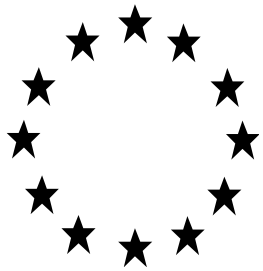
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



BRODITEC P-17F2

Product type 14

Brodifacoum

Case Number (NA-BBP) in R4BP: BC-EF058801-50
Case Number (NA-MIC) in R4BP: BC-GK086432-37

Evaluating Competent Authority: France

Date: February 2023
Revised: May 2024

Table of Contents

Note to the reader

This consolidated PAR is based on the PAR of the first authorisation of the reference product BRODITEC P-17F and has been updated with the NA-MIC data on the product BRODITEC P-17F2 provided by the applicant.

In this consolidated PAR, the assessments related to the new data of the product BRODITEC P-17F2 are at the end of the concerned section and are highlighted in grey.

The SPC (in the section 2.1 of the PAR) corresponds to the currently authorised uses in France of the product BRODITEC P-17F2.

HISTORY OF THE DOSSIER

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)
NA-APP	*FR*	BC-FU058759-00	17/02/2023	Initial National Authorisation of BRODITEC P-17F
NA-BBP	*FR*	BC-EF058801-50	06/03/2023	National authorisation of same biocidal product BRODITEC P-17F2
NA-MIC	*FR*	BC-GK086432-37	13/05/2024	Minor change application: - replacement of a non-active substance intentionally incorporated - change in the shelf life (from 2 to 3 years) - addition of names for the biocidal product

1 CONCLUSION

France received an application for the first authorization of the biocidal product BRODITEC P-17F (PT14) based on 0.00170 % w/w of brodifacoum.
It is intended to be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and mice (*Mus musculus*), for use in and around buildings, by professional and non-professional users.

Disclaimer

Regarding the user category:
For the risk assessment of PT14, two user categories have been addressed depending on the quantity of manipulated product and the possibility of using PPE: non-professional users and professional users.

In France, any professional user needs a dedicated national certificate, hence it is expected that he/she has the required competence to access to biocidal products that are authorized for professional users they are thus considered as « trained professional users ».

Consequently, in the SPC in section 2, uses for "professionals" are mentioned according to the agreed standard SPC, but they are not relevant in France. It is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

Regarding the loose packaging for the general public:
In order to comply with the specific conditions of use of biocidal products containing brodifacoum addressed by the Commission Implementing Regulation (EU) 2017/1381 renewing the approval of brodifacoum as an active substance for use in PT 14, the products in the form of loose bait formulations, are only authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment for the general public.

Regarding the first aid instructions in the SPC:
The SPC follows the mentions and RMMs agreed in the CA-Nov16-Doc.4.1.b - Final - harmonised sentences SPC AVKs.
However, the "Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment" under the section 5.3 of the SPC have been updated to be in line with the document CG-43_SE Guidance for first aid instructions_Vf.

Conclusion on Physico-chemical properties and analytical methods

BRODITEC P-17F is a ready to use light red paste with a characteristic odour. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
There is no effect of high temperature on the stability of the formulation since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed.
Based on the accelerated storage tests, the 2-year storage test and the efficacy data, a shelf life up to 2 years can be granted in the LDPE bag and the non-coated electrolytic tin plate metal can.
As the formulation is a ready-to-use paste bait and as the stability was performed on LDPE bag and metal can packagings, the blister, the bucket/pot with or without inner liner, the

box (carton)/carton box with the inner liner (or bag or the bait station envelopped in a polyolefin film) and the sack packagings can be considered as acceptable.
The product BRODITEC P-17F is not explosive and has no oxidizing properties. The product is not flammable.

Analytical method for the determination of the active substance brodifacoum in the formulation is available and validated.

- **Minor change application (2024)**

New data were provided to support the change of the shelf life from 2 years to 3 years. Physico-chemical results are acceptable. Thus a shelf life of up to 3 years at ambient temperature can be granted when stored in commercial packaging.
The change in the composition is accepted as it has no effect on physico-chemical properties; only the colour of the product was impacted.

Conclusion on Efficacy

The product BRODITEC P-17F has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and mice (*Mus musculus*), for use in and around buildings, by professional and non-professional users.

The validated application rates are the following:

Rats (*Rattus norvegicus* and *Rattus rattus*): 60-80 g secured bait point separated by 5-10 m.

Mice (M*us musculus*): 30-50 g secured bait point separated by 2-5 m.

- **Minor change application (2024)**

The French competent authority (FR CA) assessed that the new formulation of the product BRODITEC P-17F2 has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*) and mice (*Mus musculus*) with a shelf life of 3 years.

The application rates validated are the following:

- Rats (*Rattus norvegicus* and *Rattus rattus*): 60-80 g secured bait points separated by 5-10 m.
- House mice (*Mus musculus*): 30-50 g secured bait points separated by 2-5 m.

Conclusion on Human Health

The risk is acceptable for the professional user when using PPE and for the non professional user without PPE.

- **Minor change application (2024)**

The minor change implying a replacement of a non-active substance intentionally incorporated has no impact on the classification of the product, the identification of any substance of concern and the risk assessment for Human Health.

Conclusion on indirect exposure via food

Any exposure of food, drinking water or livestock exposure is not foreseeable. Thus, dietary exposure is considered as not relevant.

Conclusion on Environment

The risk assessment has been conducted for the active substance only. No substance of concern has been identified for the environment.

For the indoor uses (uses 1, 2, 4, 5, 7), the estimated risks are acceptable for all the environmental compartments (surface water, sediment, soil and groundwater).

For the outdoor uses around building (uses 3, 6, 8), unacceptable risks are foreseen for the sediment compartment if baits are used near water bodies. The following risk mitigation measure must be applied:
"*Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).*"

Moreover, for all uses, the risk for primary and secondary poisoning of non-target animals cannot be excluded. Specific use restrictions must be applied to mitigate these risks.

For professionals and trained professionals:
- 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 open the sachets containing the bait

For professionals, trained professionals and non-professionals:
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

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

- Store in places prevented from the access of children, birds, pets and farm animals.
- Remove the remaining bait or the bait stations at the end of the treatment period.

For professionals and non professionals:
- use in tamper resistant bait stations only

➢ **Minor change application (2024)**
The minor change implying a replacement of a non-active substance intentionally incorporated has no impact on the classification of the product, the identification of any substance of concern and the risk assessment for the environment.

Substances of concern (SoCs)

The biocidal product does not contain any substance of concern.

Post-authorisation conditions:

- **in France only** : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum. Results of the resistance monitoring must be submitted at the renewal of the product.

Overall conclusion:

According to the assessment performed for the biocidal product BRODITEC P-17F, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the SPC below (§ 2):

Target organisms	**Application rate**	**Conditions of use**
Rats (*Rattus norvegicus and rattus rattus*)	60 - 80 g / bait point separated by 5-10 meters	Trained professionals Professionals Non professionals Indoor and outdoor around buildings
Mice (*Mus musculus*)	30 - 50 g / bait point separated by 2-5 meters	Trained professionals Indoor and outdoor around buildings
		Professionals Non professionals Indoor

- **Minor change application (2024)**

The minor change has no impact on the overall conclusion on the authorised uses of the biocidal product BRODITEC P-17F2.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment – Minor Change 2024

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
BRODITEC P-17F2 BRODITOP STRIKE PF2 BRODITOP MATRIX PF2 BRODITOP LC PF2 ZED STRIKE PF2 ZED MATRIX PF2 ZED LC PF2 RODIBROD STRIKE PF2 RODIBROD MATRIX PF2 RODIBROD LC PF2 PROTEMAX STRIKE PF2 PROTEMAX MATRIX PF2 PROTEMAX LC PF2 DEVILTOP STRIKE PF2 DEVILTOP MATRIX PF2 DEVILTOP LC PF2 ZAPI-TOP STRIKE PF2 ZAPI-TOP MATRIX PF2 ZAPI-TOP LC PF2 ZAPI-RAT STRIKE PF2 ZAPI-RAT MATRIX PF2 ZAPI-RAT LC PF2 MUSKIL 17PB DEVILTOP 17PB BRODITOP 17PB RODIBROD 17PB SAKARAT BRODI PATE	France

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Zapi S.p.A.
	Address	Via Terza Strada 12, 35026 Conselve Italy
Authorisation number	FR-2023-0018	
Date of the authorisation	06/03/2023	
Expiry date of the authorisation	16/02/2028	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Zapi S.p.A.
Address of manufacturer	Via Terza Strada 12, 35026 Conselve Italy
Location of manufacturing sites	Via Terza Strada 12, 35026 Conselve Italy

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

Active substance	Brodifacoum
Name of manufacturer	P.M. Tezza S.r.l. (Art. 95 list: ACTIVA S.r.l.)
Address of manufacturer	Via del Lavoro 326, 37050 Angiari (VR) Italy
Location of manufacturing sites	Via Tre Ponti 22, 37050 S.Maria di Zevio (VR) Italy

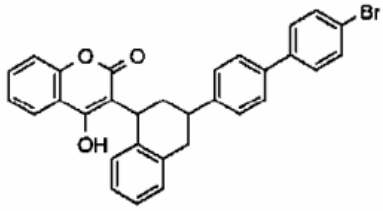
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Brodifacoum
IUPAC or EC name	3-[(1RS,3RS;1RS,3SR)-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	992 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

Brodifacoum does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012. Brodifacoum does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for substitution.

A comparative assessment has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council. 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.

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (technical %)
Brodifacoum (technical)	3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	Active substance	56073-10-0	259-980-5	0.0017

2.1.2.4 Information on technical equivalence

The source of the active substance is Activa Srl and is the same as indicated in the CAR. The Letter of Access is provided in section 13 of the IUCLID dossier.

2.1.2.5 Information on the substance(s) of concern

The biocidal product does not contain any substance of concern.
Please see the confidential annex for further details.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product

The biocidal product contains the active substance "Brodifacoum", which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

Please see the confidential annex for further details.

2.1.2.7 Type of formulation

RB - Bait (ready to use paste)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	-
Hazard statement	-
Labelling	
Signal words	-
Hazard statements	-
Precautionary statements	-
Note	**-**

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – House mice – general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[1].
Application rate(s) and frequency	Bait products: 30-50g of bait per baiting point separated by 2-5m.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats) Single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g Single dose filter paper sachets (15g) packed in: - 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET)

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

	- 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET * the bait station could be enveloped in a protective polyolefin film.

2.1.4.1.1 Use-specific instructions for use

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

2.1.4.1.2 Use-specific risk mitigation measures

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

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

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

2.1.4.2 Use description

Table 2. Use # 2 – Rats – general public – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[2].
Application rate(s) and frequency	Bait products: 60-80g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats): single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g Single dose filter paper sachets (15g) packed in: - 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) * the bait station could be enveloped in a protective polyolefin film.

2.1.4.2.1 Use-specific instructions for use

- 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.

2.1.4.2.2 Use-specific risk mitigation measures

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

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

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

2.1.4.3 Use description

Table 3. Use # 3 – Rats – general public – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[2].
Application rate(s) and frequency	Bait products: 60-80g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: - 150g (product for mice and rats): single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g

	Single dose filter paper sachets (15g) packed in: - 30g to 150g Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 30g to 150g Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) - 30g to 150g Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) - 30g to 150g Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) * the bait station could be enveloped in a protective polyolefin film.

2.1.4.3.1 Use-specific instructions for use

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

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

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

2.1.4.3.2 Use-specific risk mitigation measures

- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

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

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

2.1.4.4 Use description

Table 4. Use # 4 – Not relevant in France – House mice – professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[2]
Application rate(s) and frequency	Bait products: 30-50 g of bait per baiting point spaced 2-5m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film - 3 kg to 25 kg Sack (LDPE or LDPE/paper)

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

2.1.4.4.1 Use-specific instructions for use

- The bait stations should be visited at least every 2 to 3 days for mice 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.

2.1.4.4.2 Use-specific risk mitigation measures

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

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

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

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

2.1.4.5 Use description

Table 5. Use # 5 – Not relevant in France – Rats – professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[3]
Application rate(s) and frequency	Bait products: 60-80 g of bait per baiting point spaced 5-10m apart.

