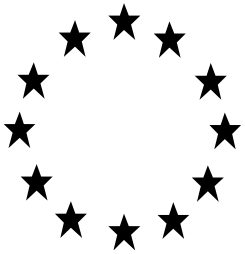
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Brodifacoum 25 ppm Blocks - Professional Use

Product type 14

Brodifacoum as included in the Union list of approved active substances

Case Number in R4BP: BC-UT027250-22

Evaluating Competent Authority: The Netherlands

Date: February 2019

* additional text added in yellow (October 2019, in the process of Mutual Recognition in Sequence)

Table of Contents

1 CONCLUSION

The Dutch CA considers the information provided for the intended uses sufficient for the authorisation of the product.

The appearance of Brodifacoum 25 ppm Blocks after storage has not been addressed. This should be addressed at the renewal of the product.

National specific regulations in the Netherlands:

Due to Dutch national specific regulations in the Netherlands, only trained professionals are allowed to apply rodenticides (no professional use) and additional IPM training is needed for outdoor application of rodenticides (around buildings and food storage locations). In addition, the use against house mice is restricted to use in buildings and for both house mice and rats use in covered and protected bait points is not allowed.
Therefore, in the Netherlands authorised use of this product will consist of:
- use in tamper-resistant bait boxes in tamper-resistant bait boxes in buildings against house mice (*Mus musculus*) and rats (*Rattus norvegicus* & *Rattus rattus)* by trained professionals.
- use in tamper-resistant bait boxes around buildings against rats (*Rattus norvegicus* & *Rattus rattus)* by trained professionals with additional IPM training.
- use against brown rats (*Rattus norvegicus*) in sewers by trained professionals

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)**
Brodifacoum 25 ppm Blocks – Professional Use*	Netherlands
*Both Professional and Trained Professional (Professional users with demonstrated competence) uses are included in the PAR and SPC for Mutual recognition countries, under the term Professional Use. Trade Name: Solo[25] Blox and Jaguar[25] Blox	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Bell Laboratories Netherlands B.V.
	Address	De Cuserstraat 93 1081 CN Amsterdam Netherlands
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Bell Laboratories, Inc.
Address of manufacturer	Bell Laboratories Inc. Madison, Wisconsin 53704 United States
Location of manufacturing sites	Bell Laboratories Inc. Madison, Wisconsin 53704 United States

2.1.1.4 Manufacturer(s) of the active substance

Active substance	Brodifacoum
Name of manufacturer	Activa S.r.l
Address of manufacturer	Via Feltre, 32 – 20132 Milano, Italy

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

Location of manufacturing sites	Tezza s.r.l. Via Tre Ponti 37050 S. Maria di Zevio Italy

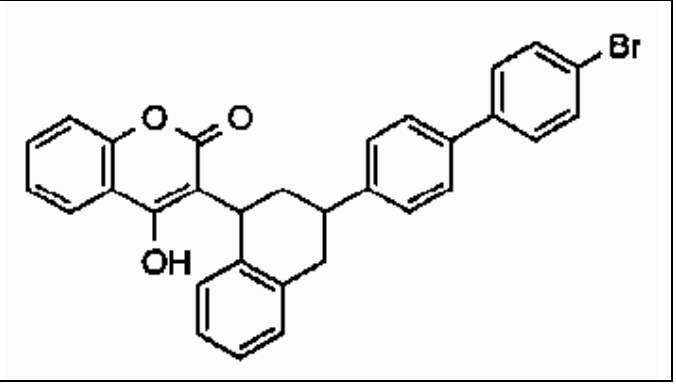
2.1.2 Product (family) composition and formulation

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	950 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance Brodifacoum does fulfil the criteria in Article 10 of the BPR and is considered to be a candidate for substitution on the basis that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

This information is provided in the confidential annex.

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
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
Potassium sorbate	Potassium (E,E)-hexa-2,4-dienoate	Non active substance	24634-61-5	246-376-1	1.00

2.1.2.4 Information on technical equivalence

The source of the active substance is Activa S. R. L manufactured at Tezza s.r.l. Via Tre Ponti, 37050 S. Maria di Zevio, Italy. This is the same manufacturing location of the active substance in the Annex I Listing.

2.1.2.5 Information on the substance(s) of concern

Please see the section 2.2.6.1 "*Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)*" for further details.

Potassium sorbate	Classification according to Regulation (EC) No 1272/2008: Eye Irrit. 2: H319, Skin Irrit. 2: H315 and STOT SE. 3:H335. As it is considered to be an active substance in the role of in-can preservative (PT06) and wood preservatives (PT08), it is identified as a SoC as it is present in the formulation ≥0.1%.

2.1.2.6 Type of formulation

RB (ready to use bait)

2.1.3 Hazard and precautionary statements[2]

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

Classification	
Hazard category	STOT RE 2; H373 (blood)
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. P103:Read label before use. P314: Get medical advice / attention if you feel unwell. P501:Dispose of contents/container in accordance with national regulations.
Note	Brodifacoum contributes to the assignment of H373 and therefore needs to be declared on the label.

2.1.4 Authorised use(s)

2.1.4.1 Use description[3]

Table 1. Use # 1 – House mice – professionals – indoor -

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Mus musculus* - House mouse - adult and juvenile
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	- 20-40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be 2-4 meters. Determine areas where rodents will likely find and consume

2 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).

3 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.

	bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 5 g or 20 g ready-to-use block baits. 5 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3 to 10 kg 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg

2.1.4.2 Use-specific instructions for use[4]

The baiting 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.

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.3 Use-specific risk mitigation measures

See section 2.1.5.6

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

- When placing bait points close to 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

See section 2.1.5.9

[4] 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.

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

See section 2.1.5.10

2.1.4.7 Use description[5]

Table 2. Use # 2 – House mice – Professional users with demonstrated competence (equivalent to trained professionals) – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Mus musculus* - House mouse - adult and juvenile-
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations or covered bait points
Application rate(s) and frequency	- High infestation: (20-40) g of bait per baiting point, every 2 meters - Low infestation: (20-40) g of bait per baiting point, every 4 meters Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 5 g or 20 g ready-to-use block baits. 5 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3 to 10 kg 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg

[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.

2.1.4.8 Use-specific instructions for use[6]

- Remove the remaining product at the end of treatment period.

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.9 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign in accordance with the applicable code of good practice.

- 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.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

- Do not use the product in pulsed baiting treatments.

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

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

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

See section 2.1.5.4

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

See section 2.1.5.5

[6] 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.

2.1.4.13 Use description[7]

Table 3. Use # 3 – Rats – professionals – indoor -

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Rattus norvegicus* - Brown rat - adult and juvenile *Rattus rattus* - Black rat - adult and juvenile
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	- 100-200 g of bait per bait station. If more than one bait station is needed, the distance between baiting point should be 5-10 meters. Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 20 g or 200 g ready-to-use block baits. 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg 200 g blocks are supplied in polyethylene bags within cardboard cartons with net weight 3 to 10 kg

2.1.4.14 Use-specific instructions for use[8]

- For rats: 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

[7] 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.

[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.

accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. - *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.15 Use-specific risk mitigation measures

See section 2.1.5.7

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

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

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

See section 2.1.5.9

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

See section 2.1.5.10

2.1.4.19 Use description[9]

Table 4. Use # 4 – rats – Professional users with demonstrated competence (equivalent to trained professionals) – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Rattus norvegicus* - Brown rat - adult and juvenile *Rattus rattus* - Black rat - adult and juvenile
Field(s) of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations or covered bait points..

[9] 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.

Application rate(s) and frequency	- High infestation: (100-200) g of bait per baiting point, every 5 meters - Low infestation: (100-200) g of bait per baiting point, every 10 meters Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 20 g or 200 g ready-to-use block baits. 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg 200 g blocks are supplied in polyethylene bags within cardboard cartons with net weight 3 to 10 kg

2.1.4.20 Use-specific instructions for use[10]

- Remove the remaining product at the end of treatment period.

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.21 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign in accordance with the applicable code of good practice.

- 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.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use the product as permanent baits for the prevention of rodent infestation or

[10] 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.

monitoring of rodent activities. - Do not use the product in pulsed baiting treatments.

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

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

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.25 Use description[11]

Table 5. Use # 5 – House mice – Professional users – outdoor around buildings –

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Mus musculus* - House mouse - adult and juvenile
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	- 20-40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2 meters. Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.

11 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.

Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 5 g or 20 g ready-to-use block baits. 5 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3 to 10 kg 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg

2.1.4.26 Use-specific instructions for use[12]

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-liable to flooding.

The baiting 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.

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

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.27 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

See section 2.1.5.9

12 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.

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

See section 2.1.5.10

2.1.4.31 Use description[13]

Table 6. Use # 6 – Mice – Professional users with demonstrated competence (equivalent to trained professionals) – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Mus musculus* - House mouse - adult and juvenile
Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations or covered bait points.
Application rate(s) and frequency	- High infestation: (20-40) g of bait per baiting point, every 2 meters - Low infestation: (20-40) g of bait per baiting point, every 4 meters Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 5 g or 20 g ready-to-use block baits. 5 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3 to 10 kg 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg

[13] 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.

2.1.4.32 Use-specific instructions for use[14]

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

- Remove the remaining product at the end of treatment period.

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.33 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign

- 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.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

- Do not use this product in pulsed baiting treatments.

- Do not apply this product directly in the burrows.

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

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

[14] 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.

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.37 Use description[15]

Table 7. Use # 7 – Rats – Professional users – outdoor around buildings –

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Rattus norvegicus* - Brown rat - adult and juvenile *Rattus rattus* - Black rat - adult and juvenile
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	- 100-200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters. Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places. Maintain an uninterrupted supply of fresh bait for 14-28 days or until signs of rat activity cease.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 20 g or 200 g ready-to-use block baits. 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg 200 g blocks are supplied in polyethylene bags within

15 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.

	cardboard cartons with net weight 3 to 10 kg

2.1.4.38 Use-specific instructions for use[16]

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-liable to flooding.

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.

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

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.39 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

See section 2.1.5.9

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

See section 2.1.5.10

16 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.

2.1.4.43 Use description[17]

Table 8. Use # 8 – Rats – Professional users with demonstrated competence (equivalent to trained professionals) – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Rattus norvegicus* - Brown rat - adult and juvenile *Rattus rattus* - Black rat - adult and juvenile
Field(s) of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations or covered bait points.
Application rate(s) and frequency	- High infestation: (100-200) g of bait per baiting point, every 5 meters - Low infestation: (100-200) g of bait per baiting point, every 10 meters Determine areas where rodents will likely find and consume bait. Generally, these areas are along walls, by gnawed openings, in corners, and concealed places. Maintain an uninterrupted supply of fresh bait for 14-28 days or until signs of rat activity cease.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 20 g or 200 g ready-to-use block baits. 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg 200 g blocks are supplied in polyethylene bags within cardboard cartons with net weight 3 to 10 kg

[17] 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.

2.1.4.44 Use-specific instructions for use[18]

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-liable to flooding.

- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

- Remove the remaining product at the end of treatment period.

- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.45 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign

- 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.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

- Do not use this product in pulsed baiting treatments.

- Do not apply this product directly in the burrows.

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

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

[18] 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.

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.49 Use description[19]

Table 9. Use # 9 – Rats – Professional users with demonstrated competence (equivalent to trained professionals) – sewers

Product Type	14
Where relevant, an exact description of the authorised use	Rodenticide.
Target organism(s) (including development stage)	*Rattus norvegicus* - Brown rat - adult and juvenile
Field(s) of use	Sewers
Application method(s)	- Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	- High infestation: 100-200 grams per manhole. - Low infestation: 100-200 grams per manhole. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. The product is available as 20 g or 200 g ready-to-use block baits. 200 g blocks are supplied in polyethylene bags within cardboard cartons with net weight 3 to 10 kg. 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight 3, 4, 8, 9, 10 kg

[19] 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.

2.1.4.50 Use-specific instructions for use[20]

- Baits must be applied in a way so that they do not come into contact with water and are not washed away. - *[When available]* Follow any additional instructions provided by the relevant code of best practice.

2.1.4.51 Use-specific risk mitigation measures

- *[If national policy or legislation requires it]* Place baits only in sewer systems which are connected to the sewage treatment plant. - Do not use this product in pulsed baiting treatments.

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use Professional users with demonstrated competence (equivalent to trained professionals)

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

[20] 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.

- 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.

- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (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 *(see section 5.1.3 for the information to be shown on the label)*.

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

- 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.

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

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

- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

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

2.1.5.2 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign

The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".

- Do not use in areas where resistance to the active substance can be suspected.

- 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 rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

- Dispose dead rodents in accordance with local requirements

- When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often when baits are checked and/or replenished. Dispose of 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

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

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

- In case of:

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

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

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

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

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

- Hazardous to wildlife.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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: 24 months.

2.1.5.6 Instructions for use Professional users

- 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 (see section 5.3 for the information to be shown on the label).
- *[If national policy or legislation require it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- 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.

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

- 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 points to further places and the possibility to change to another 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 rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

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

2.1.5.7 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).

- 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").users shall properly label bait stations with the information referred to in section 5.2.3 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**.**

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be

bruising and blood present in the faeces or urine.

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

- In case of:

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

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

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

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

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

- Hazardous to wildlife.

2.1.5.9 Instructions for safe disposal of the product and its packaging

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

2.1.5.10 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:24 months.

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.

Method of application: VI.2 covered application and VI.2.1 in bait stations (covered application).
Application aim: VII.2 health protection.
Type of formulation: VIII.3.3 block-bait (solid formulation).

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 user (e.g. professional,	Compatibility of the product with the

				non-professional)	proposed packaging materials (Yes/No)
Block 5 g Pail	3 to 10 kg	opaque high density polyethylene (HDPE) pail	opaque low density polyethylene lid (LDPE)	Professional	Yes
Block 20 g Pail	3 kg, 4 kg, 8 kg, 9 kg, 10 kg	opaque high density polyethylene (HDPE) pail	opaque low density polyethylene lid (LDPE)	Professional	Yes
Block 200 g Cardboard carton	3 to 10 kg	polyethylene bag within cardboard carton	Not applicable	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A list of references has been included in Annex 3.1.

2.1.8.2 Access to documentation

In support of this product dossier, Bell Laboratories has access to the data included in the active substance dossier for Brodifacoum submitted by Activa S.r.l. to Italy as RMS for inclusion in Annex I.
A letter of access from Activa S. r. l. is attached in Section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

Table 10. Intended use # 1 – Rodenticide (ready-to-use blocks)

Product Type(s)	PT14
Where relevant, an exact description of the authorised use	Rodenticide The product must not be used to protect plants or plant products from damage caused by rodents.
Target organism (including development stage)	This formulation is intended to be used for the control of Brown rat (*Rattus norvegicus*), Black rat (*Rattus rattus*) and House mouse (*Mus musculus*) adult and juvenile for the maintenance of human hygiene.
Field of use	Brodifacoum is intended for indoor and restricted outdoor use by professional operators, to control rats and mice in and around buildings and rats in sewer systems. The active

	substance is only used by industrial users who manufacture the products for use by professional and non-professional users.
Application method(s)	Ready-to-use bait blocks (5 g, 20 g and 200 g) to be placed in bait stations or covered bait points
Application rate(s) and frequency	Blocks 5 g, 20 g and 200 g Use against rats: Place one 200 g block or 2 to 10 blocks (20 g) in bait stations or covered bait points and place at 5 to 10 metre intervals per placement where rats or their signs have been observed. Maintain an uninterrupted supply of fresh bait for 14-28 days or until signs of rat activity cease. Use against rats in sewers: Secure one 200g block to available structure to ensure the block is not washed away. Regularly check bait consumption and replace consumed or spoilt bait for 14-28 days or until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation. Use against mice: Place 2 to 6 blocks (5 g) or 1 to 2 blocks (20 g) in bait stations or covered bait points and place at 2 to 4 metre intervals per placement where mice or their signs have been observed. Maintain an uninterrupted supply of fresh bait for 14-28 days or until signs of mouse activity cease.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	The product is available as 5 g, 20 g, or 200 g ready-to-use block baits. Baits are supplied in opaque HDPE pail with LDPE lid or cardboard carton with polyethylene bag. 5 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight up to 10 kg 20 g blocks are supplied in opaque HDPE pails with LDPE lids; net weight up to 10 kg 200 g blocks are supplied in polyethylene bags within cardboard cartons with net weight up to 10 kg

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 Determination	Brodifacoum 0.0025%	Solid	Christopher D. Thomas, Ph.D, June 2016, Product Properties of Brodifacoum

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Blocks, Bell Laboratories, Inc., Study Number BEL/0616/C485, GLP, unpublished
Colour at 20 °C and 101.3 kPa	Visual Determination	Brodifacoum 0.0025%	Red	As above
Odour at 20 °C and 101.3 kPa	Olfactory Determination	Brodifacoum 0.0025%	Sweet, Grainy	As above
Acidity / alkalinity	N/A	Brodifacoum 0.0025%	Not applicable as the product is not aqueous and is not dispersed in water during use.	
Relative density / bulk density	OECD 109, Pycnometer method for solids	Brodifacoum 0.0025%	1.13 g/mL (22 °C)	Christopher D. Thomas, Ph.D, June 2016, Product Properties of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number BEL/0616/C485, GLP, unpublished
Storage stability test – **accelerated storage**	Accelerated storage stability	Brodifacoum 0.0025%	Stable over 2 weeks at 54 °C Tested during 2 weeks at 54 °C in polyethylene **Before storage**: Brodifacoum content: 0.00266% w/w **After storage:** Brodifacoum content: 0.00261% w/w Packaging: No deviation **Active substance decrease during**	Kurt R. Freeders, B.S., November 2015, Accelerated Storage Stability of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number BEL/0915/C465, GLP, unpublished

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			storage: 1.88% w/w	
Storage stability test – **long term storage at ambient temperature**	Ambient storage stability	Brodifacoum 0.0025%	2 years study in polyethylene at 16-26 °C and 25% - 76% relative humidity. Justification for range storage temperature: The long term storage stability samples are stored in the original packaging (sealed polyethylene pails), in a closed cabinet, in a storage room. This room is within our entire building that house the labs, IT, Quality Control, etc. The building has central air and heating. Located in Wisconsin, USA, where the outside temperatures can be 37 ºC in summer and -30 ºC in winter. Humidity can range from near 100 % in summer to near zero in winter. While the central air handling systems try to keep up, they	Christopher D. Thomas, Ph.D, October, 2017, Storage Stability and Corrosion Characteristics of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number BEL/0915/C468, GLP, unpublished

