houses for professional, general public use and domestic use against rodent pests. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. In this dossier the professional as well as the general public use is intended. NEO-ACTIBLOCK-BROD is suitable on public and domestic premises.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Target organisms die due to massive internal haemorrhages.
NEO-ACTIBLOCK-BROD is used for the control of brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*).
Effectiveness trials that have been conducted on *R. norvegicus* and *M. musculus* to assess the efficacy of NEO-ACTIBLOCK-BROD in field trials are presented herein. The results of field trials are summarised in **Table 2.2.5.5-1**. The trials were conducted in compliance with the EPPO guideline PP 1/114(2) and the guidance document on efficacy evaluations of rodenticides (Product Type 14) from the European Commission (European Commission, 2009). For all these 2 field trials, a pre-treatment census gave evidence that sufficient numbers of target organisms were present. The test item showed a good acceptance and provided 100% effectiveness. The studies are fully supportive.
As a supportive data to demonstrate the mortality of the product having the reduced concentration of the active substance laboratory trials carried out both on Mus musculus and Rattus norvegicus have been supplied. These trials have been based on a Pasta bait formulation definitely similar to the ones actually in discussion and containing 0,0025 % Difenacoum. Difenacoum is a known active substance ranking at a lower level of toxicity (LD50) in comparison to Brodifacoum so that a bait formulations based on Difenacoum 0,0025 % can be waived to the fully comparable bait formulations based on Brodifacoum 0,0025 % (according to TNsG PT14 Dec 2016, point 2.7.1). Such trials demonstrated 100% mortality in both species.
Further studies on the palatability and storage stability of Brodifacoum are presented as bridging trials using the related product [redacted], according to the Technical Notes for Guidance on Product Evaluation, Appendices to Chapter 7, PT 14, Efficacy Evaluation of Rodenticidal Biocidal Products (European Commission, 2009); this related product contains Brodifacoum 0.005% w/w under the formulation of "wax block", and is intended for the same field of use as the product NEO-ACTIBLOCK-BROD. More specifically, two choice trials were conducted for [redacted]: one with *R. norvegicus* and one with *M. musculus* (**Table 2.2.5.5-2**). The studies showed that [redacted]

is palatable with a mean palatability against ground laboratory diet of 27.3% (*R. norvegicus*) and 53.7% (*M. musculus*). The formulation also resulted in 100% mortality for *R. norvegicus* and *M. musculus* after a four-day choice between this formulation and challenge diet. According to the TNsG (European Commission, 2009) in the bait choice feeding test the percentage of ingested bait containing the product should be normally ≥ 20%. When the test results in ≥ 90% mortality, a lower level than 20% of the total food consumption is acceptable. It can therefore be concluded that the two bait choice feeding tests are fully supportive.

In addition, one bait-choice trial was conducted with [redacted] aged formulation with the target organism *R. norvegicus* to account for the effect of ageing of [redacted] (**Table 2.2.5.5-3**). The related product was subjected to an accelerated aging process consisting in the storage of the product under the challenging conditions of 30°C ± 2°C/65% R.H. ± 5% R.H. for 17 weeks. The study showed that [redacted] aged formulation is palatable with a mean palatability against ground laboratory diet of 24.7%. The formulation resulted in 90% mortality after a four-day choice between this formulation and challenge diet. It can therefore be concluded that the bait choice feeding test is fully supportive and ageing of [redacted] has no influence, neither on the palatability nor on the efficacy of the product. Nevertheless, NEO-ACTIBLOCK-BROD contains preservatives compounds and a self-life of less than 24 months is claimed; based on expert opinion, most bait products have been found to be effective and palatable for 24 months (with preservatives) and 12 months (without preservatives). Efficacy testing should therefore only be provided for bait products with preservatives that claim a shelf life of longer than 24 months, according to TNsG on Product Evaluation, Appendices to Chapter 7, PT 14, Efficacy Evaluation of Rodenticidal Biocidal Products (European Commission, Draft Version December 2014).
Two further field trials with Vertox Wax Block Bait, one with *R. norvegicus* (Wade 1997a, RFT/97/1932) and one with *M. musculus* (Wade 1997b, RFT/97/1933) were presented in the CAR (CAR, 2010)[12]. Vertox Wax Block contains the same active ingredient, the same concentration of active ingredient and is intended for the same target organisms as the product [redacted]. These field trials were located on agricultural holdings. These studies have been considered satisfactorily and reliable.

To sum this up a variety of choice and field trials with NEO-ACTIBLOCK-BROD and other comparable products ([redacted]) as test products were presented spread among all intended target organisms (*R. norvegicus* and *M. musculus*) to prove its effectiveness and attractiveness in various pest incidences. Overall a good to very good efficacy of NEO-ACTIBLOCK-BROD was shown.

2.2.5.4 Mode of action, including time delay

The active substance Brodifacoum disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, in profuse haemorrhage and death. Like all anticoagulant rodenticides, Brodifacoum is structurally similar to vitamin K. Blood forms a clot at the site of injury by virtue of a complicated 'clotting cascade', involving numerous

[12] Brodifacoum Product-type 14 (Rodenticide), Italy, 17 September 2009, revised 16 December 2010[13] Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.

clotting factors. The clotting factors are made in the liver as inactive precursors, converted to active form and allowed to circulate in the bloodstream. Vitamin K is employed in the liver in the activation process, and is used in a continuous cyclic process involving several enzymes. The anticoagulant rodenticides block these enzymes, preventing regeneration of the vitamin K and preventing activation of the clotting factors.

2.2.5.5 Efficacy data

Table 2.2.5.5-1: Efficacy of Brodifacoum from its use in the biocidal product NEO-ACTIBLOCK-BROD

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	NEO-ACTIBLOCK-BROD (0.0025% w/w Brodifacoum) Block bait, ready to use	Brown rat (*Rattus norvegicus*) Wild lines	**Field trial** Location: farm with and cows breeding stables, fodder and equipment warehouses.	Baiting *ad libitum* 8 bait stations 200 g bait per box Baiting period: 14 days	100% mortality Pre baiting: 6631 g non poisoned placebo bait consumed during 5 days -an average daily consumption of 1384 g -average tracking score values from 18 to 26 recorded. -initial pest population estimates: 65 - 75 rats Post baiting: 0 g placebo bait consumed and tracking score values of 0. Final pest population estimates: 0 rats. - 6441 g of test substance consumed in 14 days (Max consumption in day 3 of the baiting period) -an average daily bait consumption of 460.07 g	[redacted], 2016a 2039.BCD.SA G15
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	NEO-ACTIBLOCK-BROD (0.0025% w/w Brodifacoum) Block bait, ready to use	House mouse (*Mus musculus*) Wild lines	**Field trial** Location: farm with hens breeding stable, fodder and equipment warehouses	Baiting *ad libitum* 8 bait stations 40 g bait per box Baiting period: 12 days	100% mortality Pre baiting: 633 g non poisoned placebo bait consumed during 5 days -an average daily bait consumption of 138.5 g -average tracking score values from 16 to 21 recorded. -initial pest population estimates: 40 - 50 mice Post baiting: 0 g placebo bait consumed and tracking score values of 0. Final pest population estimates: 0 mice. 774 g of test substance consumed in 12 days -an average daily bait consumption of 64.5 g	[redacted], 2016b 2040.BCD.SA G15
III.2.1.1.1 Anticoagulant;	*In and around*	[redacted] (0.0025%	House mouse (Mus	**Laboratory trial**	**Choice test** Baiting *ad libitum*	Mean palatability against ground laboratory diet of 64.39% (S.D.	[redacted], 2017

Ingestion toxin, Ingestion by eating	*buildings*	w/w Difenacoum) Pasta ready to use	musculus) 5 females, 5 males Wild lines	Cages for single mice with two food pots placed either side at the front of the cage.	Alternative food without active ingredient (ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	23.27). The formulation resulted in 100% mortality after a four-day choice between this formulation and the challenge diet.	2022.BCD.SA G17
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.0025% w/w Difenacoum) Pasta ready to use	Brown rat (Rattus norvegicus) 5 females, 5 males Wild lines	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	Mean acceptance of 90.2% (S.D. 13.21) showing the formulation to be palatable to Brown rats. Mortality was 100% of efficacy.	[redacted], 2017 2031.BCD.SA G16

Table 2.2.5.5-2: Efficacy of Brodifacoum from its use in the biocidal product [redacted] (bait choice trials) - Bridging trials

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.005% w/w Brodifacoum) Block bait, ready to use	Brown rat (*Rattus norvegicus*) 5 females, 5 males	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	100% mortality Average time to death 4.7 days Consumed bait per rat: 23.6 g (= 5.9 g/rat/day) Consumed alternative food per rat: 57.6 g (= 14.4 g/rat/day) Ratio of bait and alternative food consume: 1: 2.4 Mean [redacted] consumption of rats: 27.3%	[redacted], 2011a VPU/10/060
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.005% w/w Brodifacoum) Block bait, ready to use	House mouse (*Mus musculus*) 5 females, 5 males	**Laboratory trial** Cages for single mice with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	100% mortality Average time to death 5.9 days Consumed bait per mouse: 11.6 g (= 2.9 g/mouse/day) Consumed alternative food per mouse: 9.9 g (= 2.5 g/mouse/day) Ratio of bait and alternative food consume: 1: 0.85 Mean [redacted] consumption of mice: 53.7%	[redacted], 2011b VPU/10/059

Table 2.2.5.5-3: Efficacy of Brodifacoum from its use in the biocidal product [redacted] (aged formulation) - Bridging trials

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (aged formulation) (0.005% w/w Brodifacoum) Block bait (aged). [redacted] (aged formulation) was manufactured by ACTIVA S.r.l. on 22nd September 2010 and subsequently stored at 30°C ± 2°C/65% R.H. ± 5% R.H. for 17 weeks.	Brown rat (*Rattus norvegicus*) 5 females, 5 males	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	90% mortality, one animal survived after consuming only 0.1 g of [redacted] (aged formulation). Average time to death 5.4 days Consumed bait per rat: 22.9 g (= 5.7 g/rat/day) Consumed alternative food per rat: 67.4 g (= 16.9 g/rat/day) Ratio of bait and alternative food consume: 1: 2.9 Mean [redacted] (aged formulation) consumption of rats: 24.7%	[redacted], 2011c VPU/11/034

Conclusion on the efficacy of the product
On the base of the field trials on the target organisms and considering the read across with the lab trials carried out with difenacoum 0,0025% on the same target organisms, the product Neo-Actiblock-Brod is considered effective.