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

Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film - 3 kg to 25 kg Sack (LDPE or LDPE/paper)

2.1.4.5.1 Use-specific instructions for use

- 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.

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

2.1.4.5.2 Use-specific risk mitigation measures

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

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

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

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

2.1.4.6 Use description

Table 6. Use # 6 – Not relevant in France – House mice and rats – professionals outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field 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	Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film - 3 kg to 25 kg Sack (LDPE or LDPE/paper)

2.1.4.6.1 Use-specific instructions for use

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

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

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

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

2.1.4.6.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.
- Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

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

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

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

2.1.4.7 Use description

Table 7. Use # 7 – House mice and rats – trained professionals – indoor

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations[4] - Covered and protected baiting points
Application rate(s) and frequency	Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart.

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

	Rats: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. *(**In France only** : minimum pack size of 5 kg)* Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s)* enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) - 3 kg to 25 kg Sack (LDPE or LDPE/paper) * the bait station could be enveloped in a protective polyolefin film.

2.1.4.7.1 Use-specific instructions for use

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

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

2.1.4.7.2 Use-specific risk mitigation measures

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

- 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.

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

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

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

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

2.1.4.8 Use description

Table 8. Use # 8 – House mice and rats – trained professionals – outdoor around buildings

Product Type	14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	Bait formulations: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points - Direct application of ready-to-use bait into the burrow
Application rate(s) and frequency	Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. (***in France only :*** Minimum pack size of 5 kg) Single dose filter paper sachets (10 or 15g) packed in: - 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE)

	- 3 kg to 25 kg Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner liner (LDPE) - 3 kg to 25 kg Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg - 3 kg to 25 kg Carton box or box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - 3 kg to 25 kg Sack (LDPE or LDPE/paper) * the bait station could be enveloped in a protective polyolefin film.

2.1.4.8.1 Use-specific instructions for use

- 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 (except for direct application into the burrow).
- *[When available]* Follow any additional instructions provided by the relevant code of best practice.

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

For directly application into the burrow:
- Baits must be placed to minimise the exposure to non-target species and children.
- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

2.1.4.8.2 Use-specific risk mitigation measures

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

- 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 use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).

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

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

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

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

2.1.5 General directions for use

2.1.5.1 Instructions for use

FOR PROFESSIONAL AND TRAINED 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.

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

- 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 (glove material to be specified by the authorisation holder within the product information).

- 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.

- Do not open the sachets containing the bait.

FOR TRAINED PROFESSIONAL ONLY

- 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.

- 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.).

FOR PROFESSIONNALS ONLY

- 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.

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

- The bait station 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.).

FOR NON 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.

- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

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

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

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

- Do not open the sachets containing the bait

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

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

- Do not place bait stations near water drainage systems where they can come into contact with water.

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

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

2.1.5.2 Risk mitigation measures

FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS

- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

FOR TRAINED PROFESSIONAL ONLY

- 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 *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign [*in accordance with the applicable code of good practice, if any*].

FOR PROFESSIONAL ONLY:

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*

- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- The product information (i.e. label and/or leaflet) shall clearly show that:

  - the product shall not be supplied to the general public (e.g. "for professionals only").
  - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
  - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

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

- 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 wash the bait stations with water between applications.

- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*

FOR NON PROFESSIONAL USERS

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

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

- The product information (i.e. label and/or leaflet) shall clearly show that:

the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

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.

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

- IF SWALLOWED: Rinse mouth.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].

- If medical advice is needed, have product container or label at hand.

- 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 the uneaten bait and the packaging in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains

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: 3 years.
- Store the product at temperatures below 35°C.
- Protect from light.
- Do not store near food, drink and feed.

2.1.6 Other information

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

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

- This product contains a bittering agent and a dye.

2.1.7 Packaging of the biocidal product

Single filter-paper sachets of 10 g or 15 g packaged in the packagings as given in the packaging specification below. For a better understanding, the appliquant has provided an excel file to explain all the packagings.


BRODITEC_P-17F_Packagings.xlsx

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Blister with or without inner bag	from 30g to 150g	Blister: PVC or PVC + carton (the latter not in contacts with the product) Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET		non-professional	Yes
Bucket or pot with or without inner liner	from 30g to 150g	Bucket or pot: PP or PET or PVC or HDPE Liner: LDPE	Lid of the bucket/pot: PP or PET or PVC or HDPE	non-professional	Yes
Bucket or pot with or without inner bag	from 30g to 150g	Bucket or pot: PP or PET or PVC or HDPE Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET	Lid of the bucket/pot: PP or PET or PVC or HDPE	non-professional	Yes
Bag	from 30g to 150g	LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET		non-professional	Yes
Can with or without inner bag	from 30g to 150g	Can: Internally non-coated electrolytic tin plate metal	electrolytic tin plate metal	non-professional	Yes

		Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET			
Box with inner bag	from 30g to 150g	Box: carton Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET		non-professional	Yes
Box with inner tamper resistant bait station(s) with inner bag	from 30g to 150g	Box: carton bait station*: PP or PET or PVC or HDPE Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET		non-professional	Yes
Box with inner tamper resistant bait station(s) enveloped in a protective polyolefin film	from 30g to 150g	Box: carton bait station: PP or PET or PVC or HDPE enveloped in a protective polyolefin film		non-professional	Yes
Bag with inner tamper resistant bait station(s) with or without inner bag	from 30g to 150g	Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET bait station*: PP or PET or PVC or HDPE		non-professional	Yes
Bucket with or without inner liner	from 3kg to 25 kg	Bucket: PP or PET or PVC or HDPE Liner: LDPE	Lid of the bucket/pot: PP or PET or PVC or HDPE	professional	Yes
Bucket with inner bag(s)	from 3kg to 25 kg	Bucket: PP or PET or PVC or HDPE Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET	Lid of the bucket/pot: PP or PET or PVC or HDPE	professional	Yes

Carton box or box with inner liner	from 3kg to 25 kg	Carton box or box: carton Liner: LDPE		professional	Yes
Carton box or box or box with inner bag(s)	from 3kg to 25 kg (inner bag(s) each up to 1 kg)	Carton box or box: carton Bag: LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET		professional	Yes
Carton box or box with inner tamper resistant bait station(s)	from 3kg to 25 kg	Carton box or box: carton bait station: PP or PET or PVC or HDPE enveloped in a protective polyolefin film		professional	Yes
Sack	from 3kg to 25 kg	LDPE or LDPE/paper		Professional	Yes

* the bait station could be enveloped in a protective polyolefin film.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New studies concerning the product have been submitted with respect to physical-chemical properties, efficacy, dermal absorption and analytical studies. The studies are listed in annex 3.1.

Efficacy data

The following efficacy studies were submitted:

- A free-choice laboratory test was carried out with house mice (***Mus musculus***), with exposure to a 3 years aged formulation of Brodifacoum 0.0017 % w/w Pasta for 4 days.
- A free-choice laboratory test was carried out with brown rats (***Rattus norvegicus***), with exposure to a 3 years aged formulation of Brodifacoum 0.0017 % w/w Pasta for 4 days.
- A free-choice laboratory test was carried out with black rats (***Rattus rattus***), with exposure to a 3 years aged formulation of Brodifacoum 0.0017 % w/w Pasta for 4 days.
- A field test was carried out with house mice (***Mus musculus***), with exposure to a fresh formulation of Brodifacoum 0.0017 % w/w Pasta.
- A field test was carried out with brown rats (***Rattus norvegicus***), with exposure to a fresh formulation of Brodifacoum 0.0017 % w/w Pasta.
- A field test was carried out with black rats (***Rattus rattus***), with exposure to a fresh formulation of Brodifacoum 0.0017 % w/w Pasta.

➢ **Minor change application (2024)**

The following storage stability study was submitted in order to support the change of the shelf life from 2 years to 3 years:

- Nichetti S. (2022). Brodifacoum 0.0017% w/w pasta: Three Years Storage Stability and Corrosion Characteristics. ChemService S.r.l. Controlli e Ricerche. Report Number CH – 0506/2019.

The study was conducted on the product BRODITEC P-17F (reference product).

See annexe 3.1 for the list of submitted efficacy studies

2.1.8.2 Access to documentation

The applicant has provided a letter of access to the data included in the active substance dossier for Brodifacoum, 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 (MIC 2024)

Table 5. Use # 1 – House mice – general public - indoor

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 30-50g of bait per baiting point separated by 2-5m
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats) Single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g Single dose filter paper sachets (15g) packed in: - Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (30g-150g). * the bait station could be enveloped in a protective polyolefin film.

Use # 2 – Rats – general public – indoor

Product Type	PT-14

Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 60-80g of bait per baiting point spaced 5-10m apart
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats) Single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g Single dose filter paper sachets (15g) packed in: - Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (30g-150g). * the bait station could be enveloped in a protective polyolefin film.

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

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field 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	Bait products: 60-80g of bait per baiting point spaced 5-10m apart
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Maximum quantity of bait per unit sold: 150g (product for mice and rats) Single dose filter paper sachets : - for pre-filled bait station: 10g or 15g - for the other packs: 15g Single dose filter paper sachets (15g) packed in: - Blister (PVC or PVC + carton) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 30g to 150g); - Bucket or pot (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Non-coated electrolytic tin plate metal can with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (from 30g to 150g); - Box (carton) with inner pre-filled tamper resistant bait station(s) enveloped in a protective polyolefin film (PP or PET or PVC or HDPE) (from 30g to 150g); - Bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) with inner pre-filled tamper resistant bait station(s)* (PP or PET or PVC or HDPE) with or without inner bag (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) (30g-150g). * the bait station could be enveloped in a protective polyolefin film.

Use # 4 – Not relevant in France - House mice – professionals – indoor

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides

Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 30-50 g of bait per baiting point spaced 2-5m apart
Category(ies) of users	Professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (in France only : Minimum pack size of 5 kg). Single dose filter paper sachets (10 or 15g) packed in: - Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 3 kg to 25 kg); - Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner liner (LDPE) (from 3 kg to 25 kg); - Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - Sack (LDPE or LDPE/paper) (from 3 kg to 25 kg).

Use # 5 – Not relevant in France - Rats – professionals – indoor

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Bait products: 60-80 g of bait per baiting point spaced 5-10m apart
Category(ies) of users	Professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (in France only : Minimum pack size of 5 kg). Single dose filter paper sachets (10 or 15g) packed in: - Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 3 kg to 25 kg); - Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner liner (LDPE) (from 3 kg to 25 kg); - Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg);

	- Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - Sack (LDPE or LDPE/paper) (from 3 kg to 25 kg).

Use # 6 – Not relevant in France – House mice and rats – professionals – outdoor around buildings

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field 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	Bait products: Mice: 30-50 g of bait per baiting point spaced 2-5m apart. Rats: 60-80 g of bait per baiting point spaced 5-10m apart.
Category(ies) of users	Professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (in France only : Minimum pack size of 5 kg). Single dose filter paper sachets (10 or 15g) packed in: - Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 3 kg to 25 kg); - Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner liner (LDPE) (from 3 kg to 25 kg); - Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - Sack (LDPE or LDPE/paper) (from 3 kg to 25 kg).

Use # 7 – House mice and rats – trained professionals – indoor

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Indoor
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequency	Bait products: Mice: 30-50 g of bait per baiting point Rats: 60-80 g of bait per baiting point
Category(ies) of users	Trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (in France only : Minimum pack size of 5 kg). Single dose filter paper sachets (10 or 15g) packed in: - Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 3 kg to 25 kg); - Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner liner (LDPE) (from 3 kg to 25 kg); - Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - Sack (LDPE or LDPE/paper) (from 3 kg to 25 kg).

Use # 8 – House mice and rats – trained professionals – outdoor around buildings

Product Type	PT-14
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism (including development stage)	*Mus musculus* (house mice) juveniles and adults *Rattus norvegicus* (brown rat) juveniles and adults *Rattus rattus* (black or roof rat) juveniles and adults
Field of use	Outdoor around buildings
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations; - Covered and protected baiting points; - Direct application of ready-to-use bait into the burrow.