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			sometimes fall temporarily behind. Temperature and humidity were measured continuously, and so those more extreme numbers were occasional and of short duration. It is unlikely that the stored product is fluctuating so much, it is sealed, in polyethylene pails, in a closed cabinet; whereas the temperature and humidity gauges are in the open room. **Before storage**: Brodifacoum content: 0.00262% w/w Packaging: No corrosion **After storage:** Brodifacoum content: 0.00243% w/w Packaging: No corrosion **Active substance decrease during storage:** 7.25% w/w	
Storage stability test – **low temperature stability test for liquids**	N/A	Not Applicable	Not applicable as the product is a solid and testing is for liquids only	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	N/A	Not Applicable	Not applicable as the product is only packed in opaque packagings and the baits are only placed in bait stations or covered areas that are not exposed to light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Included in ambient storage stability	Brodifacoum 0.0025%	See long term and accelerated storage stability	Christopher D. Thomas, Ph.D, November, 2016, BEL/0915/C487 and October, 2017, BEL/0915/C468 Storage Stability and Corrosion Characteristics of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number, GLP, unpublished Kurt R. Freeders, B.S., November 2015, Accelerated Storage Stability of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number BEL/0915/C465, GLP, unpublished
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Included in ambient storage stability	Brodifacoum 0.0025%	See long term storage stability	Christopher D. Thomas, Ph.D, November, 2016, BEL/0915/C487 and October, 2017, BEL/0915/C468 Storage Stability and

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Corrosion Characteristics of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number, GLP, unpublished
Wettability, Suspensibility, spontaneity and dispersion stability	N/A	Not Applicable	The bait will not be diluted prior to use, therefore this test is not required. The bait is in a ready to use form.	
Wet sieve analysis and dry sieve test	N/A	Not Applicable	The bait is not a WP, SC, granule or a tablet, therefore this test does not apply.	
Emulsifiability, re-emulsifiability and emulsion stability	N/A	Not Applicable	The bait is not an EC or ready to use emulsion, therefore this test is not required.	
Disintegration time, Particle size distribution, content of dust/fines, attrition, friability	N/A	Not Applicable	The bait is not a tablet, powder or granule, it is a large solid block, therefore these tests are not required.	
Persistent foaming	N/A	Not Applicable	The bait will not be diluted with water before use. This test is therefore not required.	
Flowability/Pourability/ Dustability	N/A	Not Applicable	The bait is not a granule or a suspension, therefore this test is not required.	
Physical and chemical compatibility	N/A	Not Applicable	The product will not be used in combination with other products.	
Degree of dissolution and dilution stability	N/A	Not Applicable	The bait will not be diluted prior to use, therefore this test is not required. The bait is in a ready to use form.	
Surface tension & viscosity	N/A	Not Applicable	These tests are not required as the bait is a solid.	

Conclusion on the physical, chemical and technical properties of the product

It can be concluded that Brodifacoum 25 ppm Blocks are ready-to-use solid blocks, red in colour with a sweet grainy odour and a relative density of 1.13 g/mL.

Accelerated storage stability at 54 ˚C for 2 weeks in polyethylene has shown the product is stable.

The 2 year results at ambient temperature indicate that Brodifacoum Blocks stored in polyethylene should have a shelf life of at least 24 months in polyethylene.

The appearance of Brodifacoum 25 ppm Blocks after storage has not been addressed. This should be addressed at the renewal of the product.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Explosive properties have not been tested, as none of the constituents have explosive properties and therefore the bait itself will not be explosive.			
Oxidising properties	Oxidising properties have not been tested, as none of the constituents have oxidising or reducing properties and therefore the bait itself will not be oxidising.			
Flammable properties	Flammability and auto-flammability have not been tested, as none of the constituents are flammable and therefore the bait itself will not be flammable.			
Self-reactive substances and mixtures	None of the constituents of the bait are thermally unstable and therefore the bait itself will not have explosive properties. A study for Brodifacoum 25 ppm Blocks is not required.			
Pyrophoric solids	None of the constituents of the bait have pyrophoric properties. Experience in manufacture and handling does not result in the Brodifacoum block bait spontaneously igniting on coming into contact with air at normal temperatures. Therefore a study for Brodifacoum 25 ppm Blocks – Professional Use is not required.			
Self-heating substances and mixtures	Self-heating properties are applicable to mixtures when present in large quantities and after long periods of time. This is not applicable to Brodifacoum 25 ppm Blocks which are produced in blocks up to 200 g in weight and not packaged in large quantities (up to 10 kg packs). A study for Brodifacoum 25 ppm Blocks – Professional Use is not required.			
Substances and mixtures which in contact with water emit flammable gases	Not applicable for ready-to-use block baits			
Oxidising solids	None of the components of the product are oxidising agents.			
Organic peroxides	None of the components of the product are organic peroxides.			
Corrosive to metals	None of the components of the product are corrosive to metals.			
Relative self-ignition temperature for solids	None of the constituents of the bait have pyrophoric properties and self-heating properties are not applicable to Brodifacoum 25 ppm Blocks. Therefore a study for Brodifacoum 25 ppm Blocks – Professional Use is not required.			

Conclusion on the physical hazards and respective characteristics of the product
It can be concluded that Brodifacoum 25 ppm Blocks – Professional Use is not classified and will not be labelled with respect to physical hazards.

2.2.4 Methods for detection and identification

Sample preparation for determination of the active substance in the product (BELL Standard Operating Procedure CHEM500.7)

1. The sample was ground to a fine powder using a homogenizer/blender for approximately 30 seconds.
2. Two grams of ground bait was accurately weighed into a glass extraction liner (record vessel tare weight and sample weight).
3. 20 mL of methanol were added to the extraction liner and the extraction vessel was assembled.
4. The vessel was microwaved for 10 minutes at 80 °C and then cooled for 15 minutes.
5. The glass extraction liner was reweighed to determine the amount of solvent remaining.
6. 1.5 mL of solution were transferred to a HPLC sample vial using a syringe and a fluoropolymer membrane to filter out any dissolved material.

Conditions

Method: HPLC-UV 305 nm
Column: Waters Novapak C18 Reverse Phase Column 4.6x250 mm, or equivalent
Eluent: Component A = 99% methanol HPLC grade / 1% glacial acetic acid
Component B = 99% water HPLC grade / 1% glacial acetic acid

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	Precision n=5 nominal analyte concentration = 25 µg/g. Accuracy n=3 at each of 3 concentration levels (25, 50, 75 µg/g)	5 injections of 7 standard solutions Range 1.24 µg/mL to 12.5 µg/mL R^2 = 1.0000 Linearit	No significant background signals were observed in the region of the peak of interest in the matrix blank.	25 µg/g 96.9-97,5% 50 µg/g 97.0-97.9% 75	25 µg/g 97.3% 50 µg/g 97.5% 100 µg/g 98.6%	Precision Day 1 1.0% Day 2 0.8% Based on the Horwitz equation the relative stand	LOQ = 1.6 µg/g in blocks	Christopher D. Thomas, Ph.D, June 2016, Product Properties of Brodifacoum Blocks, Bell Laboratories, Inc., Study Number BEL/0616/C485, GLP,

			y equation: Y=0.5066x-0.0068		µg/g 98.0-99.1%		ard deviation must be less than 6.6%		unpublished

Analytical methods for monitoring									
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		
Waiver: not required since the product will not come in contact with food producing animals, food of plant and animal origin or feeding stuffs.									

Analytical methods for soil									
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		
By means of a letter of access, refer to the analytical method for the measurement of residues of Brodifacoum in soil submitted and reviewed in the active substance dossier.									

Analytical methods for air									
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		
There is no requirement to develop a method of analysis for Brodifacoum in air as the vapour pressure is <0.01 Pa (2.6E-22 Pa at 20°C) and the formulation will not be sprayed.									

Analytical methods for water									
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		

By means of a letter of access, refer to the analytical method for the measurement of residues of Brodifacoum in water submitted and reviewed in the active substance dossier.

Analytical methods for animal and human body fluids and tissues									
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		
By means of a letter of access, refer to the analytical method for the measurement of residues of Brodifacoum in animal and human body fluids and tissues submitted and reviewed in the active substance dossier.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
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		
By means of a letter of access, refer to the analytical method for monitoring of active substances and residues in food and feeding stuff submitted and reviewed in the active substance dossier.									

Conclusion on the methods for detection and identification of the product
It may be concluded that adequate methodology exists for the determination of Brodifacoum levels in the Brodifacoum 25 ppm Blocks product.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Brodifacoum 25 ppm Blocks is a rodenticide (PT14) containing 0.0025% brodifacoum. The product is a ready-for-use bait block, which is intended for use by trained professionals (Professional users with demonstrated competence) and professionals.

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

This anticoagulant bait formulation is intended to be used for the control of brown rat (*Rattus norvegicus*), black rat (*Rattus rattus)* and house mouse (*Mus musculus*) for the maintenance of human hygiene. Effects on target organisms, including unacceptable suffering

Mortality is the required effect induced by the product.

It is recognised that slow acting anticoagulant rodenticides like brodifacoum do cause pain for several days in rodents and are generally not considered as a humane method to control rodents. Other, more humane control methods are available: alternative active substances or biocidal products as well as non-chemical alternatives. However, as there are concerns whether these alternatives are sufficiently effective or do present other practical or economical disadvantages, anticoagulant rodenticides containing biocidal products should be accepted.

2.2.5.3 Mode of action, including time delay

Brodifacoum is a vitamin K antagonist. The main site of its action is the liver, where several of the blood coagulation precursors under vitamin K dependent post translation processing take place before they are converted into the respective procoagulant zymogens. The point of action appears to be the inhibitionof K_1 epoxide reductase. Anticoagulant rodenticides are slow acting with the minimum time to death generally considered to be 2 to 3 days. In the laboratory studies with Brodifacoum 25 ppm Blocks – the first mouse mortality was on day 3 and the first rat mortality was also on day 3.

2.2.5.4 Efficacy data

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**
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	Young Adult Swiss Webster Mice House mice (*Mus Musculus*)	Laboratory test, choice feeding test 10 Males and 10 Females. Groups of 5 mice per sex were caged in stainless steel caging.	Each group was provided 2 glass jars containing 0.0025% Brodifacoum Blocks and 2 glass jars EPA challenge diet. Both diets were provided *ad libitum* (2 x *ca* 200 g test diet and 2 x *ca* 200 g EPA diet). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 15 days ± 2 hours bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 22-24°C and 34-51%.	100% mortality Overall (M +F) average time to death 6.5 days with a range of 4-10 days. Palatability: 58.2% The control animals remained active and healthy in appearance throughout the 21 day test period	[redacted] 12 November 2015, Efficacy of 0.0025% Brodifacoum Blocks on Young Adult Swiss Webster Mice, [redacted] Study Number BEL/0915/BE884
PT14 rodenticide	In and around buildings and in sewers	0.0025% Weatherised Brodifacoum Blocks[1]	Young Adult Swiss Webster Mice House mice (*Mus Musculus*)	Laboratory test 10 Males and 10 Females. Groups of 5 mice per sex were	Each group was provided 2 glass jars containing 0.0025% weatherised Brodifacoum Blocks and 2 glass jars EPA challenge diet. Both	100% mortality Overall (M +F) average time to death 7 days with a range of 5-10	[redacted] 12 November 2015, Efficacy of 0.0025% Weatherised Brodifacoum Blocks on Young

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**
				caged in stainless steel caging.	diets were provided *ad libitum* (2 x *ca* 200 g test diet and 2 x *ca* 200 g EPA diet). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 15 days ± 2 hours bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 22-24°C and 34-51%.	days. Palatability: 62.5% The control animals remained active and healthy in appearance throughout the 21 day test period.	Adult Swiss Webster Mice, [redacted] Study Number BEL/0915/BE887
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	Young Adult Wistar Rats Brown rat (*Rattus Norvegicus*)	Laboratory test 10 Males and 10 Females. Each animal was singly housed in stainless steel caging.	Each animal was provided 1 glass jar containing 0.0025% Brodifacoum Blocks and 1 glass jar containing EPA challenge diet. Both diets were provided *ad libitum* (*ca* 400g per jar). EPA Challenge Diet was offered *ad libitum* to the control group	100% mortality Overall (M +F) average time to death 7.6 days with a range of 5-11 days. Palatability: 63.6% The control	[redacted] 12 November 2015 Efficacy of 0.0025% Brodifacoum Blocks on Young Adult Wistar Rats, [redacted] Study Number BEL/0915/BE888

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**
					(10 M + 10 F) during the exposure period. Food consumption was recorded. 15 days ± 2 hours bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 22-25°C and 31-54%.	animals remained active and healthy in appearance throughout the 21 day test period	
PT14 rodenticide	In and around buildings and in Sewers	0.0025% Weatherised Brodifacoum Blocks[1]	Young Adult Wistar Rats Brown rat (*Rattus Norvegicus*)	Laboratory test 10 Males and 10 Females. Each animal was singly housed in stainless steel caging.	Each animal was provided 1 glass jar containing 0.0025% weatherised Brodifacoum Blocks and 1 glass jar containing EPA challenge diet. Both diets were provided *ad libitum* (*ca* 400g per jar). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 15 days ± 2 hours bait	100% mortality Overall (M +F) average time to death 7.8 days with a range of 4-12 days. Palatability: 65.6% The control animals remained active and healthy in appearance throughout the 21 day test period	[redacted] 12 November 2015, Efficacy of 0.0025% Weatherised Brodifacoum Blocks on Young Adult Wistar Rats, [redacted] Study Number BEL/0915/BE890

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**
					exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 22-25°C and 31-54%.		
PT 14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	Young Adult Swiss Webster Mice House mice (*Mus Musculus*)	Laboratory test 10 males and 10 females singly housed in stainless steel caging.	Each animal was provided 1 glass jar containing 0.0025% Brodifacoum Blocks and 1 glass jar containing EPA challenge diet. Both diets were provided *ad libitum* (1 x *ca* 160 g test diet and 1 x *ca* 160 g EPA diet). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 4 days ± 2 hour bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 23-26°C and 15-35%.	100% mortality Overall (M +F) average time to death 5.7 days with a range of 3-7 days. Palatability: 35.5% The control animals remained active and healthy in appearance throughout the 18 day test period.	NEW study [redacted] 2018. Efficacy of 0.0025% Brodifacoum Blocks on Young Adult Swiss Webster Mice. [redacted] Study number BELL-1371

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**
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	Young Adult Wistar Rats Brown rat (*Rattus Norvegicus*)	Laboratory test 10 males and 10 females singly housed in stainless steel caging.	Each animal was provided 1 glass jar containing 0.0025% Brodifacoum Blocks and 1 glass jar containing EPA challenge diet. Both diets were provided *ad libitum* (1 x *ca* 350 g test diet and 1 x *ca* 350 g EPA diet). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 4 days ± 2 hour bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 21-24°C and 37-54%.	100% mortality Overall (M +F) average time to death 6.3 days with a range of 3-10 days. Palatability: 58.4% The control animals remained active and healthy in appearance throughout the 18 day test period.	NEW study [redacted] 2018. Efficacy of 0.0025% Brodifacoum Blocks on Young Adult Wistar Rats. [redacted] Study number BELL-1374
PT14 rodenticide	In and around buildings and in Sewers	0.0025% Weatherised Brodifacoum Blocks[1]	Young Adult Wistar Rats Brown rat (*Rattus Norvegicus*)	Laboratory test 10 males and 10 females singly housed in stainless steel	Each animal was provided 1 glass jar containing 0.0025% Weatherised Brodifacoum Blocks and 1 glass jar containing EPA	100% mortality Overall (M +F) average time to death 6.3 days with a range of 4-8	NEW study [redacted] 2018. Efficacy of 0.0025% Weatherized Brodifacoum Blocks on Young

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**
				caging.	challenge diet. Both diets were provided *ad libitum* (1 x *ca* 350 g test diet and 1 x *ca* 350 g EPA diet). EPA Challenge Diet was offered *ad libitum* to the control group (10 M + 10 F) during the exposure period. Food consumption was recorded. 4 days ± 2 hour bait exposure period. 12 h light / 12 h dark cycle, measured temperature and humidity ranges were 21-24°C and 37-54%.	days. Palatability: 64.4% The control animals remained active and healthy in appearance throughout the 18 day test period.	Adult Wistar Rats. [redacted] Study number BELL-1375
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	*Rattus norvegicus* (brown rat) wild population	Field study conducted according to the BPD TNsG on Product Evaluation Appendices to Chapter 7, PT14.*	Mixed age and sex population; separate and discrete at the test site - a commercial urban site in New Orleans, Louisiana. pre-trial census: 21 days, 10 bait stations with 4x20 g control bait	Pre-treatment census: consumption: 81.49 g per day Tracking:1.9 per day Post-treatment census:	[redacted] (2016) Norway rat #1

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**
					pre-treatment census: 3 days, 10 bait stations with 100g bulgur wheat pre-treatment lag period: 7 days treatment period: 32 days, 10 bait stations with 4 x 28 g Brodifacoum blocks were placed 5-10 m apart within the infested area. post-treatment lag period: 7 days post-treatment census: 3 days, 10 bait stations with 100g bulgur wheat Efficacy assessment was based on consumption and tracking indices before and after the treatment period.	consumption: 0.33 g per day Tracking:0.1 per day 99.6% decrease in consumption index was achieved in 32 days. A 94.7% decrease in the tracking index was achieved in 32 days. The study confirmed efficacy in the control of an active population of Brown rat. No signs of resistance were found.	
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	*Rattus norvegicus* (brown rat)	Field study conducted according to the	Mixed age and sex population; separate and discrete at the	Pre-treatment census:	[redacted] (2016) Norway rat #2

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**
			wild population	BPD TNsG on Product Evaluation Appendices to Chapter 7, PT14*.	test site - a commercial urban site in New Orleans, Louisiana. pre-trial census: 20 days, 11 bait stations with 4x20 g control bait pre-treatment census: 3 days, 10 bait stations with 100g bulgur wheat pre-treatment lag period: 7 days treatment period: 17 days, 11 bait stations with 4 x 28 g Brodifacoum blocks were placed 5-10 m apart within the infested area. post-treatment lag period: 8 days post-treatment census: 3 days, 10 bait stations with 100g bulgur wheat Efficacy assessment was based on	consumption: 9.95 g per day Tracking:1.57 per day Post-treatment census: consumption: 0.0 g per day Tracking:0.0 per day 100% decrease in consumption and tracking indices was achieved in 17 days. The study confirmed efficacy in the control of an active population of Brown rat. No signs of resistance were found.	