2.2.5.6 Occurrence of resistance and resistance management

Based on the submitted studies no significant resistance against NEO ACTIBLOCK-BROD has been found. Furthermore it was concluded in the assessment report for Brodifacoum (CAR, 2010) that there is no reason to suspect a lack of efficacy of Brodifacoum-based products.

Resistance to the first generation anticoagulants has been widely reported in both Rattus norvegicus and Mus domesticus since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.
The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.
For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.
For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.
Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 198213; Lund, 198414; Pelz et al. 199515). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 198816). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being

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

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

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

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

attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b17).
Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.
House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone.
So, resistance to second generation anticoagulant rodenticides should not be minimized.
An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program "impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators").
The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.
The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.
The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.
To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

The label claim for the efficacy has to report information according to points 2.1.4 and 2.1.5.

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

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be authorized for use with other biocidal products.

2.2.6 Risk assessment for human health

The biocidal product NEO-ACTIBLOCK-BROD was not evaluated as a representative product during evaluation of the active substance. All data presented here are data on a new product. No new data on the active substance is included.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

The acute irritating/corrosive effects to the skin of the product [redacted], containing higher amounts of Brodifacoum, have been investigated experimentally in studies according to current guidelines.

In view of the very similar formulations differing only in content of active ingredient, the results are considered to apply to NEO-ACTIBLOCK-BROD as well.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404 GLP Reliability:1	3 male New Zealand white rabbits per group	[redacted] (batch 201001679), containing 0.00053% Brodifacoum, was applied at 500 mg/patch in distilled water to the skin of rabbits for 4-hour semiocclusive exposure	Erythema: 0.0 Oedema: 0.0 No clinical signs of toxicity were noted. The test material is not irritating to rabbit skin.	Initially one rabbit was tested. Based on the results obtained at 24 h post instillation observation, the irritation response was confirmed by testing two additional rabbits simultaneously.	[redacted] M.R. (2011c) Acute dermal irritation study of [redacted] in rabbits

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	[redacted] is not skin irritating.
Justification for the value/conclusion	No skin irritation was observed in a GLP and guideline confirming study in rabbits.
Classification of the product according to CLP and DSD	No classification according to CLP

Eye irritation

The acute irritating/corrosive effects to the eye of the product [redacted], containing higher amounts of Brodifacoum, have been investigated experimentally in studies according to current guidelines.

In view of the very similar formulations differing only in content of active ingredient, the results are considered to apply to NEO-ACTIBLOCK-BROD as well.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 405 GLP Reliability:1	3 female New Zealand white rabbits per group	[redacted] (batch 201001679), containing 0.00053% Brodifacoum, was installed at 100 mg into the conjunctival sac of the eyes of rabbits. The eyes were rinsed with aqueous 0.9% NaCl solution 24 h after installation.	Cornea: 0.0 Iris: 0.0 Conjunctival redness: 0.44 (1.0 at 24 h, 0.33 at 48 h, 0 t 72 h) Chemosis: 0.11 (0.33 at 24 h, 0 at 48 h) Reversible within 72 hours No signs of systemic toxicity were noted.	Initially one rabbit was tested. Based on the results 24 h post instillation, response was confirmed by testing two additional rabbits.	[redacted] M.R. (2011d) Acute eye irritation study of [redacted] in rabbits

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	[redacted] is not eye irritating.
Justification for the value/conclusion	No eye irritation was observed in a GLP and guideline confirming study in rabbits.
Classification of the product according to CLP and DSD	No classification according to CLP

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Not applicable
Classification of the product according to CLP and DSD	Not classification according to CLP

Data waiving	
Information requirement	Not applicable
Justification	No data requirement according to Annex III of Reg. EC no. 528/201

Skin sensitization

The potential to induce delayed hypersensitivity on dermal contact of the product [redacted] has been investigated experimentally.

In view of the very similar formulations [redacted], the results are considered to apply to NEO-ACTIBLOCK-BROD as well.

In a skin sensitisation maximisation test according to Magnusson & Kligman, no dermal sensitisation was observed.

The product is considered not sensitising to guinea pigs.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure**	**Results**	**Remarks**	**Reference** [redacted] (2011) Skin sensitization study of [redacted] in guinea pigs (guinea pig maximization test),
OECD 406 GLP Considered reliable	10 female Dunkin Hartley guinea pigs per group	[redacted] (batch 201001679), containing 0.00053% Brodifacoum, was tested for skin sentisitising properties according to the M&K guinea pig maximization test. Induction phase: 1.0% test substance in distilled water (intradermally) and 100 mg in 0.2 mL 80% aqueous ethanol (topically)	48h after challenge: Vehicle induced: 0/5 Test article induce: 0/10 No skin reactions 72 h after challenge: Vehicle induced: 0/5 Test article induce: 0/10 No skin reactions All guinea-pigs survived the study. Body weights were comparable between the two groups. No systemic intolerance other than skin reactions was noted.	None	

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Under the conditions of this test, [redacted] did not induce delayed contact hypersensitivity in any of the animals (0%, sensitisation rate).
Justification for the value/conclusion	A response of 0% (< 30% of the animals) in this adjuvant test was achieved, hence, the test item is not sensitising and does not require labelling as being a skin sensitizer.
Classification of the product according to CLP and DSD	No classification according to CLP.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	Weight of evidence
Classification of the product according to CLP and DSD	Not classified according to CLP

Data waiving	
Information requirement	IUCLID 8.4 – Respiratory sensitisation Justification_non submission respiratory sensitisation
Justification	Based on the available data for all ingredients, no evidence for respiratory sensitisation is available. Therefore, no classification of the product is considered to be required. Moreover, currently no testing methods or test guidelines are available. Hence, no further data are considered necessary.

Acute toxicity

Acute toxicity by oral route

The acute toxicity of the product NEO-ACTIBLOCK-BROD has not been investigated experimentally.

However, a similar formulation containing 50 ppm active ingredient instead of 25 ppm, was tested. As both formulations are similar regarding any other ingredient the results are considered to apply to NEO-ACTIBLOCK-BROD as well.

NEO-ACTIBLOCK-BROD exhibited low acute oral toxicity to female rats with an oral LD_{50} exceeding 2000 mg/kg bw. Dermal application of 2000 mg NEO-ACTIBLOCK-BROD /kg bw did not cause death or systemic clinical signs of toxicity in rats.

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423 GLP Reliability:1	3 female Wistar rats per group	[redacted] (batch 201001679), containing 0.00053% Brodifacoum, was administered by single oral gavage at 300 and 2000 mg/kg bw	No mortalities occurred, no signs of toxicity were noted. All animals showed expected gains in bodyweight. No abnormalities were noted at necropsy at both dose levels. No other significant effects noted.	LD_{50} > 2000 mg/kg bw	None	[redacted] (2011a) Acute oral toxicity study of [redacted] in rats

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	[redacted] was not acute toxic by the oral route in a GLP and guideline confirming study in rats.
Classification of the product according to CLP and DSD	No classification according to CLP

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATE = 61000 µg/L
Justification for the selected value	Based on extrapolation from active substance (LC_{50} (4 h) = 3.05 mg/m³ to female rats). Other ingredients are not classified with regard to their toxicological properties and/or are present in concentrations (< 1%) that do not trigger classification according to CLP.
Classification of the product according to CLP and DSD	No classification according to CLP

Data waiving	
Information requirement	IUCLID 8.5.2 – Acute toxicity by the inhalation route Justification_non submission inhalation toxicity
Justification	The active substance Brodifacoum is classified for acute inhalation toxicity (cat. 4) according to EC Regulation No. 1272/2008. No other ingregients in the formulation are classified for acute inhalation toxicity. Based on the ATE_{mix} calculation, the product is considered not to be toxic by inhalation according to to Reg. (EC) no. 1272/2008.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**

OECD 402 GLP Reliability: 1	5 female Wistar rats per sex per group	[redacted] (batch 201001679), containing 0.00053% Brodifacoum, was administered by single dermal semi-occlusive application for 24 h at 2000 mg/kg bw	There were no mortalities, no signs of systemic toxicity, no signs of dermal irritation. Animals showed expected gains in bodyweight over the study period. No abnormalities were noted at necropsy.	LD_{50} > 2000 mg/kg bw	None	[redacted] (2011b) Acute dermal toxicity study of [redacted] in rats

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	[redacted] was not acute toxic by the dermal route in a GLP and guideline confirming study in rats.
Classification of the product according to CLP and DSD	No classification according to CLP

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Brodifacoum
Value(s)*	0.047% (for b.p. containing 0.05% a.s.) 0.2% for the current formulation Neo-actiblock brod (containing 0.025% a.s.)
Justification for the selected value(s)	In view of the similarity of the active ingredients Difenacoum and Brodifacoum and the similarity of wax bait formulations in accordance with the CAR on Brodifacoum (IT, 2010), read-across principles are applied. However, the new formulation contains only a half concentration of the a.s. with respect to the formulation tested in the available dermal absorption study. The other components are the same with the same content and therefore the two formulations can be considered as closely related.