Application rate(s) and frequency	Bait products: Mice: 30-50 g of bait per baiting point Rats: 60-80 g of bait per baiting point
Category(ies) of users	Trained professional
Pack sizes and packaging material	Minimum pack size of 3 kg. (in France only : Minimum pack size of 5 kg). Single dose filter paper sachets (10 or 15g) packed in: - Bucket (PP or PET or PVC or HDPE) with or without inner liner (LDPE) (from 3 kg to 25 kg); - Bucket (PP or PET or PVC or HDPE) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner liner (LDPE) (from 3 kg to 25 kg); - Carton box or box (carton) with inner bag(s) (LDPE or LDPE/OPA or LDPE/PET or LDPE/OPA/PET) each up to 1 kg (from 3 kg to 25 kg); - Carton box or box (carton) with inner pre-filled tamper resistant bait station(s) (PP or PET or PVC or HDPE) enveloped in a protective polyolefin film (from 3 kg to 25 kg); - Sack (LDPE or LDPE/paper) (from 3 kg to 25 kg).

2.2.2 Physical, chemical and technical properties

The product BRODITEC P-17F is a ready to use bait that contains 0.0017% of technical brodifacoum.

The product does not contain H304 co-formulants.

The product contains a bittering agent at the content of 0.001%. It contains also a preservative and a dye.

The product is for professional and non-professional users.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
Physical state at 20 °C and 101.3 kPa	OPPTS 830.6303 GLP 10g single dose paper sachet in PE bottle	Brodifacoum 0.0017% w/w pasta Batch 090140	Solid (paste)	Acceptable	Nichetti S. (2019), Report No. CH-0503/2019
Colour at 20 °C and 101.3 kPa	OPPTS 830.6302¨ GLP 10g single dose paper sachet in PE bottle	Brodifacoum 0.0017% w/w pasta Batch 090140	Light red	Acceptable	Nichetti S. (2019), Report No. CH-0503/2019
Odour at 20 °C and 101.3 kPa	OPPTS 830.6304 GLP 10g single dose paper sachet in PE bottle	Brodifacoum 0.0017% w/w pasta Batch 090140	Characteristic odour	Acceptable	Nichetti S. (2019), Report No. CH-0503/2019
Acidity / alkalinity	CIPAC MT 75.3 OECD No. 122 GLP	Brodifacoum 0.0017% w/w pasta	pH value of 1%w/v aqueous dispersion at 20°C = 6.3	Acceptable	Nichetti S. (2019), Report No.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td>10g single dose paper sachet in PE bottle</td><td>Batch 090140</td><td>Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.</td><td></td><td>CH-0503/2019</td></tr>
<tr><td>Relative density / bulk density</td><td>EC 440/2008 No. A.3
GLP
10g single dose paper sachet in PE bottle</td><td>Brodifacoum 0.0017% w/w pasta
Batch 090140</td><td>Density at 20°C = 1.1380</td><td>Acceptable</td><td>Nichetti S. (2019), Report No. CH-0503/2019</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>GIFAP Monograph n°17
CIPAC MT 46.3
OPPTS 830.6302
OPPTS 830.6303
OPPTS 830.6304
EC 440/2008 No. A.3
MT 75.3
MT 193

Initial characterisation of 10g single dose paper sachet in LDPE bottle

12 weeks at 35°C in :</td><td>Brodifacoum 0.0017% w/w pasta
Batch 090140</td><td><u>Brodifacoum active ingredient content</u>:
<table><tr><td></td><td>T0
LDPE bottle</td><td>T12w
Pack 1</td><td>T12w
Pack 2</td></tr><tr><td>a.s content (% w/w)</td><td>0.0018 ± 0.00005</td><td>0.0019 ± 0.00002</td><td>0.0019 ± 0.00004</td></tr></table>
<u>Appearance (physical state, colour, odour)</u>:
<table><tr><td></td><td>T0
PE Bottle</td><td>T12w
Pack 1</td><td>T12w
Pack 2</td></tr><tr><td>Sample aspect</td><td>Solid paste</td><td>No changes</td><td>No changes</td></tr><tr><td>Sample color</td><td>Light Red (shortcode RE 8)</td><td>No changes</td><td>No changes</td></tr><tr><td>Sample odor</td><td>Characteristic odour</td><td>No changes</td><td>No changes</td></tr></table>
The plastic LDPE bag was investigated for:
<table><tr><td></td><td>T0
PE Bottle</td><td>T12w
Pack 1</td></tr></table></td><td>The product is stable for 12 weeks at 35°C in plastic LDPE bag and metal can.

Appropriate label phrase will be added to indicate that the biocidal product must be stored at temperature below 35°C.
The applicant agreed on this previous risk mitigation measure.</td><td>Nichetti S. (2019), Report No. CH-0505/2019</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
	- Plastic LDPE bag (pack 1); - Metal can : non-coated electrolytic tin plate metal (pack 2) For appearance ,for the active substance content Plastic LDPE bag for pH and density HPLC-UV (validation data reported in 2.2.4) OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 EC 440/2008 No. A.3 MT 75.3		pH (1%w/v aqueous dispersion): 6.3 / 6.3 Relative density at 20°C: 1.1380 g/mL / 1.1320 g/mL		

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td>MT 193

GLP</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP Monograph No. 17
OPPTS 830.6302
OPPTS 830.6303
OPPTS 830.6304
CIPAC MT 75.3
OECD No. 122
CIPAC MT 191
EC No 440/2008 A.3
EC 440/2008 No. A.3
MT 75.3
MT 193

GLP

Initial characterisation of 10g single dose paper sachet in LDPE bottle

- Plastic LDPE bag (pack 1);</td><td>Brodifacoum 0.0017% w/w pasta
Batch 090140</td><td><u>Pack 1:Plastic PE bag</u>
<u>Pack 2: metal can</u>

<u>Brodifacoum active ingredient content</u>:
<table><tr><td></td><td>T0 LDPE bottle</td><td>T12m Pack 1</td><td>T12m Pack 2</td></tr><tr><td>a.s content (% w/w)</td><td>0.0018 ± 0.00005</td><td>0.0018 ± 0.00001</td><td>0.0018 ± 0.00002</td></tr><tr><td>a.s deviation from T0 (%)</td><td>/</td><td>-0.54</td><td>-1.19</td></tr></table>
<table><tr><td></td><td>T18m Pack 1</td><td>T18m Pack 2</td><td>T24m Pack 1</td><td>T24m Pack 2</td></tr><tr><td>a.s content (% w/w)</td><td>0.0018 ± 0.00002</td><td>0.0018 ± 0.00002</td><td>0.0018 ± 0.00001</td><td>0.0018 ± 0.00001</td></tr><tr><td>a.s deviation from T0 (%)</td><td>-1.98</td><td>- 2.13</td><td>- 1.71</td><td>+ 2.04</td></tr></table></td><td>Acceptable

a shelf life up to 2 years could be proposed in LDPE bag and metal can.

➢ Minor change application (2024)
Acceptable
The product is stable during 36 months at ambient temperature in packaging claimed.</td><td>Nichetti S. Study Plan CH – 0506/2019</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td>- Metal can : non-coated electrolytic tin plate metal (pack 2)</td><td></td><td>
➢ Minor change application (2024)
<table>
<tr><td></td><td>T30m Pack 1</td><td>T30m Pack 2</td><td>T36m Pack 1</td><td>T36m Pack 2</td></tr>
<tr><td>a.s content (% w/w)</td><td>0.0019 ± 0.00003</td><td>0.0019 ± 0.00003</td><td>0.0019 ± 0.00001</td><td>0.0019 ± 0.00003</td></tr>
<tr><td>a.s deviation from T0 (%)</td><td>+3.30</td><td>+ 4.79</td><td>+3.27</td><td>+ 5.70</td></tr>
</table>
<u>Appearance (physical state, colour, odour)</u>:
<table>
<tr><td></td><td>T0
PE Bottle</td><td>T12m
Pack 1</td><td>T12m
Pack 2</td></tr>
<tr><td>Sample aspect</td><td>Solid paste</td><td>No changes</td><td>No changes</td></tr>
<tr><td>Sample color</td><td>Light Red (shortcode RE 8)</td><td>No changes</td><td>No changes</td></tr>
<tr><td>Sample odor</td><td>Characteristic odour</td><td>No changes</td><td>No changes</td></tr>
</table>
<table>
<tr><td></td><td>T18m Pack 1</td><td>T18m Pack 2</td><td>T24m Pack 1</td><td>T24m Pack 2</td></tr>
<tr><td>Sample aspect</td><td>No changes</td><td>No changes</td><td>No changes</td><td>No changes</td></tr>
<tr><td>Sample color</td><td>No changes</td><td>No changes</td><td>No changes</td><td>No changes</td></tr>
<tr><td>Sample odor</td><td>No changes</td><td>No changes</td><td>No changes</td><td>No changes</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>The plastic LDPE bag was investigated for:
<table>
<tr><td></td><td>T0
LDPE
Bottle</td><td>T12m
Pack 1</td><td>T18m
Pack 1</td><td>T24m
Pack 1</td></tr>
<tr><td>pH (1%w/v aqueous dispersion)</td><td>6.3</td><td>6.3</td><td>7.0</td><td>6.8</td></tr>
<tr><td>Relative density at 20°C</td><td>1.1380 g/mL</td><td>1.1191 g/mL</td><td>1.1028 g/mL</td><td>1.1212 g/mL</td></tr>
</table>
➢ Minor change application (2024)
<table>
<tr><td></td><td>T30m
Pack 1</td><td>T36m
Pack 1</td></tr>
<tr><td>pH (1%w/v aqueous dispersion)</td><td>6.3</td><td>6.4</td></tr>
<tr><td>Relative density at 20°C</td><td>1.1217 g/mL</td><td>1.1117 g/mL</td></tr>
</table></td><td></td><td></td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>Not applicable</td><td></td><td>Not relevant: the product is a solid</td><td>Acceptable</td><td></td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td></td><td></td><td>According to the label, the product must be stored away from light.</td><td>Data is missing but in the SPC the applicant specifies that the product</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>should be store away from light</td><td></td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity</td><td></td><td></td><td>No effect of temperature has been noticed during the accelerated storage stability study.</td><td>See data on the accelerated storage study 12 weeks at 35°C.

For humidity, in the SPC the applicant specifies that the product should stored in a dry, cool and well ventilated place</td><td></td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material</td><td>GIFAP Monograph n°17
CIPAC MT 46.3

12 weeks at 35°C and 12 months at ambient temperature in
- Plastic LDPE bag (pack 1)
- Metal can : non-coated electrolytic tin</td><td>Brodifacoum 0.0017% w/w pasta
Batch 090140</td><td><u>Compatibility (resistance) of the packaging material</u>:
<table><tr><th></th><th>T12w
Pack 1</th><th>T12w
Pack 2</th></tr><tr><td>Packaging</td><td>No deformation or loss of sample or evident corrosion phenomena</td><td>No deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena</td></tr><tr><td>Weight deviation</td><td>-1.73%</td><td>-0.05%</td></tr></table></td><td>Acceptable

The product is compatible with plastic LDPE bag, and the metal can.</td><td>Nichetti S. (2019), Report No. CH-0505/2019

Nichetti S. Study Plan CH – 0506/2019</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td>plate metal (pack 2)

GLP</td><td></td><td>
<table>
<tr><td></td><td>T12m
Pack 1</td><td>T12m
Pack 2</td></tr>
<tr><td>Packaging</td><td>No deformation or loss of sample or evident corrosion phenomena</td><td>No deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena</td></tr>
<tr><td>Weight deviation</td><td>-0.35%</td><td>-0.07%</td></tr>
</table>
<table>
<tr><td></td><td>T18m
Pack 1</td><td>T18m
Pack 2</td></tr>
<tr><td>Packaging</td><td>No deformation or loss of sample or evident corrosion phenomena</td><td>No deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena</td></tr>
<tr><td>Weight deviation</td><td>-0.22%</td><td>- 0.03%</td></tr>
</table>
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Evaluation FR</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>T24m
Pack 1</td><td>T24m
Pack 2</td></tr>
<tr><td>Packaging</td><td>No deformation or loss of sample or evident corrosion phenomena</td><td>No deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena</td></tr>
<tr><td>Weight deviation</td><td>- 0.27%</td><td>- 0.01%</td></tr>
</table>