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**
					consumption and tracking indices pre-trial to post-trial.		
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	*Rattus rattus* (roof rat) wild population	Field study conducted according to the BPD TNsG on Product Evaluation Appendices to Chapter 7, PT14*.	Mixed age and sex population; separate and discrete at the test site - a residential urban site in Metairie, Louisiana. pre-trial census: 21 days, 10 bait stations with 4x20 g control bait pre-treatment census: 3 days, 10 bait stations with 100g bulgur wheat pre-treatment lag period: 7 days treatment period: 31 days, 10 bait stations with 4 x 28 g Brodifacoum blocks were placed 5-10 m apart within the infested area. post-treatment lag period: 8 days post-treatment	Pre-treatment census: consumption: 50.59 g per day Tracking:1.23 per day Post-treatment census: consumption: 0.0 g per day Tracking:0.0 per day 100% decrease in consumption and tracking indices was achieved in 31 days. The study confirmed efficacy in the control of an active population of	[redacted] (2016) Roof rat #1

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**
					census: 3 days, 10 bait stations with 100g bulgur wheat Efficacy assessment was based on consumption and tracking indices pre-trial to post-trial.	Roof rat. No signs of resistance were found.	
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	*Rattus rattus* (roof rat) wild population	Field study conducted according to the BPD TNsG on Product Evaluation Appendices to Chapter 7, PT14*.	Mixed age and sex population; separate and discrete at the test site - a residential urban site in Metairie, Louisiana. pre-trial census: 21 days, 10 bait stations with 4x20 g control bait pre-treatment census: 3 days, 10 bait stations with 100g bulgur wheat pre-treatment lag period: 7 days treatment period: 31 days, 10 bait stations with 4 x 28 g Brodifacoum blocks were placed 5-10 m apart within the	Pre-treatment census: consumption: 29.01 g per day Tracking:1.10 per day Post-treatment census: consumption: 0.0 g per day Tracking:0.0 per day 100% decrease in consumption and tracking indices was achieved in 31 days.	[redacted] (2016) Roof rat #2

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**
					infested area. post-treatment lag period: 8 days post-treatment census: 3 days, 10 bait stations with 100g bulgur wheat Efficacy assessment was based on consumptio n and tracking indices pre-trial to post-trial.	The study confirmed efficacy in the control of an active population of Roof rat. No signs of resistance were found.	
PT14 rodenticide	In and around buildings	0.0025% Brodifacoum Blocks	*Mus musculus* (House mouse) wild population	Field study conducted according to the BPD TNsG on Product Evaluation Appendices to Chapter 7, PT14*.	Mixed age and sex population; separate and discrete at the test site - a commercial urban site in New Orleans, Louisiana. pre-trial census: 30 days, 10 bait stations with 4x20 g control bait pre-treatment census: 3 days, 10 bait stations with 50 g bulgur wheat pre-treatment lag period: 7 days	Pre-treatment census: consumption: 4.58 g per day Tracking:0.53 per day Post-treatment census: consumption: 0.0 g per day Tracking:0.0 per day 100% decrease in	[redacted] (2016) House mouse #1

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**
					treatment period: 32 days, 10 bait stations with 1 x 28 g Brodifacoum blocks were placed 5-10 m apart within the infested area. post-treatment lag period: 8 days post-treatment census: 3 days, 10 bait stations with 50g bulgur wheat Efficacy assessment was based on consumption and tracking indices pre-trial to post-trial.	consumption and tracking indices was achieved in up to 32 days. The study confirmed efficacy in the control of an active population of House mouse. No signs of resistance were found.	

*****under field conditions in accordance with Transitional Guidance on the Biocidal Product Regulation, Transitional Guidance on Efficacy Assessment for Product Type 14 Rodenticides, § 2.6.1, Field Trials. Necessary to satisfy criterion for authorization in Article 19(1)(b)(1) of the BPR (Biocidal Products Regulation).

[1] The weatherisation procedure consists of placing the bait in a chamber that maintains it at 100ºF (*ca* 37ºC) and near 100% humidity for two weeks. The weatherisation procedure is described in detail in Bell Laboratories document SOP BI0002.4, this document is attached to the relevant summaries in IUCLID Section 6.7.

Conclusion on the efficacy of the product
The results from 7 laboratory efficacy studies and 5 field efficacy studies have been presented in the table above. For an evaluation of the label claims, see section 2.2.5.8.

It is considered that the data package demonstrates that the product is sufficiently efficacious against the House mouse (*Mus musculus*), the brown rat (*Rattus norvegicus*) and the black rat (*Rattus rattus*) with a shelf-life of 2 years.

2.2.5.5 Occurrence of resistance and resistance management

The occurrence of resistance to second generation anticoagulants has been well described and documented in the public domain. The documents RRAC guidelines on Anticoagulant Resistance Management, CropLife International, October 2016 and the Anticoagulant resistance in the Norway rat and Guidelines for the management of resistant rat infestations in the UK, Rodenticide Resistance Action Group (RRAG) June 2010 are useful publications on resistance management that have been taken into account in the labelling and directions for use for the 25 ppm Brodifacoum Blocks – for both professional and trained professional (Professional users with demonstrated competence) use product.

Resistance is a limitation to efficacy. Whilst specific resistance mutations to Brodifacoum in rats have not been identified unlike other second-generation anticoagulants, (Environmental Risk Mitigation Measures for Second Generation Anticoagulant Rodenticides Proposed by the UK, HSE, 2012b) it remains a concern that permanent and proactive baiting can increase the pressure for populations of target rodents to development anticoagulant resistance.

Guidance published by the UK Rodenticide Resistance Action Committee (RRAC, 2003) states "To avoid the development of resistance in susceptible rodent populations, do not use anticoagulant rodenticides as permanent baits routinely. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas." In addition, guidance published by the pest control and rodenticide industries (BPCA, 2001; CRRU, 2012) states; "In most cases, any anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined and documented. If bait continues to be consumed without effect, a more potent anticoagulant should be considered. If bait take is poor, relative to the apparent size of the infestation, consideration should be given to re-setting the bait points and possibly changing to another bait base, as well as making other environment changes".

In conclusion, whilst resistance is a limitation to efficacy, risk mitigation measures can help with resistance management and these have been included on the SPC.

The labels include the statements below for the management of resistance:

Professional:
Resistance:
The resistance status of the rodent population to brodifacoum should be taken into account when considering the choice of rodenticide to be used.

Where resistance to brodifacoum has been shown or is suspected, resistance management strategies should be employed.

Such strategies include the use of maximum label dose levels to ensure that sufficient bait is available for the entire rodent population to feed on a daily basis.

For mice: The baiting 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.
For rats: 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.

Long Term Use:
Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment. If rodent activity is still observed seek advice from the product supplier or call a pest control service.

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 rodent 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.

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

Trained Professional (Professional users with demonstrated competence):
Resistance:
The resistance status of the rodent population to brodifacoum should be taken into account when considering the choice of rodenticide to be used.

Do not use in areas where resistance to the active substance can be suspected.

Where resistance to brodifacoum has been shown or is suspected, resistance management strategies should be employed.

Such strategies include the use of maximum label dose levels to ensure that sufficient bait is available for the entire rodent population to feed on a daily basis.

The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice

Long Term Use:
Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits.

Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

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 rodent 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.

Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

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

2.2.5.6 Known limitations

No limitations known.

2.2.5.7 Evaluation of the label claims

The ready-to-use bait blocks are intended for use only as a rodenticide by professionals and trained professionals (Professional users with demonstrated competence) for the control of rats and mice indoor and outdoor around buildings and for the control of brown rats in sewers The blocks have a shelf-life of 24 months.

In total, 12 studies were provided to test the use of the product against house mice (*Mus musculus),* brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*), namely 7 laboratory efficacy studies and 5 field efficacy studies. The field studies were carried out in the US and were conducted almost totally in accordance with the available guidance for PT14 products. The Label/SPC use instructions are to 'maintain an uninterrupted supply of fresh bait for14-28 days'. The exposure periods used are slightly longer than this but are representative of this time period (32, 17, 31, 31, 32 days). Also, anticoagulant baits should achieve control within 35 days and the label/SPC states that 'Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.' Therefore these studies are considered to be acceptable to support the efficacy in the field for 0.0025% brodifacoum blocks.

House mice (*Mus musculus*):

- One laboratory mouse (*Mus musculus*) study was performed using 0.0025% brodifacoum blocks with a 15 day exposure period. This resulted in 100% mortality with an average time to death of 6.5 days (4-10 day range) and a palatability of 58.2%
- One laboratory mouse study was performed using weatherised 0.0025% brodifacoum blocks with a 15 day exposure period. This resulted in 100% mortality with an average time to death of 7 days (5-10 day range) and a palatability of 62.5%
- One mouse study was performed using 0.0025% brodifacoum blocks with a 4 day exposure period. This resulted in 100% mortality with an average time to death of 5.7 days (3-7 day range) and a palatability of 35.5%.

The weatherised bait test for mice is not directly relevant for this dossier and was conducted for US registration requirements and label claims and is included here as additional information only.
The two studies with a 15 day exposure time have not been conducted according to the current guidance where an exposure period of 3-5 days is recommended and are therefore included as additional information only.

However, in all 3 laboratory tests with mice 100% mortality was achieved and palatability was sufficient (>20%).

- One mouse (*Mus musculus*) field study was performed using 0.0025% brodifacoum blocks at an urban commercial location. The degree of control is expressed as a percentage reduction in the pre-treatment index for consumption and for tracking. A 100% decrease in both consumption and tracking indices was achieved in 32 days.

Brown rats (*Rattus norvegicus*)

- One laboratory brown rat (*Rattus norvegicus*) study was performed using 0.0025% brodifacoum blocks with a 15 day exposure period. This resulted in 100% mortality with an average time to death of 7.6 days (5-11 day range) and a palatability of 63.6%
- One laboratory brown rat study was performed using weatherised 0.0025% brodifacoum blocks with a 15 day exposure period. This resulted in 100% mortality with an average time to death of 7.8 days (4-12 day range) and a palatability of 65.6%

- One laboratory brown rat (*Rattus norvegicus*) study was performed using 0.0025% brodifacoum blocks with a 4 day exposure period. This resulted in 100% mortality with an average time to death of 6.3 days (3-10 day range) and a palatability of 58.4%
- One laboratory brown rat study was performed using weatherised 0.0025% brodifacoum blocks with a 4 day exposure period to assess efficacy for use against brown rats in sewers. This resulted in 100% mortality with an average time to death of 6.3 days (4-8 day range) and a palatability of 64.4%

The two studies with a 15 day exposure time have not been conducted according to the current guidance where an exposure period of 3-5 days is recommended and are therefore included as additional information only.

However, in all 4 laboratory tests with brown rats 100% mortality was achieved and palatability was sufficient (>20%). The use of weatherised Brodifacoum Blocks demonstrated the product as efficacious in the control of brown rat (*Rattus norvegicus*) for use in sewers.

- Two brown rat field studies were performed using 0.0025% brodifacoum blocks at an urban commercial location. The degree of control is expressed as a percentage reduction in the pre-treatment index for consumption and for tracking. For one study a 99.6% decrease in consumption and 94.7% in tracking indices was achieved in 32 days. For the other study a 100% decrease in both consumption and tracking indices was achieved in 17 days.

Roof rat (*Rattus rattus*)

Two black rat (*Rattus rattus*) studies were performed using 0.0025% brodifacoum blocks at an urban residential location. The degree of control is expressed as a percentage reduction in the pre-treatment index for consumption and for tracking. For both studies a 100% decrease in both consumption and tracking indices was achieved in 32 days.

Overall conclusion

In all the laboratory tests 100% mortality was achieved and palatability was sufficient (>20%). In all fieldtests >90% reductions in food consumption and tracking indices pre-trial to post-trial were achieved within up to 32 days. In some trials the wild population was eradicated. At the very high rates of reduction of infestation achieved in the field it was considered that no resistance was observed.
Therefore efficacy data presented in the dossier supports the labels claim use of Brodifacoum 25 ppm Blocks- for both professionals and trained professionals (Professional users with demonstrated competence) use for the control of brown rats (*rattus norvegicus*), black rats (*Rattus rattus*) and housemice (*Mus musculus*). As the product

contains a preservative, a shelf-life of 2 years is authorised in line with the Technical Agreements on Biocides (TAB).

The product will be authorised for the following uses:

- Use # 1 – House mice – professionals – indoor -
- Use # 2 – House mice – Professional users with demonstrated competence (equivalent to trained professionals) – indoor
- Use # 3 – Rats – professionals – indoor -
- Use # 4 – Rats – Professional users with demonstrated competence (equivalent to trained professionals) – indoor
- Use # 5 – House mice – Professional users – outdoor around buildings –Use # 6 – House Mice – Professional users with demonstrated competence (equivalent to trained professionals) – outdoor around buildings
- Use # 7 – Rats – Professional users – outdoor around buildings –
- Use # 8 – Rats – Professional users with demonstrated competence (equivalent to trained professionals) – outdoor around buildings
- Use # 9 – Rats – Professional users with demonstrated competence (equivalent to trained professionals) – sewers

National specific regulations in the Netherlands:

Due to Dutch national specific regulations in the Netherlands, only trained professionals are allowed to apply rodenticides (no professional use) and additional IPM training is needed for outdoor application of rodenticides (around buildings and food storage locations). In addition, the use against house mice is restricted to use in buildings and for both house mice and rats use in covered and protected bait points is not allowed.
Therefore, in the Netherlands authorised use of this product will consist of:
- use in tamper-resistant bait boxes in buildings against house mice (*Mus musculus*) and rats (*Rattus norvegicus* & *Rattus rattus)* by trained professionals,
- use in tamper-resistant bait boxes around buildings against rats (*Rattus norvegicus* & *Rattus rattus)* by trained professionals with additional IPM training.
- use against brown rats (*Rattus norvegicus*) in sewers by trained professionals.

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

Brodifacoum 25 ppm Blocks-) are not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

No new studies have been carried out. A product dossier for Brodifacoum Blocks (professional use) containing 50 ppm active substance has been submitted and approved by Ireland under the Biocidal Products Directive whilst the renewal of this authorisation has been completed by the UK for Solo Blox containing 50 ppm Brodifacoum in July 2018.

The composition of Brodifacoum Blocks containing 50 ppm is the essentially the same as Brodifacoum 25 ppm Blocks – Professional Use product with minor differences of percentage content for 2 of the coformulants (See Confidential annex for the comparison of compositions). Read-across to the 50 ppm studies submitted in the product dossier is therefore applicable.

The toxicological properties of Brodifacoum 25 ppm Blocks – Professional Use product may be derived from the data generated for the 50 ppm Brodifacoum blocks and from the properties of the active ingredient, brodifacoum (**Brodifacoum (PT14) AR Italy, 2010)** by means of a letter of access**.**

2.2.6.1 Assessment of effects on Human Health

No new studies have been carried out- the studies below have been submitted and approved by Ireland, for the 50 ppm product dossier under the Biocidal Products Directive, however for the sake of completeness these are presented here.

Skin corrosion and irritation

Extracted from the Bell Laboratories 50 ppm Brodifacoum Blocks Dossier

Brodifacoum has been tested in the rabbit for skin irritation potential. Results are summarised in the table below.

Summary table of animal studies on skin corrosion /irritation						
Species	**Method**	**Average score 24, 48, 72 h**		**Reversibility yes/no**	**Result**	**Reference**
		Erythema	**Edema**			
Rabbit	40 CFR § 158.340 OPPTS 870.2500 - Acute Dermal Irritation OECD Guideline 404 Acute Dermal Irritation /Corrosion	The score was 0 at all timepoints.	The score was 0 at all timepoints.	Not applicable	Not irritating to skin	[redacted] (2011c) Acute Dermal Irritation/Corrosion Evaluation of 0.005% Brodifacoum Blocks on Young Adult New Zealand White Rabbits, [redacted] Report No. BEL/0811/BT758, Unpublished, GLP, 23 September 2011

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Negative for irritation
Justification for the value/conclusion	See data waiving section below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	A skin corrosion and irritation study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use as results may be read across to the skin irritation study summarised and reported for 50 ppm Brodifacoum blocks.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not need to be classified as a skin irritant.

Eye irritation

Extracted from the Bell Laboratories 50 ppm Brodifacoum Blocks Dossier

Brodifacoum has been tested in the rabbit for eye irritation potential. Results are summarised in the table below.

Summary table of animal studies on serious eye damage and eye irritation								
Species	**Method**	**Average Score**				**Result**	**Reversibility**	**Reference**
		Cornea	**Iris**	**Redness Conjunctiva**	**Chemosis**			
Rabbit	FIFRA 40 CFR, Section 158.115, Subdivision F, Guideline Reference No. 81-4	The average score was 0 at all timepoints	The average score was 0 at all time points	The average score was 0.33, 0, and 0 at 24, 48 and 72h, respectively	The average score was 0 at all timepoints	Not irritating to eyes	Yes, all effects returned to normal within 48 hours of treatment	[redacted] (2011c), Acute Eye Irritation/Corrosion Evalauation of 0.005% Brodifacoum Blocks in Young Adult New Zealand White Rabbits, (Unpublished), [redacted] Report No. BEL/0811/BT757, 23 September 2011 (IIIB6.2E

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	Negative for irritation
Justification for the value/conclusion	See data waiving section below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	An eye corrosion and irritation study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use as results may be read across to the eye irritation study summarised and reported for 50 ppm Brodifacoum blocks.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not need to be classified as an eye irritant.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Negative for irritation
Classification of the product according to CLP and DSD	See data waiving section below

Data waiving	
Information requirement	A respiratory irritation study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use since operator exposure through inhalation is unlikely to occur based on the directions for use of the blocks and the low vapour pressure of Brodifacoum (2.6E-22 Pa at 20°C) making inhalation exposure negligible.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not require to be classified for respiratory tract irritation **(Brodifacoum (PT14) AR Italy, December 2010.)**

Skin sensitisation

Extracted from the Bell Laboratories 50 ppm Brodifacoum Blocks Dossier

Brodifacoum has been tested in the guinea pig for skin sensitization potential. Results are summarised in the table below.