	According to the EFSA guidance on dermal absorption 2012, an extrapolation of the dermal absorption values between the two formulations is acceptable. Considering the lower content of a.s. in the new formulation, by applying a pro-rata correction a value of 0.2 is considered acceptable.

For risk assessment a rounded value of **0.2%** is applied for the product NEO ACTIBLOCK-BROD.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Brodifacoum
Value(s)*	0.047% (for b.p. containing 0.05% a.s.) 0.2% for the current formulation Neo-actiblock brod (containing 0.025% a.s.)
Justification for the selected value(s)	In view of the similarity of the active ingredients Difenacoum and Brodifacoum and the similarity of wax bait formulations in accordance with the CAR on Brodifacoum (IT, 2010), read-across principles are applied. However, the new formulation contains only a half concentration of the a.s. with respect to the formulation tested in the available dermal absorption study. The other components are the same with the same content and therefore the two formulations can be considered as closely related. According to the EFSA guidance on dermal absorption 2012, an extrapolation of the dermal absorption values between the two formulations is acceptable. Considering the lower content of a.s. in the new formulation, by applying a pro-rata correction a value of 0.2 is considered acceptable.

For risk assessment a rounded value of **0.2%** is applied for the product NEO ACTIBLOCK-BROD.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

No ingredients are included in the formulated product, which are considered to be of toxicological concern in view of their toxicity profile and concentration in the product.

Available toxicological data relating to a mixture

Not applicable, see above.

Other: Available data of residues in food and feeding stuff

According to the CAR (IT, 2010) on Brodifacoum point 3.3, Brodifacoum-containing baits should not be placed where food, feedingstuffs or drinking water could be contaminated. Thus, it is not intended to use NEO-ACTIBLOCK-BROD in premises where food for human consumption of feeding stuf for livestock is prepared.
Moreover, the baits are applied in a manner not allowing direct contact to such stuff (e.g. tamper-resistant boxes).
Since no contamination of food and feeding stuffs will occure, no further tests of information are required.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**General public use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.*	No	No	n.a.*	Negligible	Negligible	No
Dermal	n.a.*	Yes	Yes	n.a.*	Yes	Yes	No
Oral	n.a.*	No	No	n.a.*	No	Yes	No

* industrial use (manufacture of active substance and formulation) are not covered by the BPR

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application	Deploying (loading bait station with 10 baits) – Primary	Professional
2.	After application	Cleaning/disposal – Primary	Professional
3.	Application	Deploying (loading bait station with 10 baits) – Primary	General public
4.	After application	Cleaning/disposal – Primary	General public
5.	Indirect exposure	Ingestion of bait by children – secondary	General public

Industrial exposure

Due to the low vapour pressure of the active ingredient and the production process according most recent legislation for dangerous substances, occupational inhalation exposure is negligible.
Direct dermal contact with Brodifacoum or NEO-ACTIBLOCK-BROD is not foreseen. However, incidental contact is possible during maintenance work within the production process.
Since all workers are equipped with appropriate protective gloves and coveralls, occupational exposure from production is considered to be not relevant.

Given that the modelling of exposure and subsequent risk assessment during production and formulation of active ingredients and the formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Directive 98/8/EC and subsequently under Regulation (EU) No 528/2013 as agreed on Technical Meeting TM I 2006, exposure from manufacture is not considered further.

Professional exposure

Scenario 1 - Deploying (loading bait station with 10 baits)

Description of Scenario 1 - deploying (loading bait station with 10 baits)		
The risk assessment for application of the biocidal product, NEO-ACTIBLOCK-BROD, is based on the results of an operator exposure study conducted by the CEFIC Rodenticide Working Group and the recommendations of Human exposure Expert Group[18]. In this study exposure was monitored associated with all activities required for application of rodenticidal block baits, including loading and securing bait points and clean-up or disposal of bait stations. Measurements were performed in 10 replicates from 1, 5 or 10 manipulations, i.e. the filling of 1 bait station with 100 g of block bait (5 blocks per bait station, 20 g each). Dermal exposure was monitored using cotton gloves as dosimeter during all steps. Based on the results of this study, exposure estimates as summarized below were calculated from the whole data set after conversion of the results from 1, 5 or 10 manipulations to amount of product/manipulation. Dermal exposure estimates are presented as 75th percentiles, as suggested by the Biocide Technical Meeting (II 2006) and employed for other biocidal product dossiers. Inhalation exposure estimate is not taken into account for wax baits[19]. The number of manipulations to be assessed for professional operators is based on the Addendum of the CEFIC study, presenting 90th percentiles for the frequency of handlings. Accordingly, for a professional pest control operator, 60 manipulations (90th percentile) per day, handling 200 g of bait, is considered for risk assessment.		
	Parameters	Value
Tier 1	Dermal exposure (based on study results, 5 contacts, 20 g per bait)	27.79 mg product/man
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Application	20 contacts, 60 operations
	Body weight HEEG opinion (2013)[20]	60 kg
	Dermal penetration	0.2%
Tier 2	Gloves (TNsG Human Exposure to Biocidal Products, 2007)	95% protection

18 HEEG (2012) HEEG Opinion on an Harmonised Approach for the Assessment of Rodenticides (Anticoagulants)

19 Snowdon, P.J., (2003), Pilot study to primary sources of exposure to operators during simulated use of anticoagulant rodenticide baits, Synergy laboratories ltd, Study Nº SYN/1301

20 HEEG (2013) Default human factor values for use in exposure assessments for biocidal products)

Cleaning/disposal

Description of Scenario 2 – cleaning/disposal		
Loaded bait stations containing wax bait are emptied into a plastic bucket, any remaining material is removed by sweeping from the bait station directly into the same bucket. In accordance to the latest proposals of the Human Exposure Expert Groups (HEEG)[21] and as agreed at the Technical Meeting (TM III, 2010) 20% (equal to 15 manipulations) of tasks (75) are to be considered for cleaning and disposal, hence 60 loading manipulations and 15 cleaning manipulations are assumed. (not to be corrected for number of baits handled)		
	Parameters	Value
Tier 1	Dermal exposure (based on study results, 5 contacts, 20 g per bait)	5.7 mg product/manipulation
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Operations	15 cleaning/disposal operations
	Body weight HEEG opinion (2013)[22]	60 kg
	Dermal penetration	0.2%
Tier 2	Gloves (TNsG Human Exposure to Biocidal Products, 2007)	95% protection

Calculations for Scenario 1 and Scenario 2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1	Tier 1 – no PPE	n.a.*	5.56×10^{-6} mg/kg bw	n.a.*	5.56×10^{-6} mg/kg bw
Scenario 1	Tier 2 – protective gloves	n.a.*	2.78×10^{-7} mg/kg bw	n.a.*	2.78×10^{-7} mg/kg bw
Scenario 2	Tier 1 – no PPE	n.a.*	7.1×10^{-8} mg/kg bw	n.a.*	7.1×10^{-8} mg/kg bw
Scenario 2	Tier 2 – protective gloves	n.a.*	3.56×10^{-9} mg/kg bw	n.a.*	3.56×10^{-9} mg/kg bw

21 HEEG (2010) Harmonizing the number of manipulations in the assessment of rodenticides

22 HEEG (2013) Default human factor values for use in exposure assessments for biocidal products)

* Not a relevant route of exposure

Further information and considerations on scenario [1,2]

None

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1 and 2, Tier 1	n.a.*	5.63×10^{-6} mg/kg bw	n.a.*	5.63×10^{-6} mg/kg bw
Scenario 1 – Tier 2 (protective gloves) and Scenario 2 – Tier 1	n.a.*	3.50×10^{-7} mg/kg bw	n.a.*	3.50×10^{-7} mg/kg bw

* Not a relevant route of exposure

General public exposure

Scenario 3 - Deploying (loading bait station with 10 baits)

Description of Scenario 3 - Deploying (loading bait station with 10 baits)		
The application pattern of [redacted] by general public users is mainly similar to professional users. However, fewer manipulations as compared to professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a general public user (in accordance to HEEG opinion, 2010). For amateur users, no protection by gloves is considered. However, gloves may be recommended to help preventing rodent-borne diseases.		
	Parameters[1]	Value
Tier 1	Dermal exposure (based on study results, 5 contacts, 20 g per bait)	27.79 mg product/man
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Application	5 operations

	Body weight HEEG opinion (2013)[23]	60 kg
	Dermal penetration	0.2%

Scenario 4 -Cleaning/disposal

Description of Scenario 2 – cleaning/disposal		
Loaded bait stations containing wax bait are emptied into a plastic bucket, any remaining material is removed by sweeping from the bait station directly into the same bucket. The application pattern of [redacted] by general public users is mainly similar to professional users. However, fewer manipulations as compared to professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a general public user (in accordance to HEEG opinion, 2010). For amateur users, no protection by gloves is considered. However, gloves may be recommended to help preventing rodent-borne diseases. (not to be corrected for number of baits handled)		
	Parameters	Value
Tier 1	Dermal exposure (based on study results, 5 contacts, 20 g per bait)	5.7 mg product/manipulation
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Operations	5 cleaning/disposal operations
	Body weight HEEG opinion (2013)[24]	60 kg
	Dermal penetration	0.2%