According to the accelerated storage stability studies and the long term storage stability, the product is compatible with the tested container materials.</td><td></td><td></td></tr>
<tr><td>Wettability</td><td>Not applicable</td><td></td><td>Not relevant: the bait will not be dispersed in water.</td><td>Acceptable</td><td></td></tr>
<tr><td>Suspensibility, spontaneity and dispersion stability</td><td>Not applicable</td><td></td><td>Not relevant: The bait will not be diluted prior to use.</td><td>Acceptable</td><td></td></tr>
<tr><td>Wet sieve analysis and dry sieve test</td><td>Not applicable</td><td></td><td>Not relevant: The bait is not a wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules, water soluble powders, dustable powders or granules</td><td>Acceptable</td><td></td></tr>
<tr><td>Emulsifiability, re-emulsifiability and emulsion stability</td><td>Not applicable</td><td></td><td>Not relevant: the bait is not an EC or ready to use emulsion.</td><td>Acceptable</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
Disintegration time	Not applicable		Not relevant: the bait is not a water soluble tablets or a water dispersible tablets formulation.	Acceptable	
Particle size distribution, content of dust/fines, attrition, friability	Not applicable		Not relevant: the bait is not a tablet, powder or granule.	Acceptable	
Persistent foaming	Not applicable		Not relevant: The bait will not be diluted with water before use.	Acceptable	
Flowability/Pourability/Dustability	Not applicable		Not relevant: the bait is not a granule or a suspension.	Acceptable	
Burning rate — smoke generators	Not applicable		Not relevant: the bait is not a smoke generator	Acceptable	
Burning completeness — smoke generators	Not applicable		Not relevant: the bait is not a smoke generator	Acceptable	
Composition of smoke — smoke generators	Not applicable		Not relevant: the bait is not a smoke generator	Acceptable	
Spraying pattern — aerosols	Not applicable		Not relevant: the product is a solid	Acceptable	
Physical compatibility	Not applicable		Not relevant. The product is not intended to be mixed with others products.	Acceptable	
Chemical compatibility	Not applicable		Not relevant. The product is not intended to be mixed with others products.	Acceptable	
Degree of dissolution and dilution stability	Not applicable		Not relevant: The bait will not be diluted with water before use.	Acceptable	
Surface tension	Not applicable		Not relevant: the product is a solid	Acceptable	
Viscosity	Not applicable		Not relevant: the product is a solid	Acceptable	

All the flexible packagings claimed (sacks and bags) will be protected by outer cartons during the transport. The product BRODITEC P-17F, thus, will be prevented from any physical stress caused by the effects of stacking: physico-chemical data on the biocidal product can be extrapolated from the packaging used in storage stability analysis. This was confirmed also by eCa in the pre-submission template.

In details, the following packs tested in storage stability studies sustain all the packaging for which we have applied (and listed in the relevant packaging section):
- Plastic LDPE bag (pack 1): the extrapolation have been done to all the plastic packaging in direct contact with the product.
- Metal can (pack 2): the product has been tested in order to demonstrate the stability of the product in direct contact with a metal container.

Thus, in conclusion the provided storage test for BRODITEC P-17F the tested packaging is considered to cover the whole range of packages applied for herewith.

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

Broditec P-17F is a ready to use light red paste with a characteristic odour. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
In aqueous solution (1% w/v aqueous dispersion), it has a pH value of 6.3 at 20°C. The relative density at 20°C is 1.1380g/mL.
There is no effect of temperature up to 35°C on the stability of the formulation since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed. The mitigation measure: "the biocidal product must be stored at temperature below 35°C." Is added to SPC

Based on the accelerated storage tests, the 2-year storage test and the efficacy data, a shelf life up to 2 years can be granted in the LDPE bag and the non-coated electrolytic tin plate metal can. Furthermore, the product contains a preservative.

As the formulation is a ready-to-use paste bait and as the stability was performed on LDPE bag and metal can packagings, the blister, the bucket/pot with or without inner liner, the box (carton)/carton box with the inner liner (or bag or the bait station envelopped in a polyolefin film) and the sack packagings can be considered as acceptable.

No data have been provided for the stability at light. The product should be store away from light.

Risk mitigation measure to be added:
Store the product at temperatures below 35°C.
Store the product away from light.

- **Minor change application (2024)**

New data were provided to support the change of the shelf life from 2 years to 3 years. Physico-chemical results are acceptable. Thus a shelf life of up to 3 years at ambient temperature can be granted when stored in commercial packaging.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
Explosives	UN Manual of Tests and Criteria: Part I: Classification procedures, test methods and criteria relating to explosives of Class 1 GLP	Brodifacoum 0.0017% w/w pasta Batch 090140	A test was performed to determine if the product presents exothermic reaction during DSC analysis in the temperature range used (room temperature to 600°C). One exothermic peak was observed approximatively at 240°C with an enthalpy difference of 276.6758 J/g. This exothermic decomposition energy is lower than 500 J/g and the onset of exothermic decomposition is below 500°C, therefore the product is not expected to have explosive properties.	Acceptable, the product is not explosive	Halbwachs P. (2019), Report No. 19-926005-001
Flammable gases	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not a gas	
Flammable aerosols	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not an aerosol	
Oxidising gases	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not a gas	
Gases under pressure	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not a gas	
Flammable liquids	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not a liquid	
Flammable solids	EC 440/2008 No. A.10	Brodifacoum 0.0017% w/w pasta Batch 090140	The test item sample is not highly flammable	Despite the performed test A10 instead of CLP criteria, the UN Test N.1, considering the composition, proposed test is acceptable.	Nichetti S. (2019), Report No. CH-0503/2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
				the product is not highly flammable	
Self-reactive substances and mixtures	DSC pretest		According to Regulation (EC) No 1272/2008, a mixture must be considered for classification in this hazard class unless its heat of decomposition is less than 300 J/g. As the exothermic decomposition energy is below this limit, the product is not a self reactive mixture.	Acceptable, the product is not a self-reactive mixture	Halbwachs P. (2019), Report No. 19-926005-001
Pyrophoric liquids	Not applicable		Not relevant: the product is a solid	Acceptable, the product is not a liquid	
Pyrophoric solids	Not required		Experience in manufacture or handling shows that the mixture does not ignite spontaneously on coming into contact with air at normal temperatures	Acceptable, the product is not a pyrophoric solid	
Self-heating substances and mixtures	ST/SG/AC.10/11 /Rev. 5 (2009), Part III, Section 33.3.1.6, Test N. 4	Brodifacoum 0.0017% w/w pasta Batch 090140	From the obtained experimental data test at 140°C for 24h, it can be concluded that the product is not classified as a self-heating mixtures	Acceptable, the product is not a self-heating mixture	Nichetti S. (2019), Report No. CH-0503/2019
Substances and mixtures which in contact with water emits flammable gases	Not required		The mixture contains no ingredients that are suspected to emit flammable gases in contact with water. Moreover, experience in production and handling shows that the mixture does not react with water.	Acceptable	
Oxidising liquids	Not applicable		Not relevant: the product is a solid.	Acceptable, the product is not a liquid	
Oxidising solids	Not required		There are no chemical groups that are associated with oxidizing properties, moreover, none of the ingredients possesses oxidising properties; therefore, the product is not expected to be oxidising.	Acceptable, the product is not a oxidising solid	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Evaluation FR	Reference
Organic peroxides	Not required		Based on the chemical structure of the components and their CLP classification, the product is not classified as organic peroxide.	Acceptable	
Corrosive to metals			Not applicable to solids	Acceptable	
Auto-ignition temperatures of products (liquids and gases)			Not applicable to solids	Acceptable	
Relative self-ignition temperature for solids	Not required		Applicant justification: None of the constituents of the bait have pyrophoric properties and self-heating properties. Moreover, the product is not classified as self-heating.	No data are available to set self ignition point of biocidal product. FR agrees that no special concern on the biocidal product is expected, however, for completion of the dossier, such measurement is required.	
Relative self-ignition temperature for solids	EEC A16	Brodifacoum 0.0017% w/w Pasta	Self-ignition point of biocidal product: 352°C	Acceptable.	Gledhill I. (2022), Report No. GLP3016012347R 1/2022

Conclusion on the physical hazards and respective characteristics of the product

The product BRODITEC P-17F is not explosive and has no oxidizing properties. The product is not flammable and is not a self-heating mixture.

- **Minor change application (2024)**

No change.

2.2.4 Methods for detection and identification

[Description of analytical methods used for the analysis of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product]

Report:	Nichetti S., 2019
Title:	Brodifacoum 0.0017% w/w pasta: Validation of the Analytical Method for the Determination of the Active Ingredient Content
Document No	CH-0504/2019
Test facility	ChemService S.r.l. Controlli e Ricerche GLP Studies Department Via Fratelli Beltrami, 15 20026 Novate Milanese (MI), Italy
Guidelines:	SANCO/3030/99 rev.5.
GLP	Yes

Materials and methods:
The determination of the active substance brodifacoum is performed by HPLC (Zorbax SB-Phenyl column, 5µm, 250 x 4.6 mm) using an external standard and UV detector (270nm). The quantification of the active ingredient is achieved by calculating its concentration in the final solutions in respect to a linear calibration obtained using the working standard solutions prepared starting from a reference material.

Conditions:
Eluent A: Water
Eluent C: Methanol
Eluent D: Acetic acid at 10% v/v
Elution gradient:
- From A:C:D=20:70:10 to C:D=90:10 in 25 minutes
- C:D=90:10 for 10 minutes;
- From C:D=90:10 to A:C:D=20:70:10 in 5 minutes.

Eluent flow: 1.1 mL/min
Temperature: 25°C

It is noted that the Brodifacoum retention time is strongly related to acid concentration and that lower concentrations causes increasing of the retention time.

The test item solution was prepared by weighing 15g of test item into a 100mL flask, followed by 50mL of diluting mixture (methanol:dichloromethane 40:60) and 1mL of formic acid.

Validation of the analytical method:

Specificity – Chromatograms of blank (diluting mixture), brodifacoum reference material, placebo, test item and fortified placebo were provided to determine the specificity of the method. The active ingredient peaks were well separated and interferences with placebo peaks were not evidenced. No interferences >3% of total peak area were detected for the active substance. It is concluded that the analytical method results are specific for the active ingredient in test item sample.

Linearity - To determine the linearity of the detector response, five working standard solutions ranging from 2.03 to 8.13 µg/mL (corresponding to active ingredient nominal content in formulation from 0.0007 to 0.0027% w/w) were prepared and analysed.
The range tested for the active ingredient was found to be linear (correlation coefficient r>0.99, Y = 569292*X-3896).

Repeatability (precision) – Five determinations of the test item were used to determine the precision. The mean value is 0.0018 % w/w with RSD =2.63 %.The Horrat value (RDS% / RSDr) resulted to be lower than 1 (=0.38) for the active ingredient and, therefore, the precision of the analytical method is considered acceptable.

Recovery – The recovery test was performed by spiking four aliquots of the placebo with the brodifacoum reference material at two levels in duplicate, corresponding to additions of 100% and 160% of the nominal concentration of active ingredient.
The mean recovery value (93.76%) complies with the range between 70% and 130% for active ingredient content lower than 0.01% w/w and, therefore, the recovery of the analytical method is considered acceptable.

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	n = 5 RDS% = 2.63 Horwitz RSDr = 6.92 Horrat value = 0.38 < 1	n = 5 2.03 - 8.13 µg/mL (corresponding to 0.0007 to 0.0027 % w/w) Correlation coefficient : r = 0.99988 > 0.99	The active ingredient peaks were well separated and interferences with placebo peaks were not evidenced. No interferences >3% of total peak area were detected	Two levels in duplicate corresponding to addition of 100% and 160%* of a.s	93.76	4.93	LOQ. = 0.000036% w/w	Nichetti S. (2019), Study No. CH-0504/2019

* The Spike C and D were prepared at 160% level respect to the nominal content of Brodifacoum active ingredient in the test item.