Summary table of animal studies on skin sensitisation

Species	Method	Number of animals sensitized/total number of animals	Result	Reference
Guinea Pig	OECD Guideline No.406 (Buehler Method)	0/20 test animals at the 24-hour scoring interval and 0/20 test animals at the 48-hour scoring interval	Not a sensitizer	[redacted] (2012) Dermal Sensitization Study in Guinea Pigs (Buehler Method), [redacted] Study N° 33324, 17 January 2012, GLP, Unpublished

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Negative for sensitisation
Justification for the value/conclusion	See data waiving section below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	A skin sensitisation study has not performed with Brodifacoum 25 ppm Blocks – Professional Use as results may be read across to the sensitisation study summarised and reported for 50 ppm Brodifacoum blocks.
Justification	Brodifacoum 25 ppm Blocks – Professional Use, should not be classified as a skin sensitizer.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Negative for sensitisation
Justification for the value/conclusion	See data waiving section below
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	A respiratory sensitisation study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use since operator exposure through inhalation is unlikely to occur based on the directions for use of the blocks and the low vapour pressure of Brodifacoum (2.6E-22 Pa at 20°C) making inhalation exposure negligible.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not require to be classified for respiratory tract sensitsation**.**

Acute toxicity

Acute toxicity by oral route

Extracted from the Bell Laboratories 50 ppm Brodifacoum Blocks Dossier

Summary table of animal studies on acute oral toxicity					
Method Guideline	**Species Strain Sex No./Group**	**Dose Levels / Duration of Exposure**	**Value LD_{50}/L C_{50}**	**Remarks**	**Reference**
FIFRA 40 CFR, Section 158.340, Guideline Reference No. OPPTS 870.1100	Sprague Dawley rats; 2 groups; Group 1=3♀, Group 2 = 9♀	2000 mg/kg bw/ single exposure	>2000 mg/kg bw	The test material was ground to a fine powder and suspended in distilled water.	[redacted] (2011a) Acute Limit Oral Toxicity Evaluation of 0.005% Brodifacoum Blocks on Young Adult Sprague Dawley Rats, [redacted] Report No. BEL/0911/BT763, Unpublished, GLP, 25 October 2011 (IIIB6.1.1)

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 2000 mg/kg
Justification for the selected value	No toxic effects were noted at a dose of 2000 mg/kg, Brodifacoum 25 ppm Blocks – Professional Use do not meet the criteria for classification for acute oral toxicity.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	An oral acute toxicity study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use as results may be read across to the study summarised and reported for 50 ppm Brodifacoum blocks.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not need to be classified for oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not classified
Justification for the selected value	An acute inhalation study was not performed as the vapour pressure of the active substance is significantly less than 1 x 10^2 Pa (2.6E-22 Pa at 20°C) and the test substance will not be used in preparations which generate aerosols, particles or droplets in the inhalable range, MMAD <50 µm. Exposure to Professional users through inhalation is

	unlikely to occur based on the information presented concerning professional use procedures.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Not relevant.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not require to be classified with respect to inhalation toxicity due to the physical nature of the blocks, which would not produce an inhalable powder. **Extracted from Brodifacoum (PT14) AR Italy, December 2010.** The waiving for the inhalation toxicity study has been accepted as the vapour pressure of the active substance is significantly less than 1 x 10^2 Pa (2.6E-22 Pa at 20°C) and the test substance will not be used in preparations which generate aerosols, particles or droplets in the inhalable range, MMAD <50 µm. Exposure to Professional users through inhalation is unlikely to occur based on the information presented concerning professional use procedures. In addition, Brodifacoum 25 ppm Blocks – Professional Use does not contain substances with H330/H331/H332 above relevant concentration limit.

Acute toxicity by dermal route

Extracted from the Bell Laboratories 50 ppm Brodifacoum Blocks Dossier

Summary table of animal studies on acute dermal toxicity					
Method Guideline	**Species Strain Sex No./Group**	**Dose Levels / Duration of Exposure**	**Value LD_{50}/LC_{50}**	**Remarks**	**Reference**
40 CFR § 158.340 Toxicology Data Requirements Guideline Reference No. OPPTS 870.1200	Sprague Dawley rats; One treatment group of ten animals (five/sex)	5001 mg/kg bw / single exposure	>5001 mg/kg body weight	The test material was ground to a fine powder and moistened with distilled water.	[redacted] (2011b), Acute Limit Dermal Toxicity Evaluation of 0.005% Brodifacoum Blocks on Young Adult Sprague Dawley Rats, [redacted] Report No. BEL/0911/BT764, Unpublished, GLP, 25 October 2011 (IIIB6.1.2)

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 5001 mg/kg
Justification for the selected value	No toxic effects were noted at a dose of 5001 mg/kg, Brodifacoum 25 ppm Blocks – Professional Use do not meet the criteria for classification for acute dermal toxicity.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	An acute dermal toxicity study has not been performed with Brodifacoum 25 ppm Blocks – Professional Use as results may be read across to the study summarised and reported for 50 ppm Brodifacoum blocks.
Justification	Brodifacoum 25 ppm Blocks – Professional Use do not need to be classified for dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Brodifacoum
Value(s)*	Read across to Solo Blox containing 50 ppm Brodifacoum – 0.1%. As the concentration of a.i. in the current product has been halved compared to Solo Blox a pro-rata correction has been applied. The dermal absorption value of 0.2% is used in the risk assessment for the current application for Brodifacoum 25 ppm Blocks.
Justification for the selected value(s)	**Dermal absorption for Solo Blox 50 ppm product, Extracted from the Solo Blox PAR containing Brodifacoum (PT14) UK, July 2018: '**Dermal absorption values for Solo Blox were determined in the previous PAR (2013) based on read-across to an in vitro study through human skin. The study was performed on 0.005% difenacoum wax block formulation. For the purpose of renewal, the available study and the read-across justification have been re-evaluated in accordance with the current guidance on dermal absorption (EFSA journal 2012;10(4) :2665)' **'**Therefore the finalised dermal absorption value to be used in the risk assessment for Solo Blox is 0.1%'

Data waiving	
Information requirement	No studies were performed to establish the dermal absorption of Brodifacoum as read-across to the dermal absorption value for Difenacoum has been accepted and re-evaluated for the Brodifacoum active substance renewal July 2018.
Justification	No studies were performed to establish the dermal absorption of Brodifacoum. **'**A formulation comparison between the tested

formulation and Solo Blox has been conducted by the UK eCA. The formulations are considered comparable for the purposes of determining dermal absorption (see Member State Confidential Annex to this PAR for further details). In the original evaluation the value obtained in this study and subsequently used in the risk assessment for Solo Blox was 0.047%. For this renewal the *in vivo* dermal absorption study conducted on Roban Wax Block has been re-evaluated by the UK eCA in accordance with the current guidance on dermal absorption (EFSA journal 2012;10(4):2665). This has resulted in a revision of the dermal absorption value from 0.047% to 0.1% for a product containing 0.005% active substance. Therefore the finalised dermal absorption value to be used in the risk assessment for Solo Blox is 0.1%'

As the concentration of a.i. in the current product Brodifacoum 25 ppm Blocks – Professional Use has been halved compared to Solo Blox a pro-rata correction has been applied. The dermal absorption value of 0.2% is used in the risk assessment for the current application for Brodifacoum 25 ppm Blocks – Professional Use.

Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Concentration of test substance/Label, Duration of exposure**	**Absorption data for each compartment and final absorption value**
OECD 402 GLP Davies 2007 Re-evaluated for renewal	Rat, Sprague-Dawley, males and females, 3/sex/group	Roban Oktablok, wax blocks, 0.005% difenacoum	Recovery [%] 96.7±0.402 **Dislodgeable dose** Skin wash (8 h): 96.6±0.397 Tissue swab/decontamination (8h): 0.099±0.012 Donor chamber: 0.003±0.001 Skin wash at 24 hours: 0.043±0.007 **Skin associated dose** Tape strips 1-2: 0.00077±0.001 Tape strips 3-5: 0.00045 All strips: 0.001±0.001 Skin preparation: 0.036±0.007 **Absorbed dose** Receptor fluid: 0.011±0.002 Absorption estimate (receptor fluid, skin prep, tape strips): 0.048±0.024 Absorption estimate (receptor fluid, skin prep): 0.047±0.024 Relevant absorption estimate (+SD as >25%):0.072 Relevant absorption estimate (+SD as >25%):0.071 Final estimate (rounded value): **0.1%**

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

Brodifacoum 25 ppm Blocks – Professional Use contains the preservative potassium sorbate.
Potassium sorbate is currently under the BPR review programme for PT 6 'Preservatives for products during storage' with Germany as the eCA. Potassium sorbate is approved for PT 8 'Wood Preservatives'. According to the Note for discussion with competent authorities for biocidal products CA-Nov-Doc.5.11, page 2 paragraph 2,
'Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report -CAR (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation). This criterion identifies other active substances in the biocidal product that act as co-formulants (e.g. in-can preservatives). It is noted that active substances (acting as co-formulants in a product) should be regarded as SoCs because, due to their intrinsic biological activity, they are likely to possess toxicological activity. It is also noted that as many active substances do not hold harmonised classifications under the CLP Regs, they may fail to be identified as SoCs by indents 1 and 2 of Art 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.'

Potassium sorbate may be considered a SoC according to the guidance document referenced above, falls in Band C for which quantitative risk assessment is required. A local effects risk assessment for skin, eye and respiratory irritation is not required. This has been determined on the basis that read-across to brodifacoum 50 ppm blocks demonstrates that the blocks are not classified for irritancy and that there is no risk of respiratory irritation arising from professional operators placing the solid waxy blocks in bait stations or sewers. A systemic AEL has been determined for PT 8 use and therefore a systemic risk assessment of the SoC potassium sorbate in its PT 6 'Preservatives for products during storage' use has been performed.

Endocrine disruption activity of non- active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).
According to the Endocrine disruption criteria a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product Brodifacoum 25 ppm Blocks – Professional Use may possess ED properties, a screening was performed by NL CA by examining if the co-formulants are

- Classified as CMR or PBT;

- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

As a result of the screening it was identified that an ED concern has been raised by France for one co-formulant, [redacted] and they propose to include this substance on the CoRAP list [redacted]. This substance is also known as [redacted] and is approved as food additive (anti-oxidant) and as additive for animal feed (E 320). Regarding the current application CA NL considers that the ED assessment for this co-formulant does not need to be included in the PAR and can await the outcome of the discussions at EU level.

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

The product, Brodifacoum 25 ppm Blocks – Professional Use, are solid block baits containing 0.0025% Brodifacoum (3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin). This formulation is designed to be used by professional operators. Brodifacoum is a second-generation single-dose anticoagulant rodenticide. Brodifcaoum 25 ppm Blocks – Professional Use are supplied as 5 g (1.27 x 1.27 x 2.79 cm) 20 g (2.54 x 2.54 x 4.445 cm) and 200 g (3.02 x 3.02 x 9.84 cm) blocks in pack sizes up to 10 kg.

The product is intended to be used in bait stations to control rats and mice 'in and around buildings' and rats in sewers and will not be used in direct contact with food.

As stated in document CA-March07-Doc.6.3 "In and around buildings' shall be understood as the building itself, and the area around the building that needs to be treated in order to deal with the infestation of the building. This would cover uses in sewer system or ships but not in waste dumps or open areas such as farmlands, parks or golf courses".

<u>Use Directions</u>
The bait is used as provided. No other substances are added to the bait. Typical instructions for the block bait are as follows:
Bait must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure Brodifacoum 25 ppm Blocks – Professional Use so they cannot be dragged away by rodents or surges of water if intended for use in sewers. Place bait in tamper resistant bait stations, or covered bait points (not relevant to the Netherlands).

Please refer to Section 2.1.4 for use specific directions for use for each block size.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	N/A	Not expected	N/A	N/A	N/A	No	No
Dermal	N/A	Yes	N/A	N/A	N/A	Yes	No
Oral	N/A	No*	N/A	N/A	N/A*	Yes#	No

N/A not applicable
* Professionals are not expected to be exposed via the oral route
# In theory infants could be exposed orally/dermally by chewing bait or touching their mouths with contaminated fingers, however product labels and good practices advise users to prevent access to bait by children.

Primary exposure:
Dermal exposure: exposure of users is limited to the hands during placing bait in a bait station and clean-up and disposal of bait blocks- exposure of other parts of the body is negligible.

Secondary exposure:
Dermal exposure:
Non-users are not expected to have contact with the baits during the application phase or once the baits are placed. Dermal contact is, however, considered possible if dead animals containing bait on their coats are handled. This exposure is, however, considered to be unlikely and following discussion at TMIII2010 it was agreed that child contact with dead rodents should no longer be assessed.

Oral exposure:
Children could potentially be the group at the highest risk as they may play inside or around buildings where baits have been placed. However, the blocks contain a bittering agent which would prevent ingestion of the baits and product labels and good practice advise users to prevent access to bait by children. While this scenario is not considered to be likely, it is still presented in this PAR for the sake of completeness.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application	Primary; Securing wax blocks in bait stations, HEEG Opinion 12	Professionals
2.	Post-application	Primary; Clean-up and disposal of partly consumed bait blocks, HEEG Opinion 12	Professionals
3.	Secondary dermal/adult	Secondary/indirect; Dermal Contact by an adult with Dead Rodents	General public
4.	Secondary oral/infant	Secondary/indirect; Infant accidental oral exposure	General public

Industrial exposure

Brodifacoum 25 ppm Blocks – Professional Use is neither manufactured nor formulated in the EU, therefore no human health or exposure scenarios have been examined/ investigated for these procedures.

Professional exposure

The following types of exposure are considered according to HEEG Opinion 12, HEEG Opinion on an harmonised approach for the assessment of rodenticides (anticoagulants), TMII, 2011, 7/02/2012.

Dermal Exposure
Dermal exposure is considered to be the most significant exposure. This can occur when the wax baits are placed by hand and the exposure is normally restricted to the hands. Exposure to other parts of the body is deemed to be negligible. Dermal exposure to the hands is also anticipated in the post application phase during clean-up and disposal of partly consumed bait blocks.

Inhalation Exposure
According to HEEG Opinion 12, inhalation exposure during the placement of block baits is not expected.

Oral Exposure
Professionals are not expected to be exposed via the oral route. Good hygiene such as washing hands prior to touching food or smoking is expected to mitigate any potential risk.

Scenario 1

Description of Scenario 1, Securing blocks into bait stations		
Securing blocks into bait stations based on HEEG Opinion 12 in which an agreed number of manipulations for professional use was agreed in the application phase. This activity considers the securing of compressed wax blocks into a bait station by pushing bait mounting pegs through holes in the wax blocks. Assessments have been made for a 20g wax block, as this gives the worst case number of manipulations compared to a 200g wax block.		
	Parameters	Value
20 g blocks		
Tier 1	Loading bait boxes (HEEG 12, 75th percentile 27.79 mg product for placing 5 blocks in a bait station) x2 for pacing 10 blocks in a bait station	55.58
	Number of loading bait stations per day = number of manipulations	60
	Concentration of active ingredient in the product	0.0025%
	Concentration of Substance of Concern (SoC)	1% w/w potassium sorbate
	Weight of operator[a] (kg)	60
	Dermal penetration (%)	0.2%[b] (a.s) 25%[C] (SoC)
	Reduction due to PPE[a] (%)	0
Tier 2[2]	Reduction due to PPE[a] (%)	90

a ECHA Biocides Human Health Exposure Methodology

b Read-across to the Solo Blox 50 ppm product is Extracted from the Solo Blox PAR containing Brodifacoum (PT14) UK, July 2018, including pro-rata correction

c Based on the Assessment Report on potassium sorbate (Febr 2015). According to EFSA dermal absorption guidance (2017) 70% should have been applied. With the dermal absorption of 70% the maximal exposure of a professional user will increase from 1.06% AEL to 2.97%AEL per day. As the conclusion for the acceptable risk will not change, the risk assessment performed on the SoC using dermal absorption of 25% is not further revised.

The systemic dermal dose for a.i.:

Tier 1: 55.58 mg x 60 applications x 0.0025% a.s x 0.2% dermal absorption = 1.67E-04 mg a.s. / 60 kg = **2.78E-06 mg/kg bw/day**

Tier 2 (with gloves): 2.78E-06 mg/kg bw/day x 0.1 (PPE) = **2.78E-07 mg/kg bw/day**

The systemic dermal dose for SoC:

Tier 1: 55.58 mg x 60 applications x 1% SoC x 25% dermal absorption = 8.34 mg / 60 kg = **1.39E-01 mg/kg bw/day**

Tier 2 (with gloves): 1.39E-01 mg/kg bw/day x 0.1 (PPE) = **1.39E-02 mg/kg bw/dayCalculations for Scenario 1**

Securing blocks into bait stations Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg bw/day)
Scenario 1 – 20 g blocks	1 / No PPE	Not expected	2.78E-06	Not Applicable	2.78E-06
			SoC 1.39E-01		SoC 1.39E-01
Scenario 1 – 20 g blocks	2 / PPE (gloves)	Not expected	2.78E-07	Not Applicable	2.78E-07
			SoC 1.39E-02		SoC 1.39E-02

Further information and considerations on scenario 1

Detailed calculations for the model used in this scenario are given in Annex 3.2 of this report.