Calculations for Scenario 3 and Scenario 4

Summary table: estimated exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	Tier 1 – no PPE	n.a.*	2.32×10^{-7} mg/kg bw	n.a.*	2.32×10^{-7} mg/kg bw
Scenario 4	Tier 1 – no PPE	n.a.*	2.40×10^{-8} mg/kg bw	n.a.*	2.40×10^{-8} mg/kg bw

* Not a relevant route of exposure

Further information and considerations on scenario [3,4]

23 HEEG (2013) Default human factor values for use in exposure assessments for biocidal products)

24 HEEG (2013) Default human factor values for use in exposure assessments for biocidal products)

None

Combined scenarios

Summary table: combined systemic exposure from general public uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 3 and 4, Tier 1	n.a.*	2.6×10^{-7} mg/kg bw	n.a.*	2.6×10^{-7} mg/kg bw

* Not a relevant route of exposure

Exposure of the general public

During application of NEO-ACTIBLOCK-BROD in rodent control, secondary exposure to the rodenticidal baits may occur. Two scenarios are considered, dermal contact with dead rodents by adults and incidental ingestion of baits by children.

However, it should be noted that usually deposition of active ingredients from baits on animal fur is unlikely to occur.
Moreover, according to the TM II 2006, handling of dead rodents by children is considered to be unrealistic.

Dermal contact with dead rodents

Not assessed.

Scenario 5 - Ingestion of bait (transient mouthing)

Description of Scenario 6 – Ingestion of bait (transient mouthing)		
During use in rodent control, secondary exposure to the rodenticidal baits may occur. To assess secondary exposure, two scenarios may be considered, dermal contact with dead rodents by adults and incidental ingestion of baits by children. Based on these scenarios as listed in Appendix 7.2.1 of TNsG (2002) Part 3, calculation of secondary exposure is performed. According to the TM II 2006, handling of dead rodents by children is considered to be unrealistic (see MOTA). It is assumed that a child will ingest 5 g of the wax bait (a general assumption of poison centre specialists, what children would ingest, see CAR Difethialone, Norway 2007). However, ingestion of 5 g represents a high overestimate of exposure, since baits contain a repellent (denatonium benzoate as bitter agent), which will most likely urge the children to spit the block. Therefore, the general assumption of ingestion of 10 mg of bait (TNsG default for a bait with repellent) was considered in Tier 2 calculations.		
	Parameters	Value
Tier 1	Oral ingestion	5 g bait
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Oral exposure	0.125 mg
	Oral absorption	100%
	Body weight	10 kg
Tier 2	Oral ingestion	10 mg bait
	Concentration brodifacoum in product	0.0025% (25 ppm)
	Oral exposure	0.00025 mg

Calculations for Scenario 5

Summary table: systemic exposure from general public uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 5	Tier 1 – ingestion of 5 g bait	n.a.*	n.a.*	1.25×10^{-2}	1.25×10^{-2} mg/kg bw
Scenario 5	Tier 2 – ingestion of 10 mg bait	n.a.*	n.a.*	2.5×10^{-5}	2.5×10^{-5} mg/kg bw

* Not a relevant route of exposure

Monitoring data

No data available or required.

Dietary exposure

Not relevant

Information of non-biocidal use of the active substance

[Please include a section for each area of other (non-biocidal) use of the active substance. Please insert or delete rows as needed.]

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant

Estimating transfer of biocidal active substances into foods as a result of general public use

Not relevant

Exposure associated with production, formulation and disposal of the biocidal product

Given that the modelling of exposure and subsequent risk assessment during production and formulation of active ingredients and the formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Directive 98/8/EC and subsequently under Regulation (EU) No 528/2013 as agreed on Technical Meeting TM I 2006, exposure from manufacture is not considered further.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
1.	Professional	Tier 1 – No PPE	5.56×10^{-6} mg/kg bw
1.	Professional	Tier 2 – protective gloves	2.78×10^{-7} mg/kg bw
2.	Professional	Tier 1 – No PPE	7.1×10^{-8} mg/kg bw
2.	Professional	Tier 2 – protective gloves	3.56×10^{-9} mg/kg bw
3.	General public	Tier 1 – No PPE	2.32×10^{-7} mg/kg bw
4.	General public	Tier 1 – No PPE	2.40×10^{-8} mg/kg bw
5.	General public – secondary exposure	Tier 1 – ingestion of 5 g bait	1.25×10^{-2} mg/kg bw
5.	General public – secondary exposure	Tier 2 – ingestions of 10 mg bait	2.5×10^{-5} mg/kg bw

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study*	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Rat teratogenicity study	0.001 mg/kg bw	300[1]	n.a.	3.3×10^{-6} mg/kg bw/d
$AEL_{medium\text{-}term}$	Rabbit developmental study	0.002 mg/kg bw	300[2]	n.a.	6.67×10^{-6} mg/kg bw/d
$AEL_{long\text{-}term}$	Rat two-generation toxicity study	0.001 mg/kg bw	300[1]	n.a.	3.3×10^{-6} mg/kg bw/d
ARfD	n.a.	n.a.	n.a.	n.a.	n.a.
ADI[3]	Rat two-generation toxicity study	0.001 mg/kg bw	300[1]	n.a.	3.3×10^{-6} mg/kg bw/d

* Please refer to the respective Competent Authority Report on Brodifacoum by CA Italy, 2010 for detail
1 For inter- and intrac species variability, default assessment factor of 10 is applied. An additional safety factor of 3 is applied for severity of effects as for other second generation anticoagulant rodenticides.
2 For inter- and intrac species variability, default assessment factor of 10 is applied. An additional safety factor of 3 is applied for the differences in exposure time
3 As derived in the Competent Authority Report on Brodifacoum by CA Italy, 2010

Maximum residue limits or equivalent

Not relevant.

Specific reference value for groundwater
Not relevant.

Risk for industrial users

No industrial exposure is foreseen.

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 - loading	I	0.001	3.3×10^{-6}	5.56×10^{-6}	168	no
1 - loading	II	0.001	3.3×10^{-6}	2.78×10^{-7}	8	yes
2 - disposal	I	0.001	3.3×10^{-6}	7.1×10^{-8}	2	yes
2 - disposal	II	0.001	3.3×10^{-6}	3.56×10^{-9}	<1	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 and 2	I	0.001	3.3×10^{-6}	5.63×10^{-6}	171	no
1 and 2	II	0.001	3.3×10^{-6}	3.50×10^{-7}	11	yes

Local effects
Not relevant

Conclusion
Without any protective equipment, the potential systemic exposure estimated for a professional user applying NEO-ACTIBLOCK-BROD for each of the different tasks according to the recommended models exceed the respective limit value for chronic (long-term) exposure ($AEL_{chronic}$).
The use of gloves for professional users is a mandatory.

Risk for general public users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3 - loading	I	0.001	3.3×10^{-6}	2.32×10^{-7}	7	yes
4 - disposal	I	0.001	3.3×10^{-6}	2.40×10^{-8}	<1	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3 and 4	I	0.001	3.3×10^{-6}	2.6×10^{-7}	8	yes

Local effects
Not relevant

Conclusion
Without any protective equipment, the potential systemic exposure estimated for a general public user applying NEO-ACTIBLOCK-BROD for each of the different tasks according to the recommended models does not exceed the respective limit value for acute (short-term) exposure (AEL_{acute}).
Moreover, no risk is anticipated for the total systemic exposure for use by the general public performing all tasks combined without any protective gloves.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
5 – ingestion of bait - 5 g	I	0.001	3.3×10^{-6}	1.25×10^{-2}	>>100	no
5 – ingestion of bait - 10 mg	II	0.001	3.3×10^{-6}	2.5×10^{-5}	760	no

Combined scenarios
Not relevant

Conclusion
Estimation of secondary exposure scenarios demonstrates that children are at risk by ingesting 5 g or 10 mg of pellets according to the estimations.
However, calculations are based on conservative assumptions which will likely overestimate actual exposure levels. Furthermore, baits are placed according to the risk mitigation measures proposed for anticoagulant rodenticides usually out of the reach of children in tamper-resistant bait stations. Moreover, NEO-ACTIBLOCK-BROD baits contain a highly efficient bittering agent to prevent ingestion by children.
Hence, secondary exposure of children is unlikely to occur and no risk expected.