The analytical methods for the determination of residues of the active substance brodifacoum in soil, air, water, human and animal body fluids and tissues, in food and feeding stuff are considered to be completely covered by the active substance dossier (for which a LoA has been submitted).

Conclusion on the methods for detection and identification of the product

Analytical method for the determination of the active substance brodifacoum in the formulation is available and validated.

Based on the data provided, specificity, linearity, precision and accuracy were checked and found acceptable according the guideline SANCO/3030/99 rev.5.

Since the product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of bradifacoum residue in food/feed of plant and animal origin is not required.

- **Minor change application (2024)**

No change.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 03: Pest Control.
Product Type 14: Rodenticide.

BRODITEC P-17F is intended to be used indoor and outdoor around buildings, by non-professional and professional users.

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

According to the uses claimed by the applicant, the product BRODITEC P-17F (0.0017% w/w Brodifacoum) is a ready-for-use paste bait, intended to be used to control rodents. The target organisms to be controlled are *Mus musculus*, *Rattus norvegicus* and *Rattus rattus*.

The application rates recommended by the applicant are the following:
Mice:
- High infestation: 30-50 g of bait per baiting point separated by 2m.
- Low infestation: 30-50 g of bait per baiting point separated by 5m.

Rats:
- High infestation: 60-80 g of bait per baiting point separated by 5m.
- Low infestation: 60-80 g of bait per baiting point separated by 10m.

The products, organisms or objects to be protected are public and private buildings, and farms.

➢ **Minor change application (2024)**

The product BRODITEC P-17F2 (same as the product BRODITEC P-17F) was authorised for use against rats (*R. norvegicus* and *R. rattus*) and mice (*Mus musculus*) with a shelf life of 24 months.

The application rates validated are the following:
- Rats (*Rattus norvegicus* and *Rattus rattus*): 60-80 g secured bait points separated by 5-10 m.
- House mice (*Mus musculus*): 30-50 g secured bait points separated by 2-5 m.

In the frame of the minor change application, an increase in shelf-life from 24 to 36 months and changes in the composition of the product BRODITEC P-17F2 (0.0017 % w/w brodifacoum) are claimed by the applicant (please refer to the compositions in the confidential section of the PAR for further details).

2.2.5.3 Effects on target organisms, including unacceptable suffering

Anticoagulants rodenticides disrupt the blood-cutting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance for 2-3 days the

animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. As the active substance has a long acting action, death will usually occur within 3 to 11 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

2.2.5.4 Mode of action, including time delay

Brodifacoum acts as a vitamin K antagonist. It interferes with the regeneration of prothrombin disturbing the normal blood clotting mechanisms and increasing tendency to bleed.
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.
Brodifacoum works by blocking the regeneration of vitamin K 2,3-epoxide to vitamin K hydroquinone. Since, the amount of vitamin K in the body is finite; the progressive block of the regeneration of vitamin K will lead to an increasing probability of a fatal haemorrhage.

In laboratory tests with BRODITEC P-17F, death of target animals occurs within 8 days after ingestion.

2.2.5.5 Efficacy data

The applicant provided 6 efficacy trials (laboratory and field tests) conducted with BRODITEC P-17F (0.0017% w/w Brodifacoum) and are summarised hereafter.

In order to avoid unnecessary laboratory trials on vertebrates and, therefore, minimise the number of tests on animals, the laboratory choice tests were performed on the 3 years aged product. Indeed, the aged bait represents the worst case for testing the efficacy and palatability since:
-The active substance contained in the product may vary over time (by decreasing its concentration);
-The palatability of the product may decrease over time being the latter mainly made of food material.

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	Brodifacoum 0.0017% w/w Pasta Aged bait (36 months)	House mice (*Mus Musculus*) Wild strains 5 males 5 females	Laboratory test, choice feeding test	Acclimatization : 4 days in individual cage at room temperature Day 0 : reference food and bait biocidal product have been given: -10g of reference food for the assessment of palatability -10g of biocidal product during 4 consecutive days with daily consumption measurements. Mortality was observed every 24 hours until the death of all animals.	Palatability = 65,7% Mortality = 100% (max. 8 days) R.I = 1	[redacted]
PT14 rodenticide	In and around buildings	Brodifacoum 0.0017% w/w Pasta Aged bait (36 months)	Brown rat (*Rattus norvegicus*) Wild strains 5 males 5 females	Laboratory test, choice feeding test	Acclimatization : 4 days in individual cage at room temperature Day 0 : reference food and bait biocidal product have been given: -30g of reference food for the assessment of palatability -30g of biocidal product during 4 consecutive days with daily consumption measurements. Mortality was observed every 24 hours until the death of all animals.	Palatability = 65,72% Mortality = 100% (max. 8 days) R.I = 1	[redacted]
PT14 rodenticide	In and around buildings	Brodifacoum 0.0017% w/w Pasta Aged bait (36 months)	Roof rat (*Rattus rattus*) 5 males 5 females	Laboratory test, choice feeding test	Acclimatization : 4 days in individual cage at room temperature Day 0 : reference food and bait biocidal product have been given: -30g of reference food for the assessment of palatability -30g of biocidal product during 4 consecutive days with daily consumption measurements. Mortality was observed every 24 hours until the death of all animals.	Palatability = 58,9% Mortality = 100% (max. 8 days) R.I = 1	[redacted]

PT14 rodenticide	In and around buildings	Brodifacoum 0.0017% w/w Pasta (fresh product)	House mice (*Mus Musculus*)	Field test Cellar in residential home Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites.	Mixed age and sex population; Pre-treatment census: 10 days (30 g of semolina per station per day) Treatment: 30 g of bait per day in each lockable bait station (total 18 bait stations) during 18 days Post-baiting: 8 days (30 g of semolina per station per day) Efficacy assessment was based on consumption and tracking indices pre-trial to post-trial.	Estimated efficacy = 100 % Pre-baiting plateau = 180g/day Post-baiting = 0 g R.I = 1	[redacted]

PT14 rodenticide	In and around buildings	Brodifacoum 0.0017% w/w Pasta (fresh product)	Brown rat (*Rattus norvegicus*)	Field test in a farm Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.	Mixed age and sex population; Pre-treatment census: 14 days (60 g of wheat per station per day) Treatment: 60 g of bait per day in each lockable bait station (total 13 bait stations) during 21 days Post-baiting: 9 days (60 g of wheat per station per day) Efficacy assessment was based on consumption and tracking indices pre-trial to post-trial.	Estimated efficacy = 100 % Pre-baiting plateau = 760g/d Post-baiting = 0 g R.I = 1	[redacted]

PT14 rodenticide	In and around buildings	Brodifacoum 0.0017% w/w Pasta (fresh product)	Roof rat (*Rattus rattus*)	Field test in a farm Census baiting technique, which involved the following phases: Pre-treatment census Pre-treatment lag phase Treatment census Post-treatment lag phase Post-treatment census During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.	Mixed age and sex population; Pre-treatment census: 11 days (60 g of oat per station per day) Treatment: 60 g of bait per day in each lockable bait station (total 15 bait stations) during 29 days Post-baiting: 8 days (60 g of oat per station per day) Efficacy assessment was based on consumption and tracking indices pre-trial to post-trial.	Estimated efficacy = 100 % Pre-baiting plateau = 823g/d Post-baiting = 0 g R.I = 1	[redacted]

Conclusion on the efficacy of the product
French competent authorities (FR CA) considers that the elements presented in the dossier demonstrated the efficacy of the product BRODITEC P-17F (0.0017% w/w Brodifacoum) according to the uses and doses claimed. The product BRODITEC P-17F (0.0017% w/w Brodifacoum) has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and mice (*Mus musculus*), for use in and around buildings, by professionnal and non professional users. The validated application rates are the following: Rats (*Rattus norvegicus* and *Rattus rattus*): 60-80 g secured bait point separated by 5-10 m. Mice (M*us musculus*): 30-50 g secured bait point separated by 2-5 m.

➢ **Minor change application (2024)**

Considering that the differences between the old and new composition claimed in the frame of this minor change application for the product BRODITEC P-17F2 are slight, no influence on efficacy and palatability is expected. Therefore, results from the efficacy studies with the old formulation are considered as acceptable to support the efficacy of the new formulation.

In addition, please note that from an efficacy point of view, efficacy of the product BRODITEC P-17F2 with a shelf life of 36 months has already been demonstrated (choice tests) with the old formulation for all the target organisms claimed.

Conclusion on the efficacy of the product
The French competent authority (FR CA) assessed that the new formulation of the product BRODITEC P-17F2 has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*) and mice (*Mus musculus*) with a shelf life of 3 years. The application rates validated are the following: - Rats (*Rattus norvegicus* and *Rattus rattus*): 60-80 g secured bait points separated by 5-10 m. - House mice (*Mus musculus*): 30-50 g secured bait points separated by 2-5 m.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to the first generation anticoagulants has been widely reported in both Rattus norvegicus and Mus domesticus since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.
The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.
For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.
For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.
Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982[5]; Lund, 1984[6]; Pelz et al. 1995[7)]. The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988[8)]. The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b[9)].
Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

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

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

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

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

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

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone.
So, resistance to second generation anticoagulant rodenticides should not be minimized.
An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program "impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators").
The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.
The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.
The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.
To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

No limitations known.

2.2.5.8 Evaluation of the label claims

See Efficacy conclusion

- **Minor change application (2024)**

Please refer to the efficacy conclusion.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No acute oral, dermal and inhalation toxicity studies, neither skin and eye irritation studies nor skin sensitisation study have been submitted for the product BRODITEC P-17F.

Considering there are valid data available on the components in the mixture, classification of the product has been carried out according to the calculation rules laid down in the Regulation (EC) No 1272/2008 (CLP).
For the purpose of classification of the mixture, the harmonised classification (when available) and classification proposed in the provided MSDS have been used for active substances and co-formulants. For details, see the confidential annex.

An *in vitro* dermal absorption study performed with the BRODITEC P-17F formulation has been submitted.

No human data are available.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant to skin
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for skin irritation is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

- **Minor change application (2024)**

No impact.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant for eyes
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for eye irritation is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

- **Minor change application (2024)**

No impact.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for respiratory tract irritation is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

Data waiving	
Information requirement	Not applicable
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation. The assessment is based on the available data on the composition of the product and according to the classification rules laid down in the CLP Regulation.

➢ **Minor change application (2024)**
No impact.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for skin sensitisation is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

➢ **Minor change application (2024)**
No impact.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Justification for the value/conclusion	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for respiratory sensitization is required for the product BRODITEC P-17F.
Classification of the product according to CLP and DSD	No classification

Data waiving	
Information requirement	Not applicable
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitization. The assessment is based on the available data on the composition of the product and according to the classification rules laid down in the CLP Regulation.

➢ **Minor change application (2024)**

No impact.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not toxic by oral route
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for the acute toxicity by oral route is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not toxic by inhalation route
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for the acute toxicity by inhalation route is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not toxic by dermal route
Justification for the selected value	Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation (EC) No 1272/2008, no classification for the acute toxicity by dermal route is required for the product BRODITEC P-17F.
Classification of the product according to CLP	No classification

- **Minor change application (2024)**

No impact.

Information on dermal absorption

A percutaneous absorption study performed with a formulation named "BRODIFACOUM 0.0017% w/w in PASTA" was investigated using human skin *in vitro* method (OECD 428). The applicant indicates that this formulation corresponds to the BRODITEC P-17F formulation.
The study was performed with nine human abdominal skin membranes from 4 different donors without stretchmarks and with homogeneous thickness, during 8 hours and 24h of total observation. The pasta formulation is used as it is. The methanol, in which the brodifacoum was considered sufficiently soluble, was chosen for the receptor fluid.

According to the results of the study, less than 75% of the absorption occurs within half the duration of the study and the mean total recovery is 99.99% of the applied dose.

Thus, the dermal absorption is calculated as follow:

Dermal absorption = receptor fluid + receptor chamber washes + skin sample (including tape strips 3-20)[10].