Scenario 2

Description of Scenario 2, Clean-up and disposal of partly consumed bait blocks		
This scenario was based on HEEG Opinion 12 and included the emptying of a loaded bait station by sliding the wax blocks off the mounting pegs into a 10 L plastic bucket. In this scenario it was considered that the same exposure occurred as in overturning the bait box to empty it and therefore the number of disposed blocks per bait box are not considered. Therefore the dermal exposure is based on the number of manipulations and numbers of blocks in the bait boxes and size of the bait block are ignored.		
	Parameters	Value
Tier 1	Cleaning up and emptying of loaded bait stations, sliding the blocks off into a bucket.	5.7
	Number of manipulations per day	15
	Concentration of active ingredient in the product	0.0025%
	Concentration of Substance of Concern (SoC)	1% w/w potassium sorbate
	Weight of operator[a] (kg)	60
	Dermal penetration (%)	0.2%[b] (a.s.) 25%[C] (SoC)
	Reduction due to PPE[a] (%)	0
Tier 2[2]	Reduction due to PPE[a] (%)	90

a ECHA Biocides Human Health Exposure Methodology

b Read-across to the Solo Blox 50 ppm product is Extracted from the Solo Blox PAR containing Brodifacoum (PT14) UK, July 2018

c Based on the Assessment Report on potassium sorbate (Febr 2015). According to EFSA dermal absorption guidance (2017) 70% should have been applied. With the dermal absorption of 70% the maximal exposure of a professional user will increase from 1.06% AEL to 2.97%AEL per day. As the conclusion for the acceptable risk will not change, the risk assessment performed on the SoC using dermal absorption of 25% is not further revised.

The systemic dermal dose for a.i.:

Tier 1: 5.7 mg x 15 applications x 0.0025% a.s x 0.2% dermal absorption = 4.28E-06 mg a.s. / 60kg = **7.13E-08 mg/kg bw/day**

Tier 2 (with gloves): 7.13E-08 mg/kg bw/day x 0.1 (PPE) = **7.13E-09 mg/kg bw/day**

The systemic dermal dose for SoC:

Tier 1: 5.7 mg x 15 applications x 1% SoC x 25% dermal absorption = 2.14E-01 mg / 60kg = **3.56E-03 mg/kg bw/day**

Tier 2 (with gloves): 3.56E-03 mg/kg bw/day x 0.1 (PPE) = **3.56E-04 mg/kg bw/day**

Calculations for Scenario 2

Clean-up and disposal Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2	1 / No PPE	Not expected	7.13E-08 mg/kg bw/day	Not Applicable	7.13E-08 mg/kg bw/day
			SoC 3.56E-03 mg/kg bw/day		SoC 3.56E-03 mg/kg bw/day
Scenario 2	2 / PPE (gloves)	Not Applicable	7.13E-09 mg/kg bw/day	Not Applicable	7.13E-09 mg/kg bw/day
			SoC 3.56E-04 mg/kg bw/day		SoC 3.56E-04 mg/kg bw/day

N/A not applicable

Further information and considerations on scenario 2

Detailed calculations for the model used in this scenario are given in Annex 3.2 of this report.

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& 2 20 g block Tier 1	Not Applicable	2.85E-06 mg/kg bw/day	Not Applicable	2.85E-06 mg/kg bw/day
		SoC 1.43E-01 mg/kg bw/day		SoC 1.43E-01 mg/kg bw/day
Scenarios 1& 2 20 g block Tier 2	Not Applicable	2.85E-07 mg/kg bw/day	Not Applicable	2.85E-07 mg/kg bw/day
		SoC 1.43E-02 mg/kg bw/day		SoC 1.43E-02 mg/kg bw/day

Non-professional exposure

Brodifacoum 25 ppm Blocks – Professional Use product will not be used by non-professionals.

Exposure of the general public – Indirect or Secondary Exposure

There should be no indirect exposure to Brodifacoum 25 ppm Blocks – Professional Use as long as the label instructions for use are followed i.e.
Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

- Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.
- Remove all baits after treatment and dispose of them in accordance with local requirements.
- Keep out of the reach of children.
- For products to be used in public areas, when tamper-resistant bait stations are not used, the following safety precaution shall be carried on the label of the products or elsewhere on the packaging or accompanying leaflet: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of accident, call a poison centre".
- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Two potential secondary exposure scenarios can be considered:-
1. Dermal contact by adults with rodent carcasses and
2. Mouthing of poison bait – infant

The following points have been considered when determining potential indirect exposure:-

Inhalation Exposure
Inhalation exposure will be negligible, as the bait is in the form of a wax block and Brodifacoum is not volatile. Exposure to non-users during or after application via the environment is also considered to be negligible.

Dermal Exposure
Non-users are not expected to have contact with the baits during the application phase or once the baits are placed. Dermal contact is, however, considered possible if dead animals containing bait on their coats are handled. This exposure is, however, considered to be unlikely and following discussion at TMIII2010 it was agreed that child contact with dead rodents should no longer be assessed. The 'handling of dead rodents' scenario is excluded from the risk assessment due to unrealistic assumptions.

Oral Exposure
Oral exposure to Brodifacoum should not occur. However, as a worst case scenario, the situation where an infant manages to access a bait block and then ingests a piece of the block has been assessed. This is considered to be an exceptional scenario (TNsG EU Evaluation manual for the authorisation of biocidal products, CA-Dec12-Doc.6.2.b-final). Exposure is acute and expected to occur only accidentally. In this scenario licking of the hands can be disregarded as this would be a marginal addition to the mouthing exposure. The bittering agent in the bait should reduce the magnitude of oral exposure, but not eliminate the possibility of accidental ingestion by a young child (Berning C.K. et al

(1982)). As a further worst case scenario, the situation where the bittering agent has no effect i.e. the child is not sensitive to the agent, has also been assessed.

Scenario 3

Description of Scenario 4, Mouthing of poison bait [1].		
Infant Accidental Oral Exposure The possibility of oral exposure to an infant (8 kg) is considered to represent a worst case scenario. For the purposes of this assessment it is assumed that the infant consumes 5 g in one bite, a value estimated by poison specialists (TNsG on human exposure to Biocidal Products (June 2002), User Guidance Version 1, page 67). If a bittering agent is present (in this case it always will be) then the amount ingested is assumed to be 10 mg (TNsG on human exposure, 2002, page 58).		
	Parameters	Value
Tier 1	Quantity of bait ingested (mg)	5000
	Content of active substance in product residue (%)	0.0025
	Concentration of Substance of Concern (SoC)	1% w/w potassium sorbate
	Weight of infant[a] (kg)	8
	Oral absorption[b] (%)	100
Tier 2	Quantity of bait containing a bittering agent ingested (mg)	10

[1] TNsG Evaluation Manual for the Authorisation of Biocidal Products, CA-Dec-12-Doc.6.2.b, p47

a ECHA Biocides Human Health Exposure Methodology

b Brodifacoum Assessment report, Italy, 2010

Scenario 4 – transient mouthing of poison bait for infants – a.s.

Tier 1: 5000 mg x 0.0025% a.s. x 100% oral absorption

=0.125 mg/day = **1.56E-02 mg/kg bw/day** for an infant of 8 kg bw

Tier 2: 10 mg x 0.0025% a.s. x 100% oral absorption

=0.00025 mg/day = **3.13E-5 mg/kg bw/day** for an infant of 8 kg bw

Scenario 4 – transient mouthing of poison bait for infants – SoC.

Tier 1: 5000 mg x 1% a.s. x 100% oral absorption

=0.125 mg/day = **6.25 mg/kg bw/day** for an infant of 8 kg bw

Tier 2: 10 mg x 0.0025% a.s. x 100% oral absorption

=0.00025 mg/day = **1.25E-02 mg/kg bw/day** for an infant of 8 kg bw

Calculations for Scenario 3

Summary table: systemic exposure from secondary exposure

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake** (mg/kg bw/day)	**Estimated total uptake** (mg/kg bw/day)
Scenario 3	1 / bait with no aversive agent	Not applicable	Not applicable	1.56E-02	1.56E-02
				SoC 6.25	SoC 6.25
Scenario 3	2 / bait containing a bittering agent	Not applicable	Not applicable	3.13E-05	3.13E-05
				SoC 1.25E-02	SoC 1.25E-02

Combined scenarios

Combined exposure scenarios are not applicable to the secondary exposure scenarios described above.

Monitoring data

There are no information on surveys or studies with the actual product or with a surrogate.

Dietary exposure

Dietary exposure is not applicable for 25 ppm Brodifacoum Blocks – Professional use.

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

25 ppm Brodifacoum Blocks – Professional use are manufactured outside of the EU therefore no exposure assessment is required for this step. Disposal of the product has been taken into consideration in the Professional use scenarios described previously in this section.

Aggregated exposure

Aggregated exposure is not applicable for 25 ppm Brodifacoum Blocks – Professional use.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (**mg/kg bw/day)

1. 20 g blocks	Professionals	1 / No PPE	2.78E-06
			SoC 1.39E-01
		2 / PPE (gloves)	2.78E-07
			SoC 1.39E-02
2.	Professionals	1 / No PPE	7.13E-08
			SoC 3.56E-03
		2 / PPE (gloves)	7.13E-09
			SoC 3.56E-04
Combined Scenarios 1& 2 20 g block	**Professionals**	**1 / No PPE**	**2.85E-06**
			SoC 1.43E-01
		2 / PPE (gloves)	**2.85E-07**
			SoC 1.43E-02
			SoC 5.70E-05
3.	General public (secondary exposure)	1 / bait with no aversive agent	1.56E-02
			SoC 6.25E+00
		2 / bait containing a bittering agent	3.13E-05
			SoC 1.25E-02

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Rat: developmental toxicity study#	0.001 mg/kg bw/d (maternal toxicity)	300	None	3.3E-06 mg/kg bw/d
AELmedium-	Rabbit:	0.002	300	None	6.67E-06

term	developmental study#	mg/kg bw/d (maternal toxicity)			mg/kg bw/d
AELlong-term	Rat: reproductive 2-generation study#	0.001 mg/kg bw/d	300	None	3.3E-06 mg/kg bw/d
SoC potassium sorbate AELlong-term	Dog: 90-day toxicity study with sorbic acid$	1000 mg/kg bw/d	100	None	10 mg/kg bw/d equivalent to 13.4 mg/kg bw/d Potassium sorbate

[1] From Italian AR, 2010, (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects)
Assessment Report: Italy, December 2010, PT14 Assessment Report for Brodifacoum
$ Assessment report: Germany, Februart 2025, PT08 Assessment report for Potassium sorbate

Maximum residue limits or equivalent

Residue limits are not required for Brodifacoum 25 ppm Blocks - Professional Use.

Risk for industrial users

25 ppm Brodifacoum Blocks – Professional use is a professional use product only and therefore there will be no industrial users.

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)
Scenario 1 – Securing Block Baits in Bait Stations (HEEG Opinion 12, 20 g blocks)	1	0.001	3.3E-06	2.78E-06	84.2	Yes
	1 SoC	1000 (sorbic acid)	13.4 Potassium sorbate	SoC 1.39E-01	1.04[a]	Yes
Scenario 2 – Clean Up and Disposal of Block Baits (HEEG Opinion 12)	1	0.001	3.3E-06	7.13E-08	2.2	Yes
	1 SoC	1000 (sorbic acid)	13.4 Potassium sorbate	SoC 3.56E-03	0.02[a]	Yes

[a] According to EFSA dermal absorption guidance (2017), dermal absorption value of 70% should have been applied, instead of 25%. With the dermal absorption of 70% the maximal exposure of a professional user will

increase from 1.06% AEL to 2.97%AEL per day. As the conclusion for the acceptable risk will not change, the risk assessment performed on the SoC using dermal absorption of 25% is not further revised.

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)
Scenarios 1 & 2 20 g block	1	0.001	3.3E-06	2.85E-06	86.4	Yes
	1	1000 (sorbic acid)	13.4 Potassium sorbate	SoC 1.43E-01	1.06[a]	Yes

[a] According to EFSA dermal absorption guidance (2017), dermal absorption value of 70% should have been applied, instead of 25%. With the dermal absorption of 70% the maximal exposure of a professional user will increase from 1.06% AEL to 2.97%AEL per day. As the conclusion for the acceptable risk will not change, the risk assessment performed on the SoC using dermal absorption of 25% is not further revised.

Local effects

Based on the hazard classification, local effects are not expected for this product.

Conclusion

Based on the modelled exposure data, normal use of 25 ppm Brodifacoum Blocks (containing 0.0025% w/w Brodifacoum) in accordance with label instructions will not result in significant operator exposure to professional users and gives no cause for concern.

Risk for non-professional users

Not relevant as Brodifacoum 25 ppm Blocks – Professional Use is for professional use only.

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)
3.	1[1]	0.001	3.3E-06	1.56E-02	473485	No
		1000 (sorbic acid)	13.4 Potassium sorbate	SoC 6.25	47	Yes
	2[2]	0.001	3.3E-06	3.13E-05	947	No
		1000 (sorbic acid)	13.4 Potassium sorbate	SoC 1.25E-02	<1	Yes

1 Bait with no aversive agent
2 Bait containing a bittering agent

Combined scenarios
Combined scenarios for secondary exposure to the general public are not applicable for Brodifacoum 25 ppm Blocks – Professional Use.

Local effects
Based on the hazard classification, local effects are not expected for Brodifacoum 25 ppm Blocks – Professional Use.

Conclusion
The indirect risk to infantfrom ingesting bait does present a significant concern. Therefore, the following appropriate risk mitigation measures should be implemented:

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or openedWhere possible, bait stations must be fixed to the ground or other structures.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Remove all bait after treatment and dispose of in accordance with local requirements.

Risk for consumers via residues in food

Risk for consumers via residues in food is not applicable for this product which will not come into contact with food when used according to label instructions. The following sentences are included in RMM:

- Bait should not be placed where food, feedingstuffs or drinking water could be contaminated.
- - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

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

Not applicable for this product.

2.2.7 Risk assessment for animal health

Read-across to the Solo Blox 50 ppm product PAR containing Brodifacoum (PT14) UK, July 2018, notes the following for this section

> Neither new data were provided, nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

In addition to mitigate the risk to animal health, all anticoagulant rodenticides are required to be labelled with precautionary phrases that include:

- Where possible, bait stations must be fixed to the ground or other structures.
- 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
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals (e.g. at least twice a week)
- Remove the remaining product at the end of treatment period
- Hazardous to wildlife
- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements
- Dispose dead rodents in accordance with local requirements.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

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

There are no substances of concern with respect to the environment at the concentrations present in Brodifacoum 25 ppm Blocks – Professional Use. Therefore, the ecotoxicological properties of Brodifacoum 25 ppm Blocks – Professional Use may be read-across to the active substance dossier for Brodifacoum by means of a letter of access.

Only one component of the formulation (Brodifacoum) is classified (H400 and H410 with an M factor of 10 for acute and chronic hazard according to ATP 09 of the harmonised classification - Annex VI of Regulation (EC) No 1272/2008), however as the concentration present in the Brodifacoum Blocks (0.0025% w/w) is less than 0.1% w/w divided by the M-factor the product does not require to be classified according to CLP Regulation 1272/2008.

Predicted No Effect Concentrations (PNECs)

Extracted from Brodifacoum Assessment Report (AR; PT 14) RMS Italy, December, 2010

PNEC	Value
$PNEC_{microorganisms}$	0.0038 mg/L
$PNEC_{aquatic}$	4.0E-05 mg/L
$PNEC_{sediment}$	4.0E-06 mg/L
$PNEC_{soil}$	0.88 mg/kg wwt
$PNEC_{oral\ bird}$	1.28E-05 mg/kg bw 1.3E-05 mg/kg diet
$PNEC_{oral\ mammal}$	1.10E-05 mg/kg bw 2.22E-04 mg/kg diet

No study to assess the toxicity to sediment-dwelling organisms was included in the AR of brodifacoum. Therefore the risk characterization for the sediment compartment is covered by the PEC/PNEC ratio for aquatic organisms increased by a factor of 10 to take into account the fact that the log Kow value is higher than 5.

Further Ecotoxicological studies

No further ecotoxicological studies are available for Brodifacoum 25 ppm Blocks – Professional Use. The product was not tested for potential endocrine disruption properties. As a result of the toxiciological screening it was identified that an ED concern has been raised by France for one co-formulant, [redacted] and they propose to include this substance on the CoRAP list.
[redacted].
This substance is also known as [redacted] and is approved as food additive (anti-oxidant) and as additive for animal feed (E 320). Regarding the current application CA NL considers that the ED assessment for this co-formulant does not need to be included in the PAR and can await the outcome of the discussions at EU level.
In conclusion, the product does not have endocrine disruption indications based on the current scientific knowledge as well as toxicological and ecotoxicological information available on the other co-formulants.

For brodifacoum no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Report (September 2016) states that brodifacoum would not be considered as having endocrine disrupting properties.

Therefore, Brodifacoum 25 ppm Blocks – Professional Use is not considered as having endocrine disrupting properties.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No new data is available.

Supervised trials to assess risks to non-target organisms under field conditions
No new data is available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No new data is available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
No new data is available.

Foreseeable routes of entry into the environment on the basis of the use envisaged

From studies conducted using the active substance and described in the Brodifacoum AR, RMS Italy (December 2010), the following environmental characteristics were established:-

- The active substance is not readily or inherently biodegradable.
- Brodifacoum is hydrolytically stable to hydrolysis (DT50 >1 year) and is rapidly degraded by photolysis in water.
- Brodifacoum is persistent (DT50 157 days at 20°C; 298 days at 12°C) and immobile in soil (average Koc 9155 L/kg).

Aquatic Compartment
Contamination of surface water and sediment following the placement of block baits in and around buildings is very unlikely, as stated in the Emission Scenario Document (Larsen, 2003). The scope for exposure to aquatic biota is therefore negligible and no further assessment is considered necessary. Contamination of surface water and sediment is however considered to occur from use in sewers and the derived PEC values are presented in this section.

Atmosphere
Brodifacoum has a very low vapour pressure (2.6E-22 Pa) and Henry's Law Constant (2.35E-18 $Pa.m^3.mol^{-1}$). In addition as brodifacoum is only used locally, release to the air via water is therefore expected to be negligible. This is also supported by calculations using the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (2017) for percent release to air from a sewage treatment plant where a default of 0 is given (i.e., no release to air). The manufacture of the active substance is in a closed system. There are no releases to air of Brodifacoum from manufacturing, formulating, use or disposal phases.