Risk for consumers via residues in food

Not relevant

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

Not relevant

2.2.7 Risk assessment for the environment

The product NEO-ACTIBLOCK-BROD is a rodenticide formulated as wax bait, based on the active substance Brodifacoum and is provided in bait stations. It is intended to be used for control of rodent pests in and around buildings (industrial, professional and general public use). The target species of NEO-ACTIBLOCK-BROD are brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*). All bait points will be placed in dry locations in hiding and feeding places and running tracks of the rodents and will be protected against access by non-target animals. Local releases to the environment can take place from any stage of the life cycle of the product. However, according to the emission scenario document EUBEES (2003) only very local if any environmental exposure is expected from the production process of the active substance and formulation processes of the biocidal products. The main exposure of the environment is expected to be to soil contaminated by spills during application, refilling and disposal operations. The rodents may disperse the substance during the use period. The rodenticide will be spread in the surroundings either directly by rodents carrying the bait away from the bait boxes or through urine and faeces. Residues from indoor use of the product may reach the environment from disposal by sewerage systems or cleaning. Minimal amounts during (re-)filling are expected to be released to indoor floors and only negligible amounts will end up in the sewage treatment plant via cleaning. No fractions via urine or faeces are expected to contaminate indoor floors. Therefore, this route of emission is assumed to be insignificant and will not be addressed further according to EUBEES (2003) and no indirect releases via the STP are calculated to end up in the surface water compartment. If rodent infestation occurs, NEO-ACTIBLOCK-BROD is assumed to be distributed in and around buildings and not in vicinity of ditches, ponds or streams. Therefore, direct releases to surface water or sediment are also regarded to be negligible. In addition, emissions to air are regarded to be negligible since the active substance is regarded as non volatile.

[redacted] No substance other than the active substance Brodifacoum is included in the composition of NEO-ACTIBLOCK–BROD that is defined as a substance of concern according to Regulation (EU) No 528/2012. Testing of potential effects of the product NEO-ACTIBLOCK–BROD on non-target organisms is not required since data can be extrapolated from the active substance Brodifacoum. Also in view of the limited exposure of the environment by the covered use of the formulation further studies with the product are not considered to be necessary. It is referred to the data package of the active substance Brodifacoum submitted in the context of the Annex I inclusion in the review program under the Directive 98/8/EC. A complete data package on ecotoxicity and environmental fate is available.

2.2.7.1 Effects assessment on the environment

Predicted no effect concentration values (PNEC) are derived from the Assessment Report for Brodifacoum (2010)[25] and are used in the risk assessment.

[25] Assessment Report Brodifacoum, Product-type 14 (Rodenticides), 17 September 2009 revised 16 December 2010, Annex I - Italy

Aquatic Compartment
The exposure of sewage treatment plants, surface water and sediment following the use of NEO-ACTIBLOCK-BROD in and around buildings is negligible. Thus, the risk is considered to be acceptable.

Atmosphere
With regard to exposure scenarios in and around buildings, in open areas and on waste dumps, this pathway is considered to be not relevant since the active substance is regarded as low volatile. No risk assessment was therefore been performed.

Terrestrial compartment

Terrestrial organisms
It is concluded that Brodifacoum is of low toxicity to earthworms. A PNECsoil ≥ 0.88 mg/kg wwt soil has to be used in risk assessment.

Primary poisoning
According to the Assessment Report for Brodifacoum (2010) there is a predictable potential very high risk of primary poisoning to exposed non-target vertebrates, birds and mammals. However, the risk of primary poisoning of non-target mammals and birds is likely to be overestimated where the direct exposure to Brodifacoum is mitigated by the use of bait boxes

Secondary poisoning
Brodifacoum has a bioaccumulation potential in aquatic and terrestrial organisms due to a log Kow of 6.12 and a BCF 35134. In the EU evaluation of listing of the active substance in Annex I of the directive 98/8/EC (Assessment Report for Brodifacoum (2010)), secondary poisoning for birds and mammals was already calculated. The aquatic food chain (fish-eating birds and mammals) risk for secondary poisoning is considered insignificant and the assessment of secondary poisoning through the aquatic food chain was not performed. Direct and indirect releases to surface water and sediment are regarded to be negligible for use in and around buildings.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

All relevant data can be extrapolated from the active substance Brodifacoum. Testing of the product is not required.

Further Ecotoxicological studies

No data available.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.1
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs.

	A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of fish to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to fish are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.2
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data of the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of aquatic invertrebrates to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to aquatic invertebrates are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.3
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of aquatic algae and cyanobacteria to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to aquatic algae and cyanobacteria are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.5
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to

	this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of non-target microorganisms to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to non-target microorganisms are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.9
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of sediment organisms to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to sediment organisms are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.1.10
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum. No further studies on the toxicity of the formulation on aquatic organisms are considered to be necessary. Direct exposure of aquatic plants other than algae to [redacted] can be excluded. The product will be applied inside and ouside buildings exclusively in bait stations. Since an exposure of aquatic organisms can be excluded, studies on the toxicity of the formulation to aquatic plants other than algae are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.2.1
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered

	to be feasible to extrapolate from data on the active substance Brodifacoum.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.2.2
Justification	NEO-ACTIBLOCK-BROD mainly contains food [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.2.3
Justification	NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.4
Justification	The acute oral toxicity of the active substance Brodifacoum is documented sufficiently. Besides Brodifacoum, NEO-ACTIBLOCK-BROD mainly contains food ingredients [redacted] and other ingredients approved for food stuffs. A significant change of toxicity of Brodifacoum due to this composition can definitely be excluded. Thus, it is considered to be feasible to extrapolate from data on the active substance Brodifacoum.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.5 – Effects on beneficial arthropods other than bees
Justification	Direct exposure of beneficial arthropods other than bees to NEO-ACTIBLOCK-BROD can be excluded. [redacted] will be applied inside and outside buildings exclusively in bait stations, which are not accessible for non-target organisms. Since an exposure of beneficial arthropods other than bees can be excluded the studies with the formulation are not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.5 – Acute toxicity to honey bees

Justification	Direct exposure of beneficial arthropods to NEO-ACTIBLOCK-BROD can be excluded. [redacted] will be applied inside and outside buildings exclusively in bait stations, which are not accessible for non-target organisms. Since an exposure of beneficial arthropods can be excluded a study on the acute toxicity of the formulation to honey bees is not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.5 – Acute toxicity to honey bees
Justification	Direct exposure of beneficial arthropods to NEO-ACTIBLOCK-BROD can be excluded. [redacted] will be applied inside and outside buildings exclusively in bait stations, which are not accessible for non-target organisms. Since an exposure of beneficial arthropods can be excluded a study on the acute toxicity of the formulation to honey bees is not considered to be necessary.

Data waiving	
Information requirement	IUCLID 9.2 – Further ecotoxicological studies Waiver for point 9.2.8 – Toxicity to terrestrial vertebrates other than birds
Justification	Direct exposure of non-target mammals to NEO-ACTIBLOCK-BROD can be excluded. [redacted] will be applied inside and outside buildings exclusively in bait stations. The bait boxes are designed in this way that they will be in interest for the target organism. Due to the limited exposure a study on the acute toxicity to non-target mammals with the formulation is not considered to be necessary.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No data available. Please refer to the CAR of Brodifacoum.

Supervised trials to assess risks to non-target organisms under field conditions

No data available. Please refer to the CAR of Brodifacoum.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data available. Please refer to the CAR of Brodifacoum.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Secondary ecological effects are not expected.

Further studies on fate and behaviour in the environment (ADS)

No new data presented. Please refer to the CAR of Brodifacoum

Leaching behaviour (ADS)

No new data presented. Please refer to the CAR of Brodifacoum

Testing for distribution and dissipation in soil (ADS)

No new data presented. Please refer to the CAR of Brodifacoum

Testing for distribution and dissipation in water and sediment (ADS)

No new data presented. Please refer to the CAR of Brodifacoum

Testing for distribution and dissipation in air (ADS)

No new data presented. Please refer to the CAR of Brodifacoum

Summary table of half lives identified relevant metabolites and transformation products in air

No new data presented. Please refer to the CAR of Brodifacoum

Dissipation

No new data presented. Please refer to the CAR of Brodifacoum

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Acute aquatic toxicity
No data available. Please refer to the CAR of Brodifacoum

Data waiving	
Information requirement	Not required.
Justification	The product is a bait and is therefore not intended to be sprayed near to surface waters.

Chronic aquatic toxicity
No data available. Please refer to the CAR of Brodifacoum

Data waiving	
Information requirement	Not required.
Justification	The product is a bait and is therefore not intended to be sprayed near to surface waters.

Measured aquatic bioconcentration
No data available. Please refer to the CAR of Brodifacoum.

Data waiving	
Information requirement	Not required.
Justification	All relevant data can be extrapolated from the active substance Brodifacoum.

Estimated aquatic bioconcentration
No data available. Please refer to the CAR of Brodifacoum.

Data waiving	
Information requirement	Not required.
Justification	All relevant data can be extrapolated from the active substance Brodifacoum.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Since the product is a bait, it will neither be sprayed outside nor has a potential for large scale formulation of dust. Therefore, data on overspray behaviour are not required to assess risks to bees and non-target arthropods under field conditions.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT 14
Assessed scenarios	Scenario 1: In and around buildings (professional and general public use)
ESD(s) used	EUBEES Emission Scenario Document for biocides used as rodenticides, EUBEES 2, Danish EPA, Larsen, 2003
Approach	Scenario 1: The hazard characterisation to the different environmental compartments of the product NEO-ACTIBLOCK-BROD is based on the properties of the active substance Brodifacoum. The estimations are calculated using the Emission Estimation Excel Sheet PT14 released from the European Chemical Agency (ECHA) and modelling tool EUSES 2.1.
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	No higher tier model were performed
Confidential Annexes	NO
Life cycle steps assessed	Scenario n:1 Production: No Formulation No Use: Yes Service life: Yes
Remarks	*No remarks*

Emission estimation

Scenario 1

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: In and around buildings			
Application rate of biocidal product	20-40 g × bait point every 5-10 meters	20-40 g × bait point every 5-10 meters	House mouse (*Mus musculus*)
	100-200 g × bait point every 5-10 meters	100-200 g × bait point every 5-10 meters	Brown rat (*Rattus norvegicus*)
Concentration of active substance in the product	25	mg/kg	

Calculations for Scenario 1

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
Freshwater	Negligible – not calculated	-
Freshwater sediment	Negligible – not calculated	-
Seawater	Not relevant – not calculated	-
Seawater sediment	Not relevant – not calculated	-
STP	Negligible – not calculated	-
Air	Negligible – not calculated	-
Soil	0.0234	Calculated considering worst case, 250 g product per bait point every 10 meters
Groundwater	2.65×10^{-2}	Calculated considering worst case, 250 g product per bait point every 10 meters

The assessment of the environmental risk assessment is done based on the recommendations for calculations and default values as presented in the Technical

Guidance Document (TGD) (EC, 2003)[26], and in the ECHA Guidance on the Biocidal Product Regulations (Volume IV –Part B)[27] and the suggested scenarios as detailed in EUBEES (2003)[28]. The intended uses for NEO-ACTIBLOCK-BROD are implemented.