[10] Guidance on dermal absorption, EFSA Journal 2017 ;15(6) :4873 (adopted :24 may 2017)

In accordance with the EFSA Guidance on dermal absorption (2017), a dermal absorption value of 6.1% was defined for the brodifacoum in the tested formulation (0.0017%). For calculation details, see excel file in Confidential annex.

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**
In vitro percutaneous absorption study, OECD TG 428 GLP: Yes Reliability: 1	Human abdominal skin membranes, nine skin samples, from 4 different, 8h exposure time, 24h of total monitoring period (including 16h post exposure sampling).	BRODIFACOUM 0.0017% w/w in PASTA formulation identical to the Broditec P-17F according to the applicant, Dose: 20 mg/cm2 = 80 mg/skin	Recovery [%] Mean SD Dislodgeable dose Skin wash after 24 hours 94,32 0,70 Donor chamber wash N/A N/A Skin associated dose Tape strips 1-2 0,09 0,04 Tape strips 3-7 0,05 0,02 Skin preparation 3,46 0,86 Absorbed dose Receptor fluid 2,05 0,67 Receptor chamber wash 0,03 0,03 Total recovery 99,99 0,01 Absorption complete? No Measured absorption, if LLC of t_0.5<=75% 5,58 0,69 Measured absorption corrected 5,58 0,69 Relevant absorption estimate 6,111 Final estimate (rounded) 6,1	Minor deviation: The dose of 20mg/cm^2 is above the recommendation of the OECD 428 TG. No impact on the dermal absorption value is expected.	De Servi, B. (2020) Report N. RS 63-19

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Brodifacoum 0.0017%
Value	6.1%
Justification for the selected value	Based on the *in vitro* dermal absorption study performed with the "BRODIFACOUM 0.0017% w/w in PASTA" formulation bait identical to the BRODITEC P-17F formulation (applicant data) and in accordance with the EFSA Guidance on dermal absorption (EFSA Journal 2017 ;15(6) :4873)

➢ **Minor change application (2024)**
No impact.

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

According to the definitions of a substance of concern set in the ”Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)”, BRODITEC P-17F does not contain any substance of concern.

Available toxicological data relating to a mixture

See confidential annex.

2.2.6.2 Exposure assessment and risk characterisation for human health

Please note that during the assessment, the applicant informed of the change of the technical content (0.0017% instead of 0.00171%).
The amendment was made in the active substance composition tables (in the PAR and in the Confidential annex of the PAR).
However, the technical value has not been changed in the assessment sections of the PAR, considering that the initial technical content is slightly worst case compared to the corrected value.”

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

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

The product BRODITEC P-17F is a ready-to-use paste bait rodenticide intended to be used by professional and non-professional users. The bait is packaged in paper bag of 10g and 15g in order to be applied as follow:

1. For mice control, the recommended dose is 30-50 g of bait every 2-5 meters.
2. For rats control, the recommended dose is 60-80 g of bait every 5-10 meters.

No inhalation is expected with the paste formulation.

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.	Primary dermal exposure during loading and cleaning phases	Primary dermal exposure The product is a ready-to-use product supplied in paste (in paper sachets); therefore exposure during loading and cleaning is considered.	Professional user
2.	Primary dermal exposure during loading and cleaning phases	Primary dermal exposure The product is a ready-to-use product supplied in paste (in paper sachets); therefore exposure during loading and cleaning is considered.	Non-professional user
3.	Ingestion of product by an toddler	Secondary exposure Oral exposure of toddler by ingestion of a piece of bait. Reverse scenario.	General public

Reference values to be used in risk characterization

Reference	Study	NOAEL	AF	Correction for absorption	Value
AELshort-term	Rabbit: Maternal toxicity from a Developmental study	0.002 mg/kg bw/d	300	no	6.7E-06 mg/kg bw/d
AELmedium-term	Rabbit: Maternal toxicity from a Developmental study	0.002 mg/kg bw/d	300	no	6.7E-06 mg/kg bw/d
AELlong-term	90-day oral rat toxicity study	0.001 mg/kg bw /d	300	no	3.3E-06 mg/kg bw/d

The estimated exposures are compared to the systemic $AEL_{long\text{-}term}$ and $AEL_{medium\ term}$ of brodifacoum set in AR (September 2016): 3.3×10^{-6} mg/kg bw/day and 6.7×10^{-6} mg/kg bw/day for professionals and non-professionals, respectively.

Industrial exposure

Not relevant.

Professional users

Scenario [1]

Description of Scenario [1]				
The product is a ready-to-use paste bait in paper sachet (10g to 15g). Application of sachets to bait stations and post-application consists of loading sachet in bait stations and cleaning of bait stations. According to the HEEG opinion 10[11], an exposure phase of 60 loadings and 15 cleanings is considered. Dermal exposure is based on the HEEG opinion 12[12]: Harmonised approach for the assessment of rodenticides. As a worst-case, the application dose of 80g for the use against rat considering paste of 10g is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered.				
	Parameters	Unit	Value	Sources
Tier 1	Amount of exposure to product (75th percentile) during loading	mg	27.79	HEEG opinion 12
	Amount of exposure to product (75th percentile) during clean-up	mg	5.7	HEEG opinion 12
	Manipulation per day	-	60 loading and 15 cleaning	HEEG opinion 10
	Dermal absorption value	%	6.1	Dermal absorption study
	Concentration of a.s in the product	%	0.0017	-
	Body weight	kg	60	-
	Size of handled sachets (smallest size)	g	10	Applicant's data
Tier 2	Default protection factor PPE: gloves	%	95	-

[11] HEEG opinion 10: Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants), agreed at TM III 2010, Ispra, 13/08/2010.

[12] HEEG opinion 12: Harmonised approach for the assessment of rodenticides (anticoagulants), agreed at TMII 2011, Ispra, 07/02/2012

Summary table: estimated systemic exposure and risk characterisation for professional users

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 3.3E-06 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario [1]	1/no PPE	n.a.	4.76E-05	n.a.	4.76E-05	1451	No
	2/gloves	n.a.	2.38E-06	n.a.	2.38E-06	72.5	Yes

Conclusion

The risk is acceptable for professionals when handling the product BRODITEC P-17F with gloves.

- **Minor change application (2024)**

The minor change implying a replacement of a non-active substance intentionally incorporated has no impact on the risk assessment for the human health.

Non-professional users

Scenario [2]

Description of Scenario [2]
The product is a ready-to-use paste bait in paper sachet (15g). Application of sachets to bait stations and post-application consists of loading sachet in bait stations and cleaning of bait stations. According to the HEEG opinion 10, an exposure phase of 5 loadings and 5 cleanings is considered. Dermal exposure is based on the HEEG opinion 12: Harmonised approach for the assessment of rodenticides. As a worst-case, the application dose of 80g for the use against rat considering paste sachets of 10g is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered.

	Parameters	Unit	Value	Source
Tier 1	Amount of exposure to product (75th percentile) during loading	mg	27.79	HEEG opinion 12
	Amount of exposure to	mg	5.7	HEEG opinion 12

	product (75th percentile) during clean-up			
	Manipulation per day	-	5 loading and 5 cleaning	HEEG opinion 10
	Dermal absorption value	%	6.1	Dermal absorption study
	Concentration of a.s in the product	%	0.0017	-
	Body weight	kg	60	-
	Size of handled sachets (smallest size)	g	15	Applicant's data

Summary table: estimated systemic exposure and risk characterisation for non-professional users

Summary table: estimated systemic exposure and risk characterisation for non-professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 6.7E-06 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario [2]	1/no PPE	n.a.	3.39E-06	n.a.	3.39E-06	50.7	Yes

Conclusion

The risk is acceptable for non-professionals when handling BRODITECH P-17F without PPE.

- **Minor change application (2024)**

The minor change implying a replacement of a non-active substance intentionally incorporated has no impact on the risk assessment for the human health.

Secondary exposure to general public

Scenario [3]

Indirect exposure can occur during handling of dead rodents by professionnal and general public. Due to unrealistic assumptions (TNsG on human exposure (2007)), this scenario is excluded and considered of low relevance.

However, exposure of non users can occur during ingestion of poison baits (by a toddler). For the scenario "oral exposure by ingesting bait", a worst-case reverse scenario was calculated. Based on the acute AEL of 6.7 x 10^{-6} mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 100%, ingestion of more than 3.92 mg of product per day by a toddler is needed to exceed the AEL.

The dermal exposure of non-users via dermal contact during bait transfer to the mouth is covered by the oral exposure scenario. It should be noted that the secondary risk assessment for the toddler (worst case for human health) covers the risk for the animal. The calculation indicates that toddlers are at significant risk of poisoning.

Therefore, even if products contain a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children (and non-target animals) triggering the following RMM: "Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals".
Product label ("do not open the sachet") and good practices advise users to prevent access to bait by children.

Monitoring data

None

Dietary exposure

Any exposure of food, drinking water or livestock exposure is not foreseeable. Thus, dietary exposure is considered as not relevant. Furthermore, the label needs to display the following risk mitigation measure:
Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

Maximum residue limits or equivalent

Product is not intended to come into contact with food or feeding stuffs, contamination of food and feeding stuff can be excluded.

Specific reference value for groundwater

None

Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is very unlikely since the product is not to be applied directly to food or feed but only at discrete sites in covered application and/or in bait boxes. Regarding consumer health protection, there are no objections against the intended uses. Furthermore, the label needs to display the following risk mitigation measure:

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

2.2.7 Risk assessment for animal health

The risk for the animal is covered by the risk for the general public and by the following RMM: "Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals."

2.2.8 Risk assessment for the environment

The product BRODITEC P-17F is a rodenticide paste formulation individually packaged in sachet containing 0.00171% w/w brodifacoum (0.0171 g/kg).

Please note that during the assessment, the applicant informed of the change of the technical content (**0.0017%** instead of 0.00171%). The amendment was made in the active substance composition tables (in the PAR and in the Confidential annex of the PAR). However, the technical value has not been changed in the assessment sections of the PAR, considering that the initial technical content is slightly worst case compared to the corrected value

No environmental substances of concern were identified for the product (no substances that classify the product for the environment, no biocidal substances from other PTs with a draft final CAR available, no ED or PBT, see the confidential annex) and no metabolites are formed that would need to be addressed in a risk evaluation for the environment. The following risk assessment is therefore carried out for the active substance only (Brodifacoum Renewal of approval AR, NL and IT, September 2016).

2.2.8.1 Effects assessment on the environment

No new environmental studies have been carried out with the product BRODITEC P-17F. All data pertaining to the active substance are therefore derived from the revised AR of brodifacoum (Renewal of approval, NL and IT, September 2016) and AR of October 2010.

Summary table on PNEC values of Brodifacoum					
Compartments		**Parameters**	**Values**	**Units**	**Reference**
Aquatic		$PNEC_{STP}$	3.80E-03	[mg/L]	AR October 2010
		$PNEC_{water}$	4.00E-05	[mg/L]	
Terrestrial		$PNEC_{soil}$	8.80E-01	[mg/kg_{ww}]	
Primary and secondary poisoning	**Acute**	$NAET_{birds,\ TIER\ I}$	8.27E-03	[mg/kg food]	Calculated according the revised ESD for PT14 (2018) – see explanations below
		$NAET_{mammals,\ TIER\ I}$	2.67E-02	[mg/kg food]	
		$NAET_{birds,\ TIER\ II}$	1.03E-03	[mg/kg bw]	
		$NAET_{mammals,\ TIER\ II}$	1.33E-03	[mg/kg bw]	
	Chronic	$PNEC_{oral,birds,\ TIER\ I}$	1.27E-04	[mg/kg food]	AR October 2010
		$PNEC_{oral,mammals,\ TIER\ I}$	2.22E-04	[mg/kg food]	
		$PNEC_{oral,birds,\ TIER\ II}$	1.28E-05	[mg/kg bw]	
		$PNEC_{oral,mammals,\ TIER\ II}$	1.10E-05	[mg/kg bw]	

$PNEC_{sediment}$:

A $PNEC_{sediment}$ was derived through the Equilibrium Partitioning Method in the AR of Brodifacoum. According to the Guidance of BPR Volume IV Part B+C (2017) and considering the log Kow > 5, the PEC/PNEC ratio for the aquatic compartment is increased by a factor of 10 to take into account the possible additional uptake via sediment ingestion. Therefore, the PEC values are not calculated and the risk ratios for surface water are used to derive the risk for sediment using a factor of 10.