Terrestrial Compartment
Exposure to the terrestrial compartment from the use of Brodifacoum 25 ppm blocks in and around buildings and in sewers is described in the Emission Scenario Document (Larsen, 2003). The main exposure of the environment is expected to be soil contaminated

by spills during application, refilling and disposal operations, however contributions from disperse release of rodenticide *via* urine and faeces should also be considered.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT14
Assessed scenarios	Scenario 1: Sewer System Scenario 2: In and around buildings
ESD(s) used	Emission Scenario Document for Product Type 14: Emission scenario document for biocides used as rodenticides, Larsen, J., June 2003
Approach	Scenario 1: Average professional use Scenario 2: Average professional use
Distribution in the environment	Refer to active substance dossier, Brodifacoum Assessment Report (PT14) RMS Italy, December 2010. Calculated based on Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017 and SimpleTreat 3.1.
Groundwater simulation	PEARL 4.4.4 was used for tier 2 modelling.
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1 & 2 Production: No Formulation No Use: Yes Service life: Yes
Remarks	-

Emission estimation

Scenario 1: Sewer System
Brodifacoum 25 ppm Blocks can be used in sewer systems. The blocks are placed at sites to reduce the likelihood of removal by rodents or by surges of water. Baits are secured by wire or attached to available structures.

Information on best practice presented in the Emission Scenario Document (ESD) PT14, indicates that during a control operation of 21 days the application into the cesspool/manhole may take place two to three times depending upon the level of rodent infestation e.g. on day 1, 7 and 14. On day 1, one large wax block is applied to each cesspool. On revisiting the wells on day seven another large wax block is applied, if the wax block has been eaten. If the wax blocks are also eaten at next visit on day 14, further new wax blocks are applied. As a realistic worst case it is assumed that 300 wax blocks are applied to 300 cesspools on day one in an area corresponding to 10000 person equivalents (PE). At the revisit on day seven 100 large wax blocks are eaten and are therefore replaced. At the revisit on day 14 only 50 blocks have been eaten and are replaced and at the revisit on day 21 no blocks have been eaten.
Based on this information, a realistic worst case scenario would be that 1 large bait block (200 g) is applied to 300 cesspools on one day in an area corresponding to 10000 person equivalents (PE) and that 100 large wax blocks (in total weighing 20 kg) are consumed in the first 7 days of the control operation (Q prod = weight of block x N app).

A refined worst case scenario takes into account the measured metabolism; however as the measured metabolism of Brodifacoum is limited no further refinement will be made to the model (AR, Italy 2010, page 25).

The concentration in sewage water is calculated by dividing the $Elocal_{water}$ by 2000000 L/day, which is the daily amount of sewage water emitted to a local STP (kg/L) in a city with 10000 PE.
Elimination processes in the sewage treatment plant (STP) are calculated using SimpleTreat 3.1. Due to Brodifacoum's low vapour pressure and Henry's Law Constant, and the fact that Brodifacoum is not readily biodegradable, the only significant elimination process is partitioning into suspended matter. SimpleTreat 3.1 calculations predict the following distribution to relevant compartments: water 42.5%, sludge 57.5% and air 1.11E-15%.
Potential exposure to surface water, soil and groundwater following the spread of slurry from a sewage treatment plant have been determined.

Input parameters for calculating the local emission		
Symbol	**Variable/parameters**	**Worst Case Scenario**
	Input	
Q_{prod}:	amount of product used in control operation after one week (kg)	20
$Fc_{product}$:	fraction of active substance in product	2.5E-05
Temission:	number of emission days (realistic worst case during the control operation)	7
$F_{metabolised}$:	fraction of active ingredient metabolised	-
$F_{released}$:	fraction of product released	0.900

Calculations for Scenario 1

Resulting local emission to relevant environmental compartments		
Output		
Symbol	**Variable/parameters**	**Worst Case Scenario**
$Elocal_{water}$	mean local emission of active substance to waste water during episode (kg/d)	6.4E-05
Cinfl (default STP)	concentration in sewage water to default STP (mg/L)	3.2E-05

Scenario 2: In and around buildings
Brodifacoum 25 ppm Blocks are used in and around buildings. For indoor placement, bait stations should be used to contain the bait, but covered bait points (not relevant to the Netherlands) such as trays or other containers can be used in constricted areas such as under appliances or cupboards. Outdoor placements should utilise bait stations. Where appropriate, the baits are secured at the placement site to reduce the likelihood of removal by rodents.
Two to 10 small or 1 large Brodifacoum Blocks are typically placed at intervals of 5 to 10 metres per placement for the control of rats. For house mice, up to 6 blocks are typically placed at intervals of 2 to 4 metres per placement, where mice or their signs have been observed.

A refined worst case or typical scenario normally takes into account the measured metabolism; however as the measured metabolism of Brodifacoum is limited no further refinements based on metabolism will be made to the model (AR, Italy 2010, page 25). There is a large variation of the duration of a rodenticide campaign and a 21 days period represents a realistic worst case.

Two scenarios have been considered and are presented below:

1. Worst Case

According to the emission scenario document ESD (Larsen, 2003), the worst case is that 10 bait points (containing 10 bait blocks x 20 g or 1 block x 200 g) 5 m apart are used and refilled 5 times per campaign and all of the bait is eaten during the period of the campaign. Exposure to the terrestrial environment is, according to ESD (Larsen. 2003), *via* direct release during application and indirect release through urine and faeces after ingestion of bait. The worst case scenario based on the ESD (Larsen 2003) assumes that 10% is metabolised.

2. "Typical" (Normal)

In a typical campaign (normal use), bait would be applied on day 1, replenished 100% on day 3, on day 7 there would be 25-50% replenishment, on day 14, 10%, on day 21 0%. This equals roughly the equivalent of 1.5 x 100% replenishments.
The typical scenario based on the ESD (Larsen 2003) assumes that 10% is metabolised.

Input parameters for calculating the local emission			
Symbol	**Variable/parameters**	**Worst Case Scenario**	**"Typical" Scenario**
Input			
Q_{prod}	amount of product used in control operation for each bait box (g)	200	200
$Fc_{product}$	fraction of active substance in	2.5E-05	2.5E-05

Input parameters for calculating the local emission			
Symbol	**Variable/parameters**	**Worst Case Scenario**	**"Typical" Scenario**
	product		
Nsites	number of application sites	10	10
N_{refil}	number of refilling times	5	1.5
$F_{release-D, soil}$	fraction of product released directly to soil	0.01	0.01
$F_{release-ID, soil}$	fraction released indirectly to soil	0.90	0.90
$F_{metabolised}$	fraction of active ingredient metabolised	-	-
$AREA_{exposed}$	area directly exposed to rodenticide originating from bait box (m^2)	0.09	0.09
$DEPTH_{soil}$	depth of exposed soil (m)	0.1	0.1
RHO_{soil}	density of exposed soil (kg/m^3)	1700	1700
$AREA_{exposed-ID}$	area indirectly exposed to rodenticide (m^2)	550	550

Calculations for Scenario 2

Resulting local emission to relevant environmental compartments			
Output			
Symbol	**Variable/parameters**	**Worst Case Scenario**	**"Typical" Scenario**
$Elocal_{soil-campaign, direct}$	direct emission to soil from a campaign (g/camp)	2.5E-03	7.5E-04

Fate and distribution in exposed environmental compartments

	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**
Scenario 1: Sewer System	Yes	Yes	No	No	Yes	No	Yes	Yes
Scenario 2: In and around buildings	No	No	No	No	No	No	Yes	Yes

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	232	°C	
Vapour pressure (at 20°C)	2.6E-22	Pa	
Water solubility (at 20°C)	5.8E-05	mg/L	
Log Octanol/water partition coefficient	4.92	Log 10	at pH7 and 20°C
Organic carbon/water partition coefficient (Koc)	9155	L/kg	
Henry's Law Constant	2.18E-03	$Pa/m^3/mol$	At pH 7
Biodegradability	Not readily biodegradable		
Rate constant for biodegradation in bulk soil DT_{50}	298	days	At 12°C

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario 2	
Air	1.32E-15	N/A	Calculated with SimpleTreat 3.1
Water	48.9	N/A	
Sludge	51.1	N/A	
Degraded in STP	-	N/A	

N/A not applicable

Calculated PEC values

Summary table on calculated PEC values – Scenario 1 Sewers						
	PEC_{STP}	**$PEC_{surfacewater}$**	**PEC_{sed}**	**$PEC_{soil,initial}$***	**$PEC_{soil,slurry}$**	**$PEC_{porewater}$**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[mg/ kg_{wwt}]	[µg/L]
Worst case	1.57E-05	1.55E-06	3.1E-04	1.07E-04	6.20E-05	6.37E-04

Summary table on calculated PEC values – Scenario 2 In and around buildings		
PEC_{soil} [mg/kg_{wwt}]		
	Worst Case Scenario	**"Typical" Scenario**
Local concentration in soil due to direct release after a campaign	1.63E-02	4.90E-3
Concentration in soil due to indirect (disperse) release after a campaign	2.38E-03	7.15E-04

Total concentration in soil around the bait box taking into account both direct and disperse releases	1.87E-02	5.62E-03
$PEC_{porewater}$ [µg/L]		
	Worst Case Scenario Tier II Assessment	**"Typical" Scenario Tier I Assessment**
Local concentration in porewater due to direct release after a campaign	< 0.1	0.03
Concentration in porewater due to indirect (disperse) release after a campaign	< 0.1	0.004
Total concentration in porewater around the bait box taking into account both direct and disperse releases	< 0.1	0.034

* Concentration in top soils after ten successive sludge applications – initial concentration

Primary and secondary poisoning

Qualitative Risk Assessment

It was decided by Member States, as outlined in the document entitled, "$PNEC_{oral}$ derivation for the primary and secondary poisoning assessment of anti-coagulant rodenticides, Addendum relevant to Biocides to the TGD on Risk Assessment (Endorsed at the 23rd CA meeting Nov. 2006)", that a qualitative description of the toxicity of the substance compared to the possible single uptake (acute scenario) should be given instead of performing a quantitative risk assessment. In the following sections, qualitative assessments have been performed for the following uses, as outlined in the guidance document.

Object of a qualitative risk assessment should be:

- Primary poisoning:
  - Tier 1 for 1 day exposure with and without excretion, where the PEC_{oral} is the expected concentration of the active substance in the non-target animal after 1 day exposure (single meal) [mg/kg bw]. A default excretion factor of 0.3 (for birds and mammals) should be used in case no data is available.
- Secondary poisoning:
  - Tier 1, where the PEC_{oral} is the concentration in the rodent immediately after a last meal on day 5 [mg/kg food]. For a short-term exposure PD is 1 (rodents have fed entirely on rodenticide) and F_{rodent} = 1 (non-target animals consume 100 % of their daily intake on poisoned rodents). For comparison, calculations with PD = 0.5 and PD = 0.2 could also be included.

Primary Poisoning Acute – Tier 1 (Steps 1 & 2)

The primary poisoning acute Tier 1 assessment includes two scenarios; Step 1 and Step 2.

In Step 1, which is a worst case scenario, birds are assumed to consume only bait during one day and mammals are expected to eat 600 g of bait (AV, PT and PD are all set to 1). The expected concentration of active substance (EC) in the animal is calculated (as shown in the ESD (Larsen, 2003)), with and without excretion (metabolism of Brodifacoum is not considered to be significant and therefore has not been included in the calculations) by the following equation:
EC = ETE x (1-EI)

The estimated daily uptake of a compound (ETE) is given by the following equation:
ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day)
Where FIR is the food intake rate of the indicator species, BW is the indicator species body weight, C is the concentration of the active substance in fresh diet, AV is the avoidance factor, PT is the fraction of diet obtained in treated area and PD is the fraction of the food type in the diet.

In Step 2, which is a refined scenario, the fraction of the diet from the treated area (PT) is set to 0.9 and the avoidance (AV) of mammals is set to 0.8. The fraction of the food type in the diet (PD) is set to 1.

Primary Poisoning – Acute, Tier 1 - Estimated Daily Uptake for Non-Target Mammals and Birds Ingesting Product Containing Brodifacoum

Species	Body Weight (g) BW	Daily Mean Food Intake (g) FIR	Rodenticide Consumption (g)	Concentration of Brodifacoum after a single meal (one day) (mg/kg) ETE	
				Step 1	Step 2
				EI = 0	EI= 0
Dog	10000	600	600	1.50	1.08
Pig	80000	600	600	0.19	0.14
Young Pig	25000	600	600	0.60	0.43
Tree Sparrow	22	7.6	7.6	8.64	6.22
Chaffinch	21.4	6.42	6.42	7.50	5.40
Wood Pigeon	490	53.1	53.1	2.71	1.95
Pheasant	953	102.7	102.7	2.69	1.94

EI= Excretion Factor

Secondary Poisoning – Acute – Tier 1
A Tier 1 qualitative acute assessment has been made where the PEC_{oral} is the concentration in the rodent immediately after the last meal on day 5 [mg/kg food]. PD is 1 (rodents have fed entirely on rodenticide) and F_{rodent} = 1 (non-target animals consume 100% of their daily intake on poisoned rodents) as a realistic worst case. For comparison calculations with PD = 0.5 and PD = 0.2 have also be included (intermediate and normal case, respectively).

Secondary Poisoning, Acute, Tier 1 - PEC_{oral} Predator

Parameter	Realistic worst case (100%)	Intermediate (50%)	Normal case (20%)
Concentration of product in fresh diet	25	25	25

((C); mg/kg)			
Avoidance factor (1 = no avoidance; 0 = complete avoidance) (AV)	1	1	1
Fraction of diet obtained in treated area (PT)	1	1	1
Fraction of food type (treated bait) in diet (PD)	1	0.5	0.2
Fraction of daily uptake eliminated (EI)	0	0	0
Fraction of poisoned rodents in predator's diet (F_{rodent} acute = 1)	1	1	1
Days the rodent is feeding on rodenticide until caught by predator (N)	5	5	5
Estimated daily uptake of a compound in the rodent (mg/kg bw)	2.50	1.25	0.50
Normal non-resistant rodent which stops eating on day 5 estimated concentration	**12.50**	**6.25**	**2.50**

Quantitative Risk Assessment

The document entitled, "$PNEC_{oral}$ derivation for the primary and secondary poisoning assessment of anti-coagulant rodenticides, Addendum relevant to Biocides to the TGD on Risk Assessment (Endorsed at the 23rd CA meeting Nov. 2006)" defines the objective of a quantitative risk assessment as follows:-

Object of a quantitative risk assessment should be:

- Primary poisoning:
  - Tier 1 where the PEC_{oral} is the concentration of the active substance in the food (bait) [mg/kg food]
  - Tier 2 for 5 days exposure, considering excretion, where the PEC_{oral} is the expected concentration of the active substance in the non-target animal after 5 days exposure [mg/kg bw]. A default excretion factor of 0.3 (for birds and mammals) should be used in case no data are available. As a worst case, the parameter AV, PT and PD are all 1.
- Secondary poisoning:
  - Tier 1 for a long-term exposure. The PEC_{oral} is the concentration in the rodent immediately after a last meal on day 5 [mg/kg food]; PD = 1 and F_{rodent} = 0.5 (non-target animals consume 50 % of their daily intake on poisoned rodents). For comparison, calculations with PD = 0.5 and PD =0.2 could also be included.
  - Tier 2 for a long-term exposure. The PEC_{oral} is the concentration in non-target animals after a single day of exposure [mg/kg bw]; PD = 1 and F_{rodent} = 0.5.

Primary Poisoning – Tier 1

The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the bait. The worst case Step 1 **PEC_{oral} is therefore 25 mg/kg food** (Brodifacoum present at 0.0025% w/w).

Primary Poisoning – Long-term, Tier 2

Long term primary poisoning has been calculated based on a mammal or bird eating the bait for 5 consecutive days. As indicated elsewhere, excretion (metabolism of Brodifacoum is not considered to be significant) has not been included in the calculations.

The worst case scenario exists if AV, PT and PD are all set to 1 (step 1).

Primary Poisoning - Long-term, Tier 2, Step 1 - PEC_{oral} for Non-Target Mammals and Birds Accidentally Exposed to Brodifacoum for 5 consecutive days In and Around Buildings

	Dog	Pig	Young Pig	Tree Sparrow	Chaffinch	Wood Pigeon	Pheasant
ETE	1.50	0.19	0.60	8.64	7.50	2.71	2.69
EC2	1.50	0.19	0.60	8.64	7.50	2.71	2.69
EC3	3.00	0.38	1.20	17.27	15.00	5.42	5.39
EC4	4.50	0.56	1.80	25.91	22.50	8.13	8.08
EC5	6.00	0.75	2.40	34.55	30.00	10.84	10.78
EC6	7.50	0.94	3.00	43.18	37.50	13.55	13.47

For a more realistic worst case AV = 0.9, PT = 0.8 and PD = 1 (step 2).

Primary Poisoning – Long-term, Tier 2, Step 2 - PEC_{oral} for Non-Target Mammals and Birds Accidentally Exposed to Brodifacoum for 5 consecutive days In and Around Buildings

	Dog	Pig	Young Pig	Tree Sparrow	Chaffinch	Wood Pigeon	Pheasant
ETE	1.08	0.14	0.43	6.22	5.40	1.95	1.94
EC2	1.08	0.14	0.43	6.22	5.40	1.95	1.94
EC3	2.16	0.27	0.86	12.44	10.80	3.90	3.88
EC4	3.24	0.41	1.30	18.65	16.20	5.85	5.82
EC5	4.32	0.54	1.73	24.87	21.60	7.80	7.76
EC6	5.40	0.68	2.16	31.09	27.00	9.75	9.70

Secondary poisoning Long-term, Tier 1

Secondary Poisoning, Long-term, Tier 1 - PEC_{oral} Predator

Parameter	Realistic worst case (100%)	Intermediate (50%)	Normal case (20%)
Concentration of product in fresh diet ((C); mg/kg)	25	25	25
Avoidance factor (1 = no avoid, 0 = complete avoid.) (AV)	1	1	1
Fraction of diet obtained in treated area (PT)	1	1	1
Fraction of food type (treated bait) in diet (PD)	1	0.5	0.2
Fraction of daily uptake eliminated (EI)	0	0	0
Fraction of poisoned rodents in predator's diet (chronic = 0.5)	0.5	0.5	0.5
Days the rodent is feeding on rodenticide until caught by predator (N)	5	5	5
Predicted environmental concentration of a.i. in food of predator on day N ('chronic')	7.50	3.75	1.50

Secondary Poisoning – Long-term, Tier 2

Concentrations resulting from a single day exposure assuming that predators feed 50% on poisoned rodents fed on rodenticide 5, 7 or 14 days with PD (fraction of food) 1, 0.5 and 0.2 are shown below.