According to the emission scenario document EUBEES (2003), regional contribution to release and regional background concentrations can be regarded negligible due to the low consumption and the anticipated very local emission patterns of the use of the biocidal product with soil as the main receiving compartment.

Local releases to the environment can take place from any stage of the life cycle of a substance. In accordance with the TGD (EC, 2003)[29], the potential for environmental exposure might be considered for the following stages of the product life cycle for NEO-ACTIBLOCK-BROD:

- Production
- Formulation
- Use: professional and general public use
- Service life
- Waste disposal

However, according to the emission scenario document EUBEES (2003)[30] only very local, if any, environmental exposure is expected from the production process of the active substance and formulation processes of the biocidal products. Therefore, these life cycle stages are considered to be negligible.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	yes	yes	n.r.

n.r. – not relevant

Baits are to be placed in bait stations or in other ways covered or hidden so as to minimise access of non-target animals. Target animals mainly eat the bait e.g. split or loose bait in bait boxes. The main exposure of the environment is expected to be to soil contaminated

26 EC (2003): Technical Guidance Document (TGD) 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, OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES L – 2985 Luxembourg.

27 ECHA. Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment (active substances), ver. 1.0, April 2015.

28 EUBEES Emission Scenario Document for biocides used as rodenticides, EUBEES 2, Danish EPA, Larsen, 2003

29 EC (2003): Technical Guidance Document (TGD) 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, OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES L – 2985 Luxembourg.

30 EUBEES Emission Scenario Document for biocides used as rodenticides, EUBEES 2, Danish EPA, Larsen, 2003

by spills during application, refilling and disposal operations. The contributions from disperse release of rodenticides via urine and faeces should also be considered as service life. The rodents may disperse the substance during the use period. The rodenticide will be spread in the surroundings either directly by rats carrying the bait away from the bait boxes or through urine and faeces. Mice normally behave differently to rats, as they are much more likely than rats to gnaw block baits or grains directly at or in the bait box. Therefore, only the consumption of the product by rats is calculated in the following as a worst case scenario, including the possible environmental exposure to soil during service life.

Groundwater concentrations are calculated according to the TGD (EC, 2003)[31]. As an indication for potential groundwater levels, the concentration in pore water of soil is taken. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

Residues from indoor use of the product may reach the environment from disposal by sewerage systems or cleaning. Minimal amounts during (re-)filling are expected to be released to indoor floors and only negligible amounts will end up in the sewage treatment plant via cleaning. No fractions via urine or faeces are expected to contaminate indoor floors. Therefore, this route of emission is assumed to be insignificant and will not be addressed further according to EUBEES (2003)[32] and no indirect releases via the STP are calculated to end up in the surface water compartment. If rodent infestation occurs, NEO-ACTIBLOCK-BROD is assumed to be distributed in and around buildings and not in vicinity of ditches, ponds or streams. Therefore, direct releases to surface water or sediment are also regarded to be negligible.

In the EU evaluation for listing of the active substance in Annex I of the directive 98/8/EC (Assessment Report, Brodifacoum, 2010) Brodifacoum is poorly soluble in water and is hydrolytically stable. However, Brodifacoum undergoes rapid photolytic transformation in water, with a half-life of approximately two hours. The substance was considered not readily or inherently biodegradable. No metabolites above 10% were detected. Brodifacoum is not considered volatile following a vapour pressure of 1.9×10^{-21} Pa (at 25°C, estimated by the vapour pressure curve) and the Henry's law constant of 2.35×10^{-18}. The data on degradation in soil has been taken from published source and was found to be 157 days (at 19-22°C). The K_{OC} value was taken from the published source as well and was found to be 50000 mL/g.

31 EC (2003): Technical Guidance Document (TGD) 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, OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES L – 2985 Luxembourg.

32 EUBEES Emission Scenario Document for biocides used as rodenticides, EUBEES 2, Danish EPA, Larsen, 2003

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	523.4	g/mol	
Melting point	235.8	°C	
Boiling point	Not applicable	°C	
Vapour pressure (at 25 °C)	1.9×10^{-21}	Pa	
Water solubility (at 20 °C)	5.8×10^{-2} pH7	mg/l	
Log Octanol/water partition coefficient	4.92 (20 °C, pH7)	Log 10	
Organic carbon/water partition coefficient (Koc)	50000	mL/g	
Henry's Law Constant (at 25 ° C)	1.6×10^{-17}	Pa/m3/mol	
Biodegradability	Not biodegrdable		
Rate constant for STP *[if measured data available]*	n.a.	h^{-1}	
DT_{50} for biodegradation in surface water	n.a.	d or hr (at 12ºC)	
DT_{50} for hydrolysis in surface water	n.a.	d or hr (at 12ºC /pH)	
DT_{50} for photolysis in surface water		d or hr	
DT_{50} for degradation in soil	157	d (at 19-22.5 ºC)	
DT_{50} for degradation in air	6.61	hr	

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario n	
Air			
Water			
Sludge			
Degraded in STP			

Calculated PEC values

According to the EUBEES (2003)[33] a realistic average for a rodent infested farm would be 10 bait stations placed around the farm buildings, with a large variation. A farm that has a severe rat problem presents a conservative worst case example. In this case it is assumed that 10 tamper resistant bait stations are used each filled with default amount of 250 g paste baits according to the emission scenario document, inspected and replenished 5 times (days 1, 3, 7, 14 and 21). It is an assumption that all of the bait has been eaten.

[33] EUBEES Emission Scenario Document for biocides used as rodenticides, EUBEES 2, Danish EPA, Larsen, 2003

There is a large variation of the duration of a rodenticide campaign and a 21 days period represents a realistic worst case. These assumptions were taken as a first risk characterisation following the use of NEO-ACTIBLOCK-BROD (hereafter "Worst case") although it is not in compliance with the envisaged uses for the present product.

The present product will be packed in 10 or 20 g wax block per bait. It is intended to use several 10 or 20 g wax block stations, with the maximum of 200 g wax block bait point every 5-10 meters. However, for risk assessment purposes 10 bait points per infested area (550 m²) are assumed as an additional worst case.

As refinement of the scenario, a fraction of 20% is assumed to be metabolised in rats and not to be excreted as active substance.

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m³]	[mg/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/m³]	[µg/l]	[mg/m³]
Scenario 1	n.r.	n.r.	n.r.	n.r.	n.r.	0.0234	2.65×10^{-2}	n.r.
n.r. – not relevant								

The product label for NEO-ACTIBLOCK-BROD states that NEO-ACTIBLOCK-BROD and its container must be disposed of in a safe way. In case of both around buildings and indoor applications the product is only applied by best practice, illegal disposal can therefore be excluded. This would also preclude disposal to conventional landfill waste disposal sites.

Thus, disposal to landfill waste disposal sites is not expected to contribute at all to the overall environmental exposure or environmental concentration in comparison to the emissions from other parts of the life-cycle of the product (professional/general public use and service life stage). Furthermore, since general risk management measures based on EU waste legislation (Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste) sufficiently control and provide for containment of substances ending up in landfill sites, this route of exposure is not considered to be of concern. In addition, landfill sites are required by law to have appropriate measures in place to control the entry of water from precipitation, to prevent the entry of water from the surface and ground, and to have a geological and/or artificial impermeable barrier (sealing system) combined with leachate collection to prevent leachate escaping into the groundwater.

Primary and secondary poisoning

Primary/secondary poisoning

The first step in an assessment of secondary poisoning risk is to consider whether a chemical has the potential to bioaccumulate. The potential for bioaccumulation can be estimated from the value of the n-octanol/water partition coefficient, log Kow. It is accepted that values of log Kow greater than or equal to 3 indicate that the substance may

bioaccumulate. Brodifacoum has a bioaccumulation potential in aquatic and terrestrial organisms due to a log Kow of 6.12 and a BCF 35134.

In the EU evaluation of listing of the active substance in Annex I of the directive 98/8/EC (Assessment Report for Brodifacoum (2010)[34]), primary and secondary poisoning for birds and mammals was already assessed.

It was shown that the proposed normal use of Brodifacoum causes unacceptable risk for primary and secondary poisoning of non-target vertebrates. However, the risk for primary poisoning is assumed to be negligible in the ESD, since the rodenticidal bait is used according to the label instructions. The aquatic food chain (fish-eating birds and mammals) risk for secondary poisoning is considered insignificant and the assessment of secondary poisoning through the aquatic food chain was not performed. Direct and indirect releases to surface water and sediment are regarded to be negligible for use in and around buildings. In the terrestrial food chain secondary poisoning is possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely source for Brodifacoum residues in raptorial birds and mammalian predators.