Primary and secondary poisoning:

Acute/chronic poisoning:
In the revised ESD for PT14 (2018), a quantitative approach is proposed for acute and chronic exposure of non-target organisms. Since the $PNEC_{oral}$ is generally based on chronic effect concentrations, another threshold values were defined for the acute poisoning situation, named "NAET", or "No acute Effect Threshold". It was proposed to derive NAET values for birds and mammals:

- A LD_{50} of 0.31 mg/kg bw is available on duck and thus, a **$NAET_{birds}$ of 1.03E-03** (=0.31/300) **mg/kg bw** is calculated.
- A LD_{50} of 0.4 mg/kg bw is available on rat and therefore, a **$NAET_{mammals}$ of 1.33E-03** (=0.4/300) **mg/kg bw** is calculated.

Tier I calculations:
In Tier I, the PEC_{oral} represents the concentration of the active substance in bait (for primary poisoning) or the concentration in the rodent/slug eaten by the predator/scavenger (for secondary poisoning) in mg/kg food.
Therefore, this value should be compared with a NAET (for acute poisoning) or $PNEC_{oral}$ (for chronic poisoning) converted in mg/kg food. In the Volume IV Part B+C (2017), such conversion is possible for birds and mammals according to equations 96 and 97:

$$NOEC_{birds/mammals} \text{ (in mg/kg food)} = NOAEL_{birds/mammals} \text{ (in mg/kg bw/d)} \times CONV_{bird/mammals}$$

Therefore, for Brodifacoum:

Parameters	**Values**
$NAET_{birds}$ (in mg/kg bw/d)	1.03E-03
$CONV_{birds}$	8 (reference for *Gallus domesticus,* as no value is available for mallard duck)
$NAET_{birds}$ (in mg/kg food)	**8.27E-03 mg/kg food**
$NAET_{mammals}$ (in mg/kg bw/d)	1.33E-03
$CONV_{mammals}$	20 (*Ratus norvegicus* > 6 weeks)
$NAET_{mammals}$ (in mg/kg food)	**2.67E-02 mg/kg food**

Tier II calculations:
In Tier II, the PEC_{oral} are in mg/kg bw, therefore, they can be compared with NAET/PNECoral calculated in mg/kg bw.

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

Brodifacoum is classified H400/H410, with M factors of 10 for acute and chronic classifications (Renewal of approval, NL and IT, September 2016) and no substance of concern has been identified for the environment (see confidential annex). Considering the concentration of the active substance (0.00171%) and its classification, the product BRODITEC P-17F is not classified for the environment according to Regulation (EC) No.1272/2008 (CLP).

Further Ecotoxicological studies

No new ecotoxicological studies have been carried out with the product BRODITEC P-17F.

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

Data waiving	
Information requirement	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk.

Justification	Available ecotoxicity data on the active substance and the co-formulant are considered sufficient to assess the toxicity of the product. ⇨ Based on this assessment, no additional ecotoxicological study with the product was conducted to address this point.

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

Data waiving	
Information requirement	Supervised trials to assess risks to non-target organisms under field conditions.
Justification	This endpoint relevant as the product is in the form of baits. However, available ecotoxicity data on the active substance are considered sufficient to assess the toxicity of the product. ⇨ Therefore, no additional study is deemed necessary to address this point.

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

Data waiving	
Information requirement	Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk.
Justification	This endpoint relevant as the product is in the form of baits. However, available ecotoxicity data on the active substance are considered sufficient to assess the toxicity of the product. ⇨ Therefore, no additional study is deemed necessary to address this point.

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

No data available.

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

According to the intended uses (application against mice and rats in and around buildings), two types of releases are taken into account:

- Direct releases to soil (including groundwater),
- Direct releases to surface water (including sediments)

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

No data available.

Leaching behaviour (ADS)

No data available.

Testing for distribution and dissipation in soil (ADS)

No data available.

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

No data available.

Testing for distribution and dissipation in air (ADS)

No data available.

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

Data waiving	
Information requirement	Overspray study to assess risks to aquatic organisms or plants under field conditions.
Justification	The product BRODITEC P-17F is a solid bait and will not be sprayed. ⇨ Based on this assessment, no additional study with the product was conducted to address this point.

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

Data waiving	
Information requirement	Overspray study to assess risks to bees and non-target arthropods under field conditions.
Justification	The product BRODITEC P-17F is a solid bait and will not be sprayed. ⇨ Based on this assessment, no additional study with the product was conducted to address this point.

2.2.8.2 Exposure assessment

The product BRODITEC P-17F is a rodenticide paste formulation individually packaged in sachet containing 0.00171% w/w brodifacoum (CAS n° 56073-10-0) and placed in secured bait box, in covered and protected baiting points or directly in burrows. The product is used at a maximum of 50 g for mouse and 80 g for rat / bait point. The following table is a summary of the claimed uses.

Claimed uses	Field of use	Targets	Covered by
Use 1	Indoor (general public)	Mice	Use 2
Use 2	Indoor (general public)	Rats	Scenario 1.b (on rats)
Use 3	Outdoor - Around building (general public)	Rats	Use 7
Use 4	Indoor (professional)	Mice	Use 2
Use 5	Indoor (professional)	Rats	Use 2
Use 6	Outdoor - Around building (professional)	Mice/rats	Use 7
Use 7	Indoor (trained professional)	Mice/rats	Use 2
Use 8	Outdoor - Around building (trained professional)	Mice/rats	Scenario 1.a (on rats) / Scenario 2 / Scenario 3

Scenario 1.a: Around buildings - Emission to soil due to use around building on unpaved ground,
Scenario 1.b: Indoor - Emission to soil due to the use in building and emission to soil via rat carcasses, urine and faeces,
Scenario 2: Open area,
Scenario 3: Bank slopes.

General information

Assessed PT	PT 14
Assessed scenarios	Scenario 1: In and around building, Scenario 1.a: Around buildings - Emission to soil due to use around building on unpaved ground, Scenario 1.b: Indoor - Emission to soil due to the use in building and emission to soil via rat carcasses, urine and faeces, Scenario 2: Open area, Scenario 3: Bank slopes.
ESD(s) used	Revised Emission Scenario Document for Product Type 14: Rodenticides, August 2018
Approach	Scenario 1: Consumption based Scenario 2: Consumption based Scenario 3: Consumption based
Distribution in the environment	Calculated based on Guidance for BPR IV Part B+C (2017). Assessment report: Brodifacoum (Renewal of approval, NL and IT, September 2016) Technical Agreements for Biocides of February, 2021
Groundwater simulation	Yes (FOCUS v4.4.4)
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1/2/3: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

The local emissions for each scenario were assessed according to the Revised Emission Scenario Document for Product Type 14: Rodenticides, August 2018. Updates of the Technical agreement for Biocides (February, 2021) were also taken into account.

Worst-case target and packaging of product:
For the product BRODITEC P-17F, the highest emissions to the environment is due to the treatment of rats with bulk solid baits. Therefore, for every scenario, only these worst-case situations are assessed.

Scenario 1: In and around building

Scenario 1.a: Around building - Emission to soil due to use around building on unpaved ground

The following input parameters are used to calculate the local emissions to soil.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 1.a: Exposure scenario in and around building - Emission to soil due to use around building on unpaved ground				
Worst-case rodent to be controlled	-	Rats	[-]	S
Type of bait formulation (worst-case)	-	Bagged baits	[-]	S
Amount of product used at each refill for one bait station/box	Q_{prod}	80	[g]	S
Fraction of substance in product	$Fc_{product}$	1.71E-05	[-]	S
Number of application sites	N_{sites}	10	[-]	D
Number of applications (initial baiting+refillings)	N_{appl}	5	[-]	D
Fraction of substance released directly to soil	$F_{release\text{-}D,soil}$	0.01	[-]	D – bagged bait
Fraction of substance metabolised	F_{metab}	0	[-]	D
Fraction of substance released indirectly to soil	$F_{released\text{-}ID,soil}$	0.9	[-]	D
Soil area exposed directly	$AREA_{exposed\text{-}D}$	0.09	[m²]	D
Soil area exposed indirectly	$AREA_{exposed\text{-}ID}$	550	[m²]	D
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Output				

Local direct emission of substance to soil from a campaign	**$Elocal_{soil\text{-}D\text{-}campaign}$**	**6.84E-05**	[g]	O
Local indirect emission of substance to soil from a campaign	**$Elocal_{soil\text{-}ID\text{-}campaign}$**	**6.16E-02**	[g]	O
Elocal total (Tier II)	**$Elocal_{total\ Tier\ II}$**	**6.22E-02**	[g]	**Nsites x $Elocal_{soil\text{-}D}$ + $Elocal_{soil\text{-}ID}$**

The total concentration resulting from Indirect + Direct emissions will be presented as it is proposed in the ESD (Tier I). The refined total concentration (Tier II), resulting from Indirect and Direct emissions emitted to the entire zone indirectly exposed (550 m²) will be also presented as this seems more relevant for groundwater and secondary poisoning via the terrestrial compartment.

Scenario 1.b: Indoor - Emission to soil due to the use in building and emission to soil via rat carcasses, urine and faeces

The following input parameters are used to calculate the local emissions to soil.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 1.b: Emission to soil due to the use in building and emission to soil via rat carcasses, urine and faeces				
Type of bait formulation	-	Solid baits	[-]	S
Amount of product used at each refill for one bait station/box (solid bait)	Q_{prod}	80	[g]	S
Fraction of substance in product	$Fc_{product}$	1.71E-05	[-]	S
Number of application sites	N_{sites}	44*	[-]	O - considering an interval of 5 m
Number of applications (initial baiting+refillings)	N_{appl}	5	[-]	D
Fraction of substance metabolised	F_{metab}	0	[-]	D
Fraction of substance released indirectly to soil	$F_{release\text{-}ID,soil}$	0.5	[-]	D
Soil area exposed indirectly to soil	$AREA_{exposed\text{-}ID,soil}$	1800	[m²]	D
Depth of exposed soil	$DEPTH_{soil}$	0.1	[m]	D
Output				

Local indirect emission of substance to soil from a campaign	**$Elocal_{soil\text{-}ID\text{-}campaign}$**	**1.50E-01**	[g]	O

*Nsite value for an application of baits every 5 m: 220 m / 5.

Scenario 2: Open area

The ESD scenario for open areas calculates emissions from rodenticide application into rat burrows or secured bait box. Only application in burrow is presented as the application in bait stations is covered by the use around building (scenario 1.a).

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2: Exposure scenario for open area				
Type of bait formulation (worst-case)	-	Loose solid baits applied in rodent burrow*	[-]	S
Amount of product applied in one cesspool	Q_{prod}	80	[g]	S
Fraction of substance in product	$Fc_{product}$	1.71E-05	[-]	S
Number of application sites	N_{site}	1	[-]	D
Number of applications	N_{appl}	3	[-]	D
Fraction of active ingredient released directly	$F_{release\text{-}D,soil}$	0.05	[-]	D
Fraction of substance released directly to soil during use	$F_{release\text{-}D,\ soil,\ use}$	0.2	[-]	D
Radius of exposed soil around the hole	R	0.14	[m]	D
Radius of hole	r	0.04	[m]	D
Length of exposed hole	l	0.3	[m]	D
Soil volume exposed to rodenticide	$V_{soilexposed}$	8.48E-03	[m^3]	O $V_{soilexposed} = (R^2 - r^2) \times \Pi \times l / 2$
Output				
Local direct emission rate to soil from a campaign	**$Elocal_{soil\text{-}D}$**	**1.03E-03**	[g]	O

*As the scenario for bagged solid baits applied in rodent burrow does not exist in the ESD, the worst case scenario for the application of loose bait is applied.

Scenario 3: Bank slopes

As the use "in and around buildings" is claimed, the scenario "Bank slope" is also evaluated (TAB, February, 2021, ENV180).