Secondary Poisoning – Long-term, Tier 2 - Concentrations Resulting After a Single Day Exposure Assuming Predators Feed 50% on Poisoned Rodents Fed on Brodifacoum Bait

Non-Target Animals	Concentration in Non-Target Animal (mg/kg bw Predator)		
	Rodent caught on day 5 after feeding	Rodent caught on day 7 after feeding	Rodent caught on day 14 after feeding
Barn owl *(Tyto alba)*	1.24	1.55	4.34
Kestrel *(Falco tinnunculus)*	1.88	2.35	6.59
Little owl *(Athene noctua)*	1.41	1.77	4.95
Tawny owl *(Strix aluco)*	1.14	1.42	3.99
Fox *(Vulpes vulpes)*	0.46	0.57	1.60
Polecat *(Mustela putorius)*	0.95	1.19	3.32
Stoat *(Mustela erminea)*	1.36	1.70	4.75
Weasel *(Mustela nivalis)*	1.96	2.45	6.86
Dog *(Canis familiaris)*	0.23	0.29	0.80

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Brodifacoum can be considered to be non-volatile on the basis of its vapour pressure and Henry's law constant. Atmospheric exposure is therefore insignificant and there are no other constituents of the bait that are of concern to the atmosphere.

Sewage treatment plant (STP) / Aquatic compartment

The PECs (Predicted Environmental Concentrations) have been derived using the Emission Scenario Document (ESD) (Larsen, 2003) and the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (2017) as described in the section on emission estimation.

Contamination of surface water and sediment following the placement of block baits in and around buildings is very unlikely, as stated in the ESD (Larsen, 2003). The scope for exposure to aquatic biota is therefore negligible and no further assessment is considered necessary. Contamination of surface water and sediment is, however, considered to occur from use in sewers. As stated in the AR (Italy, Dec 2010, page 66) "due to the lack of measured data for both PEC and $PNEC_{sediment}$, the risk characterization for sediments is performed on the basis of the PEC/PNEC ratio derived for the aquatic compartment. According to the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (2017), the ratio is increased by a factor of 10, so as to take into account any

possible exposure via contaminants ingestion with a log Kow > 5, expected to be strongly adsorbed to sediments.

Scenarios for which the PEC/PNEC value is <1.0 are considered to pose no unacceptable risk to the aquatic environment. The PEC/PNEC ratios determined for Brodifacoum in the aquatic compartment are set out below.

Summary table on calculated PEC/PNEC values	
	PEC/PNEC
Sewer: Surface water during emission from STP	0.039
Sewer: sediment during emission from STP	0.39*
Sewage treatment plant	0.004

* Ratio derived for aquatic compartment multiplied by 10

Conclusion: The risk characterization ratios determined for worst-case scenarios in which Brodifacoum may enter the aqueous environment (including STPs and sediment) as a result of the use of Brodifacoum Blocks indicate that there is no cause for concern (i.e. all PEC/PNEC ratios were < 1.0).

In conclusion, it is considered that there is no cause for concern following the exposure to the aquatic compartment from the use of Brodifacoum 25 ppm Blocks – Professional Use.

Terrestrial compartment

PECs in soil were derived using the ESD ([redacted], 2003) and the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (2017). Active substance use is estimated to be so low that the regional contribution is negligible and thus the estimated local concentration ($Cloca1_{soil}$) equals the PEC_{local} ($Clocal_{soil}$ = $PEClocal_{soil}$).

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1 - Sewer: Local concentration in soil after a campaign ; Worst case	< 0.001*
Scenario 2 - Around Buildings: Local concentration in soil after a campaign; Worst case	2.13E-02
Scenario 2 - Around Buildings: Local concentration in soil after a campaign; 'Typical' Scenario	6.39E-03

* Concentration in top soils after ten successive sludge applications – initial concentration

Conclusion: The risk characterisation ratios determined for worst-case scenarios in which Brodifacoum may enter the terrestrial environment as a result of the use of Brodifacoum Blocks indicate that there is no cause for concern (i.e. all PEC/PNEC ratios were < 1.0).
In conclusion, it is considered that there is no cause for concern following exposure of the terrestrial compartment to Brodifacoum 25 ppm Blocks.

Ground water

As required by Article 31 (3) of the BPR and Article 2(1) (f) of Regulation 492/2014 the following assessment is provided to address potential risks to groundwater arising from the use of AVK rodenticides. As none of the fate and behaviour endpoints for brodifacoum have changed following the review process, only the risk to groundwater has been considered.

The assessment takes the form of a tiered approach, with an initial tier 1 approach taken from the ECHA guidance on environmental risk assessment, Volume IV, part B using the following equation;

$PEClocalsoil_{porewater} = PEClocal_{soil} \times RHO_{soil} / (K_{soil\text{-}water} \times 1000)$

The resulting $PEC_{porewater}$ for scenario 1 (application in sewers) was acceptable as <0.1 µg/L; however was >0.1 µg/L for scenario 2 (application in and around buildings) therefore a refinement of tier 1 estimates using FOCUS PEARL 4.4.4. and relevant Product Type specific guidance according to Guidance on the Biocidal Product Regulation Volume IV: Environment - Part B+C (2017) was performed resulting in groundwater concentrations of < 0.1 µg/L for all nine FOCUS scenarios.

$PEC_{porewater/groundwater}$ [µg/L]			
Worst Case Scenario Tier I Assessment application in sewers	**Application in and around buildings**	**Worst Case Scenario Tier II Assessment***	**"Typical" Scenario Tier I Assessment**
6.37E-04	Local concentration in porewater due to direct release after a campaign	< 0.1	0.03
	Concentration in porewater due to indirect (disperse) release after a campaign	< 0.1	0.004
	Total concentration in porewater around the bait box taking into account both direct and disperse releases	< 0.1	0.034

Conclusion:
As porewater and groundwater concentrations < 0.1 µg/L have been calculated for use in sewers and in and around buildings the risk to groundwater from these scenarios can be considered acceptable.

Primary and secondary poisoning

It was decided by Member States, as outlined in the document entitled, "$PNEC_{oral}$ derivation for the primary and secondary poisoning assessment of anti-coagulant rodenticides, Addendum relevant to Biocides to the TGD on Risk Assessment (Endorsed at the 23rd CA meeting Nov. 2006)", that a qualitative description of the toxicity of the substance compared to the possible single uptake should be given instead of performing a quantitative risk assessment. Therefore in the following sections the risk assessments for

both primary and secondary poisoning –acute will be based on the qualitative estimations whilst the primary and secondary - long term assessments are based on the quantitative assessments.

Primary poisoning - Qualitative Risk Assessment

Qualitative Risk Characterisation Primary Poisoning – Acute, Tier 1, Step 2

Species	Concentration of Brodifacoum after a single meal (one day) (mg/kg) ETE, Step 2	LD50 dose (mg/kg bw)	PEC_{oral} Higher Than LD_{50} (Y/N)
Dog	1.08	0.4	y
Pig	0.14	0.4	N
Young Pig	0.43	0.4	Y
Tree Sparrow	6.22	0.31	y
Chaffinch	5.40	0.31	Y
Wood Pigeon	1.95	0.31	Y
Pheasant	1.94	0.31	Y

Primary poisoning - Quantitative Risk Assessment

Primary Poisoning – Long-term - Tier 2 Step 2

Species	PEC = EC (concentration of Brodifacoum after one day of elimination)	PNEC dose (mg/kg bw)	PEC/PNEC
Dog	1.08	1.10E-05	98182
Pig	0.14	1.10E-05	12727
Young Pig	0.43	1.10E-05	39091
Tree Sparrow	6.22	1.28E-05	485938
Chaffinch	5.40	1.28E-05	421875
Wood Pigeon	1.95	1.28E-05	152344
Pheasant	1.94	1.28E-05	151563

Conclusion for primary poisoning

It can be concluded that the qualitative and quantitative risk assessment indicates a concern from both acute and long-term consumption of Brodifacoum bait. If used in accordance with the label, primary poisoning incidents involving Brodifacoum 25 ppm Blocks should be rare. However, when baits are located around buildings, there is a potential for similar sized birds and mammals to access the baits. From the calculated results it can be seen that the effects from ingestion would be both lethal and sub-lethal. Therefore, risk mitigation measures are required. In NL this means a restriction to the use by (trained) professionals as part of Integrated Pest Management (IPM) principles. For further measures to protect animals and the environment we refer to the SPC which shall be duly taken into consideration for a clear labelling of the product. For other member states different mitigation measures may apply.

To reduce the risk of this occurring it is recommended that suitable bait containers such as tamper-resistant bait boxes are used.

Any remaining baits must be disposed of safely after a campaign has finished. Dead rodents should be disposed of in a similar manner, and care must be taken when handling carcasses. Rodenticide baits should be kept safely locked away.

Secondary poisoning - Qualitative Risk Assessment

Qualitative Risk Characterisation, Secondary Poisoning, Acute, Tier 1

Non-target Animal	PD (%)	PEC (Conc. in food) mg/kg	PNEC (conc in food) mg/kg diet	PEC/PNEC
Birds	20	2.5	1.30E-05	192308
	50	6.25	1.30E-05	480769
	100	12.5	1.30E-05	961538
Mammals	20	2.5	2.22E-04	11261
	50	6.25	2.22E-04	28153
	100	12.5	2.22E-04	56306

Secondary poisoning - Quantitative Risk Assessment - long term

Quantitative Risk Characterisation; Secondary Poisoning, Long term, Tier 2

Non-Target Animals	Concentration in Non-Target Animal (mg/kg bw Predator)			PNEC	PEC/PNEC		
	Rodent caught on day 5 after feeding	Rodent caught on day 7 after feeding	Rodent caught on day 14 after feeding		Rodent caught on day 5 after feeding	Rodent caught on day 7 after feeding	Rodent caught on day 14 after feeding
Barn owl *(Tyto alba)*	1.24	1.55	4.34	1.28E-05	96875	121094	339063
Kestrel *(Falco tinnunculus)*	1.88	2.35	6.59	1.28E-05	146875	183594	514844
Little owl *(Athene noctua)*	1.41	1.77	4.95	1.28E-05	110156	138281	386719
Tawny owl *(Strix aluco)*	1.14	1.42	3.99	1.28E-05	89063	110938	311719
Fox *(Vulpes vulpes)*	0.46	0.57	1.60	1.10E-05	41818	51818	145455
Polecat *(Mustela putorius)*	0.95	1.19	3.32	1.10E-05	86364	108182	301818
Stoat *(Mustela erminea)*	1.36	1.70	4.75	1.10E-05	123636	154545	431818
Weasel *(Mustela nivalis)*	1.96	2.45	6.86	1.10E-05	178182	222727	623636

Non-Target Animals	Concentration in Non-Target Animal (mg/kg bw Predator)			PNEC	PEC/PNEC		
	Rodent caught on day 5 after feeding	Rodent caught on day 7 after feeding	Rodent caught on day 14 after feeding		Rodent caught on day 5 after feeding	Rodent caught on day 7 after feeding	Rodent caught on day 14 after feeding
Dog *(Canis familiaris)*	0.23	0.29	0.80	1.10E-05	20909	26354	72727

Conclusion for secondary poisoning
It can be concluded that the qualitative and quantitative risk assessment indicates a concern from both acute and long-term consumption of Brodifacoum bait.

Overall Conclusion: The conclusion of the qualitative and quantitative risk assessments is that there are, in many cases unacceptable risks to non-target vertebrates *via* primary and secondary poisoning. Therefore, it would seem more appropriate to develop and validate risk management procedures than to refine the risk assessment procedures.

Detailed below are measures that are currently employed.

- Incorporation of 10 mg denatonium benzoate per kg, a bittering agent, into blocks will deter humans from consuming the bait and may also deter non-target animals.
- Bait placement is a key step in reducing accidental exposure. Careful application using covered bait points (not allowed in the Netherlands) or bait stations is directed. Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so they cannot be dragged away. Do not apply this product directly in the burrows.
- Formulation design is another key step in reducing accidental exposure. The use of a formulation unattractive to small birds (*e.g.* wax blocks) makes primary poisoning of birds unlikely (Cox P.R. 1990).
- Regular site inspections to check the bait points and surrounding area. The bait boxes should be inspected for damage and repaired or replaced as necessary.
- Regular removal and disposal (according to local requirements) of dead rodents thus minimising the opportunity of secondary exposure.
- Communication of the presence of a baiting campaign to all residents/workers in and around the area.
- Left over bait from a baiting campaign should be disposed of as hazardous waste, thus limiting the opportunity for exposure and reducing the primary poisoning risk to small non-target animals.
- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- 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 rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.

- Do not wash the bait stations or utensils used in covered bait (not allowed in the Netherlands) and protected bait points with water between applications.
- When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often when baits are checked and/or replenished. Dispose of dead rodents in accordance with local requirements.

Provided that baits are deployed in accordance with the product labelling and other approved guidance on good practice, the primary poisoning risk to non-target mammals may be considered to be negligible.
The risk of secondary poisoning of the active substance to birds and small mammals are expected to be significantly reduced by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the blocks and removing dead and moribund rodents during a baiting campaign to minimise the opportunity secondary exposure. These mitigation measures are described in good practice guidance documents, in training material for pest control professionals and on the labels of the products.

Mixture toxicity

This is not applicable for Brodifacoum 25 ppm Blocks – Professional Use.

Aggregated exposure (combined for relevant emission sources)

This is not applicable for Brodifacoum 25 ppm Blocks – Professional Use.

Overall conclusion on the risk assessment for the environment of the product
The risk to the aquatic, STP and terrestrial environments from the professional use of Brodifacoum 25 ppm blocks when used according to label instructions has been shown to be of no cause for concern. There are, in many cases unacceptable risks to non-target vertebrates via primary and secondary poisoning. Therefore, it would seem more appropriate to develop and validate risk management procedures than to refine the risk assessment procedures.

2.2.9 Measures to protect man, animals and the environment

Methods and precautions concerning placing on the market	The following precautions are recommended on the MSDS:- HANDLING:- Keep product in the original container. Do not handle the product near food, animal foodstuffs or drinking water. Keep out of reach of children. Do not use near heat sources, open flame, or hot surfaces. Do not eat, drink or smoke whilst handling. Wash hands thoroughly with soap and water after handling. SPECIAL PROTECTIVE EQUIPMENT:- not required VENTILATION:- Not required SKIN PROTECTION:- Rubber gloves (for example EN374) EYE PROTECTION:- Not required
Methods and precautions concerning production, handling and use of the active substance and its formulations	HANDLING:- Keep product in the original container. Do not handle the product near food, animal foodstuffs or drinking water. Keep out of reach of children. Do not use near heat sources, open flame, or hot surfaces. Do not eat, drink or smoke whilst handling. Wash hands thoroughly with soap and water after handling. SPECIAL PROTECTIVE EQUIPMENT:- not required VENTILATION:- Not required SKIN PROTECTION:- Rubber gloves (for example EN374) EYE PROTECTION:- Not required
Methods and precautions concerning storage of the active substance and its formulations	STORAGE:- Store only in original container in a cool, dry place, inaccessible to pets and wildlife. KEEP OUT OF REACH OF CHILDREN. Keep container tightly closed when not in use.
Methods and precautions concerning transport of the active substance and its formulations	CLASSIFICATION:- Not classified as Dangerous for transport. SHIPPING NAME:- Rodenticide containing Brodifacoum.
Methods and precautions concerning fire of the active substance and its formulations	EXTIGUISHING MEDIA: Extinguish with water, foam or inert gas. MEASURES UNSUITABLE FOR SAFETY REASONS: None known PROTECTIVE EQUIPMENT: Firefighters should be equipped with protective clothing and self-contained breathing apparatus.
In case of fire, nature of reaction products, combustion gases, etc.	HAZARDOUS DECOMPOSITION PRODUCTS: High temperature decomposition or burning in air can result in the formation of toxic gases, which may include carbon monoxide and traces of bromine and hydrogen bromide.
Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	EYE CONTACT: Flush with cool water for at least 15 minutes. If irritation develops, obtain medical assistance. SKIN CONTACT: Wash with soap and water. If irritation develops, obtain medical assistance. INHALATION: Not applicable INGESTION: Call physician or emergency number immediately. Do not give anything by mouth or induce vomiting unless instructed by physician. SYMPTOMS: Ingestion of excessive quantities may cause nausea, vomiting, loss of appetite, extreme thirst, lethargy,

	diarrhoea, bleeding. ADVICE TO PHYSICIAN: If ingested, administer Vitamin K_1 intramuscularly or orally as indicated for bishydroxycoumarin overdoses. Repeat as necessary as based upon monitoring of prothrombin times.
Emergency measures to protect the environment	ENVIRONMENTAL PROTECTION: Do not allow bait to enter drains or water courses. Where there is contamination of streams, rivers or lakes contact the appropriate environment agency. 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. CLEAN UP AND DISPOSAL: Sweep up spilled material immediately. Place in properly labeled container for disposal. Dispose of all wastes in accordance with all local, regional and national regulations.
Possibility of destruction or decontamination following release in the air	In view of the very low vapour pressure of the active substance, release into the air compartment is very unlikely. There is no possibility of decontamination or destruction.
Possibility of destruction or decontamination following release in water, including drinking water	There are no decontamination procedures available. The product should be kept away from drains or water courses. Any spillages should be swept up immediately and placed in a suitable container for disposal. Disposal should be in accordance with all local, regional and national regulations.
Possibility of destruction or decontamination following release in or on soil	The contaminated soil should be placed in a suitable container for disposal. Disposal should be in accordance with all local, regional and national regulations.
Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration	After treatment is done, all bait and empty packaging should be removed and disposed of in accordance with local regulations.
Possibility of re-use or recycling	The material cannot be recycled.
Possibility of neutralisation of effects	The material cannot be neutralised.
Conditions for controlled discharge including leachate qualities on disposal	The material should not be allowed to enter drains or water courses. Contaminated packaging should not be re-used. Ponds, waterways or ditches should not be contaminated with

	chemical or used containers.
Conditions for controlled incineration	No information is provided regarding incineration.
Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	Refer to Section 2.2.5
Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances	None

2.2.10 Assessment of a combination of biocidal products

This is not relevant for Brodifacoum 25 ppm Blocks – Professional Use, as it is not intended to be used in a combination with other biocidal products.