In conclusion Brodifacoum does not fulfil the environmental acceptance criteria due to bioaccumulation and unacceptable effects in the non-target vertebrates.

However, rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs, structural damage and social abhorrence. Since less hazardous substances are not available yet, the use of formulations like NEO-ACTIBLOCK-BROD is indispensable.

In order to minimize the risk to non-target organisms and secondary poisoning of the non-target animals all possible measures will be taken due to the use of NEO-ACTIBLOCK-BROD to control target rodents.

The measures include use of sealed bait boxes to limit the access of non-target animals, collection of unconsumed baits after termination of the control campaign and collection of dead rodents during and after the control campaign. These mitigation measurements are described in good practice guidance documents and on the labels of the product. By using NEO-ACTIBLOCK-BROD according to the instructions the risk for secondary poisoning is minimised.

2.2.7.3 Risk characterisation

Atmosphere

With regard to exposure scenarios in and around buildings, in open areas and on waste dumps, this pathway is considered to be not relevant since the active substance is regarded as low volatile (vapour pressure is 1.9×10^{-21} Pa at 25°C). No risk assessment has therefore been performed.

Sewage treatment plant (STP)

NEO-ACTIBLOCK-BROD is intended to be used in and around buildings and therefore exposure to sewage treatment plant (STP) micro-organisms is regarded to be negligible. Thus, no risk assessment was performed.

34 Assessment Report Brodifacoum, Product-type 14 (Rodenticides), 17 September 2009 revised 16 December 2010, Annex I - Italy

Aquatic compartment

The exposure of surface water and sediment following the use of NEO-ACTIBLOCK-BROD in and around buildings is negligible. Thus, the risk is considered to be acceptable.

Terrestrial compartment

The PEC/PNEC ratio for the soil ecosystem is derived by dividing the local PEC in soil from direct emissions, by the PNEC for terrestrial organisms. In the Assessment Report for Brodifacoum (2010) the PNEC for terrestrial organisms has been determined to be > 0.88 mg a.s./kg ww soil.

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Worst case [250 g per bait]	
Brodifacoum	< 0.027
Realistic [20 g per bait]	
Brodifacoum	$< 6.20 \times 10^{-4}$
Realistic [10 g per bait]	
Brodifacoum	$< 3.10 \times 10^{-4}$

Conclusion: The PEC/PNEC ratios for the intended use of NEO-ACTIBLOCK-BROD in and around buildings are well below 1, which indicate that the risk for the terrestrial compartment is acceptable.

Groundwater

Direct and indirect releases to surface water and sediment are regarded to be negligible. In accordance with the guidance presented in the TGD, the concentration of the active substance in soil pore water of soil has been calculated to provide an indication for potential groundwater contamination levels. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. The local predicted environmental concentrations (PEC) in groundwater after use of NEO-ACTIBLOCK-BROD are presented under point 2.2.8.2. The PEC values are far below the 0.1 µg/L criterion stipulated by Council directive 80/778/EEC. Hence a risk of relevant groundwater contaminations can be excluded.

Primary and secondary poisoning

Primary / secondary poisoning

In the EU evaluation of listing of the active substance in Annex I of the directive 98/8/EC (Assessment Report for Brodifacoum (2010)), primary and secondary poisoning for birds

and mammals was already assessed. It was shown that the proposed normal use of Brodifacoum causes unacceptable risk for primary and secondary poisoning of non-target vertebrates. However, the risk for primary poisoning is assumed to be negligible in the ESD, since the rodenticidal bait is used according to the label instructions. The aquatic food chain (fish-eating birds and mammals) risk for secondary poisoning is considered insignificant and the assessment of secondary poisoning through the aquatic food chain was not performed. In the terrestrial food chain secondary poisoning is possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely source for Brodifacoum residues in raptorial birds and mammalian predators.
In conclusion Brodifacoum does not fulfil the environmental acceptance criteria due to bioaccumulation and unacceptable effects in the non-target vertebrates.
However, rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs, structural damage and social abhorrence. Since less hazardous substances are not available yet, the use of formulations like NEO-ACTIBLOCK-BROD is indispensable.
In order to minimize the risk to non-target organisms and secondary poisoning of the non-target animals all possible measures will be taken due to the use of NEO-ACTIBLOCK-BROD to control target rodents.
The measures include use of sealed bait boxes to limit the access of non-target animals, collection of unconsumed baits after termination of the control campaign and collection of dead rodents during and after the control campaign. These mitigation measurements are described in good practice guidance documents and on the labels of the product. By using NEO-ACTIBLOCK-BROD according to the instructions the risk for secondary poisoning is minimised.

Mixture toxicity

No substance other than the active substance Brodifacoum is included in the composition of NEO-ACTIBLOCK–BROD that is defined as a substance of concern according to Regulation (EU) No 528/2012. Therefore, mixture toxicity of the product does not need to be assessed.

2.2.8 Measures to protect man, animals and the environment

In order to minimize the risk to children and non-target animals all possible measures should be taken. These measures include the use of tamper resistant bait boxes to limit the access of non-target animals, collection of unconsumed baits after termination of the control campaign and collection of dead rodents during and after the control campaign. Non-professional baits should be used in refillable tamper-resistant bait stations and supplied as units containing at most enough bait for one bait point (either rat or mouse). Units of bait for non-professionals should be laid intact at the bait point.

The instructions for use must contain the following indications:

- Always read the label before use and follow the instructions provided.
- Keep out of reach of children.
- Keep away from food, drink and animal feeding stuffs.
- Avoid contact with skin.
- If swallowed, seek medical advice immediately (show the label where possible).
- Do not smoke eat or drink while handling this product.
- Baits must be secured in tamper resistant bait boxes to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals.

- Bait boxes must be placed in areas inaccessible to children, companion animals and non-target animals.
- Bait boxes must always be clearly labelled "Do Not Touch" and warn of the contents.
- In public areas (such as business premises, schools, hospitals etc) it must be clearly signed that rodenticide control is in operation. Signage must provide information on the risks of interfering with the product and dead rodents.
- When using do not eat, drink or smoke.
- Products shall not be used as tracking powder.
- Dead rodent bodies must be collected during all control operations to minimise the risk of consumption and poisoning to children, companion animals and other non-target animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.
- Do not use in agriculture.
- Product shall not be used as tracking powder.

2.2.9 Assessment of a combination of biocidal products

Not relevant.

3 ANNEXES[35]

3.1 Output tables from exposure assessment tools

3.1.1 Human exposure assessment

Tab 3.1.1-1 Exposure estimates as calculated from the CEFIC study

	Exposure estimate
Task	**Overall 75th percentile**
Loading/securing – dermal	27.79 mg product/man.
Clean-up/disposal - dermal	5.7 mg product/man.

The number of manipulations to be assessed for professional operators is based on the Addendum of the CEFIC study, presenting 90th percentiles for the frequency of handlings.

Accordingly, for a professional pest control operator, 75 manipulations (90th percentile) per day, handling 100 g of bait, is considered for risk assessment.

In accordance to the latest proposals of the Human Exposure Expert Groups (HEEG)[36] and as agreed at the Technical Meeting (TM III, 2010) 20% (equal to 15 manipulations) of tasks are to be considered for cleaning and disposal, hence 60 loading manipulations and 15 cleaning manipulations are assumed.

Calculations are based on the following considerations:

According to the HEEG opinion (2013)[37] a body weight of 60 kg is assumed.

Dermal penetration of the active substance from a wax bait is assumed to be 0.05%. The concentration of the active substance in the product is equal to 0.0025% w/w (25 ppm).

Inhalation exposure during loading of bait stations and cleaning/disposal is considered to be negligible in view of the solid, dust-free wax bait formulation.

Tasks during application of NEO-ACTIBLOCK-BROD can be described as follows:

Loading and placing block bait boxes
Wax baits are transferred from the packaging directly into the bait box and secured. The box is closed and placed onto the floor in the corner of the usage site.

Clean up and disposal of block bait
Loaded bait stations containing wax bait are emptied into a plastic bucket, any remaining material is removed by sweeping from the bait station directly into the same bucket.

35 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

36 HEEG (2010) Harmonizing the number of manipulations in the assessment of rodenticides

37 HEEG (2013) Default human factor values for use in exposure assessments for biocidal products)

Calculation of professional exposure:

Tier I – no protective gloves

- **Deploying (loading bait station with 10 blocks)**

Dermal exposure:

Exposure data = 27.79 mg product/manipulation (75th percentile)

Number of contacts assessed in CEFIC study: 5 contacts, 20 g per bait

As a worst case, 10 g per bait are assumed, hence 10 contacts per baiting point (100 g per bait point/10 g bait)

Corrected exposure data for 10 contacts = (27.8 mg/5) × 10

= 55.6 mg product/manipulation

Considering 60 deploying operations, operator exposure is calculated at:

(55.6 mg product/manipulation × 60 manipulations × 0.05% × 0.0025%) / 60 kg bw = **6.95 × 10^{-7} mg/kg bw**.

- **Cleaning/disposal**

Dermal exposure:

Exposure data = 5.7 mg product/manipulation (75th percentile)

Considering 15 cleaning/disposal operations, operator exposure is calculated at:

(5.7 mg product/manipulation × 15 manipulations × 0.05% × 0.0025%)/ 60 kg bw = **1.78× 10^{-8} mg/kg bw**.