2.2.11 Comparative assessment

The NL CA for biocides has processed an application for the biocidal product Brodifacoum 25 ppm Blocks which contains the active substance Brodifacoum. The active substance brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR.
Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Brodifacoum 25 ppm Blocks has to be conducted.

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

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

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the NL CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

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

The opinion also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which may provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.
Therefore, the authorisation is granted for the product Brodifacoum 25 ppm Blocks for 5 years.

3 ANNEXES[21]

3.1 List of studies for the biocidal product

Type		Section information		Annex II/III requirement		UUID	
Biocidal product		**Section No.** 3.1 **Section Name:** Appearance (at 20°C and 101.3 kPa) **Name given to the Document:** Appearance (at 20°C and 101.3 kPa).001		Appearance (at 20°C and 101.3 kPa)		IUC5-2d177be3-2f83-4b4b-8e80-7fb0cc031417 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-2d177be3-2f83-4b4b-8e80-7fb0cc031417&snapshot=0]*	
Reference type: study report	Title: Product Properties of Brodifacoum Blocks	Author: Thomas, C.D.	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: Bell Laboratories Inc. 1901 Wright Street Madison, WI 53704	Report no. BEL/0616/C485	Company owner: Bell Laboratories, Inc Study number: No company study number provided	Report date: Jun 13, 2016
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.3 **Section Name:** Relative density (liquids) and bulk, tap density (solids) **Name given to the Document:** Relative density (liquids) and bulk, tap density (solids).001		Relative density (liquids) and bulk, tap density (solids)		IUC5-a9456b82-f82a-4f76-941f-eb4a3b9fc191 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-a9456b82-f82a-4f76-941f-eb4a3b9fc191&snapshot=0]*	
Reference type:	Title: Product	Author: Thomas,	Bibliographic	Testing laboratory:	Report no.	Company owner:	Report date: Jun 13,

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

study report	Properties of Brodifacoum	C.D.	source: No bibliographic source provided Year: 2016	Bell Laboratories Inc. 1901 Wright Street Madison, WI 53704	BEL/0616/C485	Bell Laboratories, Inc Study number: No company study number provided	2016
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.4.1 **Section Name:** Storage stability tests **Name given to the Document:** Storage stability tests.Accelerated		Storage stability tests		IUC5-ac68de4a-2005-46d7-ac25-06f7b4043795 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-ac68de4a-2005-46d7-ac25-06f7b4043795&snapshot=0]*	
Reference type: study report	Title: Accelerated Storage Stability of Brodifacoum Blocks	Author: Freeders, K.R.	Bibliographic source: No bibliographic source provided Year: 2015	Testing laboratory: Bell Laboratories Inc. 1901 Wright Street, Madison, WI 53704	Report no. BEL/0915/C465	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Nov 2, 2015
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.4.1 **Section Name:** Storage stability tests **Name given to the Document:** 1 year Storage stability tests.Long term ambient temperature study		Storage stability tests		IUC5-39515aca-159b-4f94-8958-55e6b5e472dd *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-39515aca-159b-4f94-8958-55e6b5e472dd&snapshot=0]*	
Reference type: study report	Title: Storage Stability and Corrosion Characteristics of Brodifacoum Blocks	Author: Thomas, C.D.	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: Bell Laboratories, Inc. 1901 Wright St. Madison, WI 53704	Report no. BEL/1116/C487	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Nov 29, 2016

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<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 3.4.1
Section Name: Storage stability tests
Name given to the Document: 1 year Storage stability tests.reactivity towards container</td><td colspan="2">Storage stability tests</td><td colspan="2">IUC5-76957415-60db-4050-9ae0-a5896c53c19f

[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-76957415-60db-4050-9ae0-a5896c53c19f&snapshot=0]</td></tr>
<tr><td>Reference type: study report</td><td>Title: Storage Stability and Corrosion Characteristics of Brodifacoum Blocks</td><td>Author: Thomas, C.D.</td><td>Bibliographic source: No bibliographic source provided

Year: 2016</td><td>Testing laboratory: Bell Laboratories, Inc. 1901 Wright St. Madison, WI 53704</td><td>Report no. BEL/1116/C487</td><td>Company owner: Bell Laboratories, Inc.

Study number: No company study number provided</td><td>Report date: Nov 29, 2016</td></tr>
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<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 3.4.1
Section Name: Storage stability tests
Name given to the Document: 50 ppm 2 year Storage Stability tests. Long term ambient temperature study</td><td colspan="2">Storage stability tests</td><td colspan="2">608b3a6c-8509-4faa-8d03-4ed745ccada9

[http://localhost:8080/webstart/launch.jnlp?uuid=608b3a6c-8509-4faa-8d03-4ed745ccada9&snapshot=0]</td></tr>
<tr><td>Reference type: study report</td><td>Title: Storage Stability and Corrosion Charcteristics of Broadifacoum Blocks</td><td>Author: Feeders, K.R.</td><td>Bibliographic source: No bibliographic source provided

Year: 2013</td><td>Testing laboratory: Bell Laboratories. Inc. 1901 Wright Street, Madison, WI 53704</td><td>Report no. BEL/0811/C433</td><td>Company owner: Bell Laboratories, Inc.

Study number: No company study number provided</td><td>Report date: Sep 24, 2013</td></tr>
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<tr><td colspan="2">Biocidal product</td><td colspan="2">Section No. 3.4.1
Section Name: Storage stability tests
Name given to the Document: 50 ppm 2 year Storage Stability tests. reactivity towards container</td><td colspan="2">Storage stability tests</td><td colspan="2">20fee864-8c52-481d-950d-3a6bbf9b7e6e

[http://localhost:8080/webstart/launch.jnlp?uuid=20fee864-8c52-481d-950d-3a6bbf9b7e6e&snapshot=0]</td></tr>
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Reference type: study report	Title: Storage Stability and Corrosion Charcteristics of Broadifacoum Blocks	Author: Feeders, K.R.	Bibliographic source: No bibliographic source provided Year: 2013	Testing laboratory: Bell Laboratories. Inc. 1901 Wright Street, Madison, WI 53704	Report no. BEL/0811/C433	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Sep 24, 2013
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.4.1 **Section Name:** Storage stability tests **Name given to the Document:** 2 year Storage stability.Long term ambient temperature study		Storage stability tests		2146f7f4-a1f3-4d9b-992b-0c20101ad267 *[http://localhost:8080/webstart/launch.jnlp?uuid=2146f7f4-a1f3-4d9b-992b-0c20101ad267&snapshot=0]*	
Reference type: study report	Title: Storage Stability and Corrosion Characteristics of Brodifacoum Blocks	Author: Christopher D. Thomas, Ph.D.	Bibliographic source: No bibliographic source provided Year: 2017	Testing laboratory: Bell Laboratories, Inc. 1901 Wright St. Madison, WI 53704	Report no.: No report number provided	Company owner: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704 Company study number: BEL/0915/C468	Report date: Oct 9, 2017
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 3.4.1 **Section Name:** Storage stability tests **Name given to the Document:** 2 year Storage stability. reactivity towards container (corrosion)		Storage stability tests		a309175d-a7ae-429b-909d-f1ea5bd28d6d *[http://localhost:8080/webstart/launch.jnlp?uuid=a309175d-a7ae-429b-909d-f1ea5bd28d6d&snapshot=0]*	
Reference type: study report	Title: Storage Stability and Corrosion Characteristics of Brodifacoum Blocks	Author: Christopher D. Thomas, Ph.D.	Bibliographic source: No bibliographic source provided Year: 2017	Testing laboratory: Bell Laboratories, Inc. 1901 Wright St. Madison, WI 53704	Report no.: No report number provided	Company owner: Bell Laboratories, Inc. 3699 Kinsman Blvd. Madison, WI 53704 Company study	Report date: Oct 9, 2017

						number: BEL/0915/C468	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 5 **Section Name:** Methods of detection and identification **Name given to the Document:** Methods of detection and identification.BEL/1115/C472 – BEL/0616/C485		Methods of detection and identification		-	
Reference type: study report	Title: Product Properties of Brodifacoum	Author: Thomas, C.D.	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: Bell Laboratories Inc. 1901 Wright Street Madison, WI 53704	Report no. BEL/0616/C485	Company owner: Bell Laboratories, Inc Study number: No company study number provided	Report date: Jun 13, 2016
Remarks: Entry added manually, therefore no UUID							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.NEW study Mice BELL-1371		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		77661bb3-05b9-4000-a0e1-4b36ea710b82 *[http://localhost:8080/webstart/launch.jnlp?uuid=77661bb3-05b9-4000-a0e1-4b36ea710b82&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Weatherized Brodifacoum Blocks on Young Adult Wistar Rats	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2018	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc., 3699 Kinsman Blvd., Madison, WI 53704 Company study number: BELL-1375	Report date: Jun 21, 2018
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7		Efficacy data to support these claims,		45e1cc4e-af97-408b-af50-bf85033ed611	

		Section Name: Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.NEW study Rats BELL-1374		including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		*[http://localhost:8080/webstart/launch.jnlp?uuid=45e1cc4e-af97-408b-af50-bf85033ed611&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Weatherized Brodifacoum Blocks on Young Adult Wistar Rats	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2018	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc., 3699 Kinsman Blvd., Madison, WI 53704 Company study number: BELL-1374	Report date: Jun 12, 2018
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.NEW study Rats BELL-1375 Weatherised		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		29164553-30d7-42d1-8d74-320b28afbd92 *[http://localhost:8080/webstart/launch.jnlp?uuid=29164553-30d7-42d1-8d74-320b28afbd92&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Weatherized Brodifacoum Blocks on Young Adult Swiss Webster Mice	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2018	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc., 3699 Kinsman Blvd., Madison, WI 53704 Company study number: BELL-1371	Report date: May 30, 2018
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards		IUC5-5f66099d-0656-4e42-80c6-b1e796fde6d5 *[http://localhost:8080/webstart/launch.jnl*	

		data to support these claims. Mice BEL/1015/BE884		where appropriate and relevant		*p?uuid=IUC5-5f66099d-0656-4e42-80c6-b1e796fde6d5&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Brodifacoum Blocks on Young Adult Swiss Webster Mice	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2015	Testing laboratory: [redacted]	Report no. BEL/0915/BE884	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Nov 12, 2015
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims. Mice BEL/1015/BE887 Weatherised		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-77a38a18-ecd7-4290-bb05-c922c696a591 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-77a38a18-ecd7-4290-bb05-c922c696a591&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Weatherized Brodifacoum Blocks on Young Adult Swiss Webster Mice	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2015	Testing laboratory: [redacted]	Report no. BEL/0915/BE887	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Nov 12, 2015
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims. Rat BEL/1015/BE888		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-58e60a49-db18-4353-a609-4d17a8f8c7ab *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-58e60a49-db18-4353-a609-4d17a8f8c7ab&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Brodifacoum	Author: [redacted]	Bibliographic source: No bibliographic source	Testing laboratory: [redacted]	Report no. BEL/0915/BE888	Company owner: Bell Laboratories, Inc.	Report date: Dec 11, 2015

	Blocks on Young Adult Wistar Rats.		provided Year: 2015			Study number: No company study number provided	
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims. Rat BEL/1015/BE890 Weatherised		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-c438781d-a89a-4c03-b7ca-ef738c83374f *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-c438781d-a89a-4c03-b7ca-ef738c83374f&snapshot=0]*	
Reference type: study report	Title: Efficacy of 0.0025% Weatherised Brodifacoum Blocks on Young Adult Wistar Rats	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2015	Testing laboratory: [redacted]	Report no. BEL/0915/BE890	Company owner: Bell Laboratories, Inc. Study number: No company study number provided	Report date: Dec 11, 2015
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.Field trial in Norway rat #1		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-8b6f2011-5ede-4517-869e-835530aab69c *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-8b6f2011-5ede-4517-869e-835530aab69c&snapshot=0]*	
Reference type: study report	Title: Field efficacy of 25 ppm Brodifacoum blocks for the control of the Norway rat, Rattus norvegicus at an urban commercial site in New Orleans, Louisiana	Author: [redacted] .	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc. Study number: No company study number provided	Report date: Aug 24, 2016

Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.Field trial in Norway rat #2		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-0cf8bde6-0373-4f07-a446-854112f79c02 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-0cf8bde6-0373-4f07-a446-854112f79c02&snapshot=0]*	
Reference type: study report	Title: Field efficacy of 25 ppm Brodifacoum blocks for the control of the Norway rat, Rattus norvegicus at an urban commercial site in New Orleans, Louisiana	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc. Study number: No company study number provided	Report date: Aug 26, 2016
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.Field trial in Roof rat #1		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-61dd7880-a605-4c84-a116-87f070f62073 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-61dd7880-a605-4c84-a116-87f070f62073&snapshot=0]*	
Reference type: study report	Title: Field efficacy of 25 ppm Brodifacoum blocks for the control of the roof rat, Rattus rattus at an urban residential site in Metairie, Louisiana	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc. Study number: No company study number provided	Report date: Sep 2, 2016
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support		Efficacy data to support these claims, including any available standard		IUC5-e4d11849-9277-4478-a18d-cdc405395692	

		these claims **Name given to the Document:** Efficacy data to support these claims.Field trial in Roof rat #2		protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		*[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-e4d11849-9277-4478-a18d-cdc405395692&snapshot=0]*	
Reference type: study report	Title: Field efficacy of 25 ppm Brodifacoum blocks for the control of the roof rat, Rattus rattus at an urban residential site in Metairie, Louisiana	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc. Study number: No company study number provided	Report date: Sep 7, 2016
Remarks: no remarks in literature reference							
Biocidal product		**Section No.** 6.7 **Section Name:** Efficacy data to support these claims **Name given to the Document:** Efficacy data to support these claims.Field trial in House mouse #1		Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant		IUC5-30762353-cd0e-4d54-b831-d428c5a7cf71 *[http://localhost:8080/webstart/launch.jnlp?uuid=IUC5-30762353-cd0e-4d54-b831-d428c5a7cf71&snapshot=0]*	
Reference type: study report	Title: Field efficacy of 25 ppm Brodifacoum blocks for the control of the House mouse, Mus musculus at an urban commercial site in New Orleans, Louisiana	Author: [redacted]	Bibliographic source: No bibliographic source provided Year: 2016	Testing laboratory: [redacted]	Report no.: No report number provided	Company owner: Bell Laboratories Inc. Study number: No company study number provided	Report date: Sep 15, 2016
Remarks: no remarks in literature reference							

3.2 Output tables from exposure assessment tools

Scenario 1: Application – securing blocks into bait station for a.s. brodifacoum

user category	professional		
number of manipulations	60		n
amount per bait station	200	g	A
amount per block	20	g	nxA
number of blocks per manipulation	10		nM
DERMAL			
dermal exposure value	55,58	mg b.p	exp
dermal exposure value to product	3334,8	mg b.p	n*exp = D
concentration active	0,0025	%	C
dermal absorption	0,200	%	DA
systemic dermal systemic dose	1,67E-04	mg a.s.	D*C*DA=sysD
body weight	60	kg	bw
protection factor for sachets	0	%	Rs
systemic dermal dose per kg bw, including reduction factor for sachets, if applicable	2,78E-06	mg a.s./kg bw	sysD/bw/Rs
protection factor for gloves	90	%	PPE
systemic dermal dose per kg bw with gloves, including reduction factor for sachets, if applicable	2,78E-07	mg a.s./kg bw	sysD/bw/Rs and PPE

Scenario 1: Application – securing blocks into bait station for SoC potassium sorbate

user category	professional		
number of manipulations	60		n
amount per bait station	200	g	A
amount per block	20	g	nxA
number of blocks per manipulation	10		nM
DERMAL			
dermal exposure value	55,58	mg b.p	exp
dermal exposure value to product	3334,8	mg b.p	n*exp = D
concentration active	1,0000	%	C
dermal absorption	25,000	%	DA
systemic dermal systemic dose	8,34E+00	mg a.s.	D*C*DA=sysD
body weight	60	kg	bw
protection factor for sachets	0	%	Rs
systemic dermal dose per kg bw, including reduction factor for sachets, if applicable	1,39E-01	mg a.s./kg bw	sysD/bw/Rs
protection factor for gloves	90	%	PPE
systemic dermal dose per kg bw with gloves, including reduction factor for sachets, if applicable	1,39E-02	mg a.s./kg bw	sysD/bw/Rs and PPE

Scenario 2: Clean-up and disposal for a.s. brodifacoum

number of cleanings	15		n
dermal exposure value per cleaning	5,7	mg b.p	exp
dermal exposure value to product	85,5	mg b.p	n*exp = D
concentration active	0,0025	%	C
dermal absorption	0,200	%	DA
systemic dermal systemic dose	4,28E-06	mg a.s.	D*C*DA=sysD
body weight	60	kg	bw
systemic dermal dose per kg bw	7,13E-08	mg a.s./kg bw	sysD/bw/Rs
protection factor for gloves	90	%	PPE
systemic dermal dose per kg bw with gloves	7,13E-09	mg a.s./kg bw	sysD/bw/Rs and PPE

Scenario 2: Clean-up and disposal for SoC potassium sorbate

number of cleanings	15		n
dermal exposure value per cleaning	5,7	mg b.p	exp
dermal exposure value to product	85,5	mg b.p	n*exp = D
concentration active	1,0000	%	C
dermal absorption	25,000	%	DA
systemic dermal systemic dose	2,14E-01	mg a.s.	D*C*DA=sysD
body weight	60	kg	bw
systemic dermal dose per kg bw	3,56E-03	mg a.s./kg bw	sysD/bw/Rs
protection factor for gloves	90	%	PPE
systemic dermal dose per kg bw with gloves	3,56E-04	mg a.s./kg bw	sysD/bw/Rs and PPE

3.3 New information on the active substance

None.

3.4 Residue behaviour

No contact with food or feed stuffs is envisaged when used according to label instructions.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[22]

Efficacy studies have been summarised in section 2.2.5 and in IUCLID in section 2.2.5.

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

3.6

3.7 Other