Total systemic exposure during application as the sum of all tasks is results in approximately **7.13 × 10^{-7} mg/kg bw/d.**

Tier II – using protective gloves

According to the TNsG Human Exposure to Biocidal Products (2007), 90% protection is considered appropriate when protective gloves are worn.

- **Deploying (loading bait station with 10 blocks)**

Dermal exposure:

Applying a factor 0.1 for gloves results in **6.95 × 10^{-8} mg/kg bw/d**

- **Cleaning/disposal**

Dermal exposure:

Applying a factor 0.1 for gloves results in **1.78 × 10^{-9} mg/kg bw/d**

Total systemic exposure during application as the sum of all tasks is results in approximately **7.13 × 10^{-8} mg/kg bw/d.**

Tab 3.1.1-2 Summary of estimated exposure estimates– professional user

Estimated systemic exposure [mg/kg bw/d]		
No. of blocks handled	10	
Task	Without gloves	With gloves
Deploying, dermal	6.95×10^{-7}	6.95×10^{-8}
Cleaning, dermal	1.78×10^{-8}	1.78×10^{-9}
Total systemic exposure	**7.13×10^{-7}**	**7.13×10^{-8}**

General public exposure

The application pattern of NEO-ACTIBLOCK-BROD by general public users is similar to professional users as assessed by CEFIC.

However, in accordance with the CARs on various Rodenticides and proposed by HEEG (2010), fewer manipulations as compared to professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a general public user.

For the general public, no protection by gloves is considered.

However gloves may be recommended to help prevent rodent-borne diseases.

Tier I – no protection

- **Deploying (loading bait station with 10 baits)**

Dermal exposure:

Exposure data= 27.79 mg product/manipulation, equal to 5 contacts (75th percentile)

Number of contacts = 10 (100 g per bait point/10 g bait)

Corrected exposure data for 1 manipulation with 10 contacts = 27.8 mg/5 contacts per manipulation × 10 contacts

= 55.6 mg product/manipulation

Considering 5 deploying tasks, operator exposure is calculated at:

(55.6 mg product/manipulation × 5 manipulations × 0.05% × 0.0025%)/ 60 kg bw = **5.79×10^{-8} mg/kg bw**.

- **Cleaning/disposal**

Dermal exposure:

Exposure data= 5.7 mg product/manipulation (75th percentile)

Considering 5 cleaning/disposal operations, operator exposure is calculated at:

(5.7 mg product/manipulation × 5 manipulations × 0.05% × 0.0025%)/ 60 kg bw = **5.94×10^{-9} mg/kg bw**.

Total systemic exposure during application results in **6.38×10^{-8} mg/kg bw/d** without protective gloves.

Tab 3.1.1-3 Summary of estimated exposure estimates– general public

Estimated systemic exposure [mg/kg bw/d]	
No. of baits handled	10
Task	Without gloves
Deploying, dermal	5.79×10^{-8}
Cleaning, dermal	5.94×10^{-9}
Total systemic exposure	**6.38×10^{-8}**

Indirect exposure as a result of use of the active substance in biocidal product

During application of NEO-ACTIBLOCK-BROD in rodent control, secondary exposure to the rodenticidal baits may occur. Two scenarios may be considered, dermal contact with dead rodents by adults and incidental ingestion of baits by children.
Based on these scenarios as listed in Appendix 7.2.1 of TNsG (2002) Part 3, calculation of secondary exposure is performed.

However, it should be noted that usually deposition of active ingredients from baits on animal fur is unlikely to occur.
Moreover, according to the TM II 2006, handling of dead rodents by children is considered to be unrealistic.

Dermal contact with dead rodents
Not a relevant scenario according to the Assessment report by CA Italy

Ingestion of bait by children
It is assumed that a child will ingest 5 g of the bait (a general assumption of poison centre specialists, what children would ingest, see CAR Difethialone, Norway 2007).

Assuming 100% oral absorption and an infant's body weight of 10 kg, systemic exposure is equal to:
(5 g **×** 0.0025% a.i.)/10 kg = **0.0125 mg/kg bw**

However, ingestion of 5 g represents a high overestimate of exposure, since baits contain a repellent (denatonium benzoate as bitter agent), which will most likely urge the children to spit the bait.

Applying the general assumption of ingestion of 10 mg of bait (TNsG default for a bait with repellent), systemic exposure is **2.5×10^{-5} mg/kg bw**.

Tab 3.1.1-4 Summary of estimated secondary exposure estimates– general public

Scenario	**Estimated systemic exposure [mg/kg bw/d]**
Ingestion of bait (child, 5 g)	1.25×10^{-2}
Ingestion of bait (child, 10 mg)	2.5×10^{-5}

3.2 Summaries of the efficacy studies[38]

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	NEO-ACTIBLOCK-BROD (0.0025% w/w Brodifacoum) Block bait, ready to use	Brown rat (*Rattus norvegicus*) Wild lines	**Field trial** Location: farm with and cows breeding stables, fodder and equipment warehouses.	Baiting *ad libitum* 8 bait stations 200 g bait per box Baiting period: 14 days	100% mortality Pre baiting: 6631 g non poisoned placebo bait consumed during 5 days -an average daily consumption of 1384 g -average tracking score values from 18 to 26 recorded. -initial pest population estimates: 65 - 75 rats Post baiting: 0 g placebo bait consumed and tracking score values of 0. Final pest population estimates: 0 rats. - 6441 g of test substance consumed in 14 days (Max consumption in day 3 of the baiting period) -an average daily bait consumption of 460.07 g	[redacted]
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	NEO-ACTIBLOCK-BROD (0.0025% w/w Brodifacoum) Block bait, ready to use	House mouse (*Mus musculus*) Wild lines	**Field trial** Location: farm with hens breeding stable, fodder and equipment warehouses	Baiting *ad libitum* 8 bait stations 40 g bait per box Baiting period: 12 days	100% mortality Pre baiting: 633 g non poisoned placebo bait consumed during 5 days -an average daily bait consumption of 138.5 g -average tracking score values from 16 to 21 recorded. -initial pest population estimates: 40 - 50 mice Post baiting: 0 g placebo bait consumed and tracking score values of 0. Final pest population estimates: 0 mice. 774 g of test substance consumed in 12 days -an average daily bait	[redacted]

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

						consumption of 64.5 g	
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.0025% w/w Difenacoum) Pasta ready to use	House mouse (Mus musculus) 5 females, 5 males Wild lines	**Laboratory trial** Cages for single mice with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	Mean palatability against ground laboratory diet of 64.39% (S.D. 23.27). The formulation resulted in 100% mortality after a four-day choice between this formulation and the challenge diet.	[redacted]
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.0025% w/w Difenacoum) Pasta ready to use	Brown rat (Rattus norvegicus) 5 females, 5 males Wild lines	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	Mean acceptance of 90.2% (S.D. 13.21) showing the formulation to be palatable to Brown rats. Mortality was 100% of efficacy.	[redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (0.005% w/w Brodifacoum) Block bait, ready to use	Brown rat (*Rattus norvegicus*) 5 females, 5 males	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	100% mortality Average time to death 4.7 days Consumed bait per rat: 23.6 g (= 5.9 g/rat/day) Consumed alternative food per rat: 57.6 g (= 14.4 g/rat/day) Ratio of bait and alternative food consume: 1: 2.4 Mean [redacted] consumption of rats: 27.3%	[redacted]
III.2.1.1.1 Anticoag	*In and around buildin*	[redacted]	House mouse (*Mus*	**Laboratory trial**	**Choice test** Baiting *ad libitum*	100% mortality Average time to death 5.9 days	[redacted]

ulant; Ingestion toxin, Ingestion by eating	*gs*	[redacted] (0.005% w/w Brodifacoum) Block bait, ready to use	*musculus*) 5 females, 5 males	Cages for single mice with two food pots placed either side at the front of the cage.	Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	Consumed bait per mouse: 11.6 g (= 2.9 g/mouse/day) Consumed alternative food per mouse: 9.9 g (= 2.5 g/mouse/day) Ratio of bait and alternative food consume: 1: 0.85 Mean [redacted] consumption of mice: 53.7%	[redacted]

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
III.2.1.1.1 Anticoagulant; Ingestion toxin, Ingestion by eating	*In and around buildings*	[redacted] (aged formulation) (0.005% w/w Brodifacoum) Block bait (aged). [redacted] (aged formulation) was manufactured by ACTIVIA S.r.l. on 22nd September 2010 and subsequently stored at 30°C ± 2°C/65% R.H. ± 5% R.H. for 17 weeks.	Brown rat (*Rattus norvegicus*) 5 females, 5 males	**Laboratory trial** Cages for single rats with two food pots placed either side at the front of the cage.	**Choice test** Baiting *ad libitum* Alternative food without active ingredient (RM3 ground laboratory diet) *ad libitum*. Drinking water *ad libitum*. Baiting period: 4 days	90% mortality, one animal survived after consuming only 0.1 g of [redacted] (aged formulation). Average time to death 5.4 days Consumed bait per rat: 22.9 g (= 5.7 g/rat/day) Consumed alternative food per rat: 67.4 g (= 16.9 g/rat/day) Ratio of bait and alternative food consume: 1: 2.9 Mean [redacted] (aged formulation) consumption of rats: 24.7%	[redacted]

3.3 Confidential annex

See the separated document.

3.4 Other

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