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3: Exposure scenario for bank slopes:				
Amount of product used at each application for one bait station/box	Q_{prod}	80	[g]	S
Fraction of substance in product	$Fc_{product}$	1.71E-05	[-]	S
Number of application sites	N_{sites}	202*	[-]	O
Number of applications	N_{appl}	1	[-]	D
Fraction of substance released directly to water	$F_{release-D,water}$	0.4	[-]	D
Water volume of channel	$V_{channel}$	450000	[L]	D
Output				
Local direct emission of substance to water	**$Elocal_{water-D-}$**	**1.11E-01**	[g]	O

*Considering a bait point every 5 m, on both side of a channel segment of 500 m, with a distance of 100m (ESDPT14, 2018)

Fate and distribution in exposed environmental compartments

	STP	Freshwater	Sediment	Soil	Ground-water	Secondary poisoning
Scenario 1.a: In and around building (Outdoor application)	-	-	-	++	+	+
Scenario 1.b: In and around building (Indoor application)	-	-	-	++	+	+
Scenario 2: Open areas				++	+	+
Scenario 3: Bank slopes	-	++	+	-	-	+

++: direct exposure *+: indirect exposure* *-: no exposure*

Input parameters for calculating the fate and distribution of the active substance in the environment were selected from the revised Brodifacoum assessment report (2016).

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	523.4	g/mol	AR Brodifacoum (2016)
Vapour pressure (at 20°C)	1E-06	Pa	AR Brodifacoum (2016)
Water solubility (at 20°C)	5.80E-02	mg/L	AR Brodifacoum (2016)
Log Octanol/water partition coefficient	6.12	Log 10	AR Brodifacoum (2016)
Organic carbon/water partition coefficient (Koc)	9155	L/kg	AR Brodifacoum (2016)
Biodegradability	Not readily biodegradable		AR Brodifacoum (2016)
DT_{50} for degradation in soil	298	d (at 12ºC)	AR Brodifacoum (2016)
BCF_{fish}	35645	L/kg_{ww}	AR Brodifacoum (2016)
$BCF_{earthworms}$	15820	L/kg_{ww}	AR Brodifacoum (2016)
BMF	10	-	AR Brodifacoum (2016)

The fractioning of the actives substance between air, water, sludge and degradation is indicated in the following table.

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	0.04282	Simple Treat v4.0, considering a concentration suspended solids effluents (Css) of 30 mg/L or 0.03 kg/m^3 (TAB 2019, ENV9)
Water	47.50	
Sludge	52.49	
Degraded in STP	0	

2.2.8.3 Calculated PEC values

A summary of the calculated PEC values for each scenario and each environmental compartment is indicated in the following table.
For scenario 1.a, the Total concentration resulting from Indirect + Direct emissions is presented as it is proposed in the ESD (Tier I). The refined Total concentration (Tier II), resulting from Indirect and Direct emissions emitted to the entire zone indirectly exposed (550 m²) is also presented as this seems more relevant for groundwater and secondary poisoning via the terrestrial compartment.

Elocal and PEC values summary						
		Elocal [g/campaign]	**PEC_{STP}** [mg/L]	**PEC_{water*}** [mg/l]	**PEC_{soil}** [mg/kg ww]	**PEC_{GW**}** [µg/l]
Scenario 1.a: In and around building (Outdoor application)	Direct emissions	6.84E-05	-	-	4.47E-03	2.77E-02
	Indirect emissions	6.16E-02	-	-	6.58E-04	4.07E-03
	Total Tier I	-	-	-	5.13E-03	**3.17E-02**

	Total Tier II	6.22E-02	-	-	6.66E-04	4.12E-03
Scenario 1.b: In and around building (Indoor applications)		1.50E-01	-	-	4.92E-04	3.04E-03
Scenario 2: Open areas		1.03E-03	-	-	7.12E-02	**4.40E-01**
Scenario 3: Bank slopes		1.11E-01	-	2.46E-04	-	-

*$PEC_{sediment}$: A $PNEC_{sediment}$ was derived through the Equilibrium Partitioning Method in the AR of Brodifacoum. According to the Guidance of BPR Volume IV Part B+C (2017) and considering the log Kow > 5, the PEC/PNEC ratio for the aquatic compartment is increased by a factor of 10 to take into account the possible additional uptake via sediment ingestion. Therefore, the PEC values are not calculated and the risk ratios for surface water are used to derive the risk for sediment using a factor of 10.

PEC_{GW}: Considering the very low AEL derived during the substance assessment of Brodifacoum, much lower threshold value for groundwater is considered (0.03 µg/L**) to prevent risks for humans via contaminated water (France proposal for specific References Values in groundwater for rodenticides, December 2012). For scenarios that leads to emissions to groundwater and for which the resulting groundwater concentrations are higher than the threshold value (in **bold** in the table above), the FOCUS groundwater model PEARL (version 4.4.4) is used as a refinement and output are presented below.

Groundwater refinements ($FOCUS_{GW}$, version 4.4.4)

Complete scenarios for calculating the application rates values to be used in FOCUS 4.4.4 are available in the Revised ESD for PT14 (2018). Input and results are presented are presented in the Tables below.

- For scenario 1, emissions indoor (1.b) and outdoor (1.a) are considered as they could be part of the same campaign.
- Although scenarios 1.a does not lead to emissions above the threshold value of 0.03 µg/L when the calculation is refined, FOCUS was used considering the Tier I concentrations values in groundwater for completeness.

Emissions to Groundwater : Input for refinement (FOCUS PEARL 4.4.4)		
Input parameters related to the Active Substance		
	Value	**Reference**
Molecular weight (g/mol)	523.4	AR (Brodifacoum, 2018)
Water solubility (g/l) at 20°C	5.80E-05	
Koc (L/kg)	9155	
Saturated vapour pressure (Pa) at 20°C	1E-06	
DT50 in soil (d) at 12°C	298	
Kom (=Koc/1.724) (L/kg)	5310.3	
1/n	1	
Plant uptake factor	0	ESDPT14 (2018)
Molar activation energy (kJ/mol)	65.4	WG-IV-2019
Input parameters related to the Scenarios		

Scenario	Scenario 1: In and around building	Scenario 2: Open areas	ESDPT14 (2018)
Targets	Rats		
Devices	Bagged baits in bait stations	Bagged baits in burrows	
Crop type	Grassland (alfalfa)		
Application type	Surface application		
Number of applications site per ha (/ha)	110	100	
Application rate from one application per ha (kg a.s/ha)	2.12E-04	3.42E-5	
Application time	On day 1, 3, 7, 14, 21 of the control campaign: September: 15th, 17th, 21th, 28th, October: 5th	On day 1, 3 and 8 of control campaign, two campaigns per year: March: 15th, 17th, 22th September: 15th, 17th, 22th	

The resulting groundwater concentrations are lower than the threshold value of 0.03 µg/L (See the tables below).

Emissions to Groundwater : PEC_{gw} in µg Brodifacoum/L, (FOCUS PEARL 4.4.4)		
Output		
Scenarios	Scenario 1: In and around building	Scenario 2: Open areas
CHATEAUDUN	0	0
HAMBURG	0	0
JOKIOINEN	0	0
KREMSMUENSTER	0	0
OKEHAMPTON	0	0
PIACENZA	0	0
PORTO	0	0
SEVILLA	0	0
THIVA	0	0

Primary and secondary poisoning

As outdoor uses such as in scenarios "In and around building", "Open area", "Waste dumps" are claimed, both primary and secondary poisoning are relevant (Table 40 from the Revised ESD for PT14, 2018).

Primary poisoning

Non-target birds and mammals may encounter bait containing brodifacoum if they are small enough to be able to reach the bait, or because the bait is inadequately safeguarded or a secured bait point has become damaged, or by finding pieces of bait which have been removed by target rodents. The scenarios assessed are taken from the Revised ESD for PT14 (2018) and the worst-case concentration of active substance in the bait (17.10 mg/kg) is used in the calculations.

TIER I (acute/chronic)
In Tier I, it is assumed that the whole day's food requirement of the non-target species consists in the consumption of the rodenticide. Avoidance is not considered to be relevant. Therefore, the concentration in the food is the same as the concentration of the active substance in the bait.
Tier 1 PEC_{oral} = 1.71E+01 mg/kg food

TIER II
In Tier II, a more realistic feeding behaviour of defined generic focal species is taken into account, considering parameters such as their food intake rate (FIR), the fraction of diet obtained in the treated area (PT), an avoidance factor…

- For acute poisoning: Risk is quantified using the estimated daily intake of a compound (ETE) by general focal species,
- For chronic poisoning: Risk is quantified using the estimated intake of a compound for 5 consecutive days (immediately after the last meal).

Input parameters for calculating the PEC values (Primary poisoning, Tier I and Tier II)				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Primary poisoning: Acute/Chronic PEC calculations				
Concentration of the active substance (bait)	C	17.10	[mg/kg]	S
Avoidance factor	AV	1	[-]	D
Fraction of diet obtained in treated area	PT	1	[-]	D
Composition of diet obtain from treated area	PD	1	[-]	D
ADME factor	ADME	0	[-]	D
Number of days the not-target species is consuming rodenticide baits	n	1 to 4	[-]	D
Food intake rate: -House sparrow -Shrew	FIR	 0.23 0.55	[g/g bw per day]	D

-Woodpigeon		0.1		
Rodenticide product consumption: -Dogs -Young pigs	RPC	0.06 0.024	[g/g bw per day]	D
Output				
Primary poisoning – Tier I				
Acute - Concentration of the active substance (bait)	$PEC_{oral,\ acute}$	1.71E+01	[mg/kg food]	O $PEC_{oral,\ acute}$ = C
Chronic - Concentration of the active substance (bait)	$PEC_{oral,\ chronic}$	1.71E+01	[mg/kg food]	O $PEC_{oral,\ chronic}$ = C
Primary poisoning – Tier II				
Acute - Estimated daily uptake of a compound (=$PEC_{oral,acute}$):				
House sparrow	ETE	3.93E+00	[mg/kg bw]	O
Shrew	ETE	9.41E+00	[mg/kg bw]	O
Woodpigeon	ETE	1.71E+00	[mg/kg bw]	O
Dogs	ETE	1.03E+00	[mg/kg bw]	O
Young Pigs	ETE	4.10E-01	[mg/kg bw]	O
Chronic - Expected concentration of an active substance in the non-target species on day 5 immediately after the 5th meal (=$PEC_{oral,chronic}$):				
House sparrow	$PEC_{oral,5-d}$	1.97E+01	[mg/kg bw]	O
Shrew	$PEC_{oral,5-d}$	4.70E+01	[mg/kg bw]	O
Woodpigeon	$PEC_{oral,5-d}$	8.55E+00	[mg/kg bw]	O
Dogs	$PEC_{oral,5-d}$	5.13E+00	[mg/kg bw]	O
Young Pigs	$PEC_{oral,5-d}$	2.05E+00	[mg/kg bw]	O

Secondary poisoning

Different types of secondary poisoning are considered in the Revised ESD for PT14 (2018):

- From consuming primarily exposed target and non-target organisms (Secondary poisoning - Tier I).
- From consuming secondary exposed non-target organisms (Secondary poisoning - Tier II).
- From consuming organisms (terrestrial or aquatic) that have been exposed to rodenticides via emissions to the environment (Secondary poisoning via environmental emissions).

    - Secondary poisoning via contaminated rodents and slugs Tier I and II

For secondary poisoning (Tier I and II), the worst-case concentration of active substance in the bait (17.10 mg/kg) is used in the calculations. Scenarios taken from the Revised ESD for PT14 (2018) are assessed below.

Input parameters for calculating the PEC values (Secondary poisoning Tier I and II)				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Secondary poisoning Tier I and II, Acute/Chronic PEC calculations:				
Concentration of the active substance (bait)	C	17.10	[mg/kg]	S
Avoidance factor	AV	1	[-]	D
Fraction of diet obtained in treated area	PT	1	[-]	D
Composition of diet obtain from treated area	PD	1	[-]	D
ADME factor	ADME	0	[-]	D
Number of days the not-target species is consuming rodenticide baits	n	1 to 4	[-]	D
Food intake rate / body weight rodent	FIR/BW_{rodent}	0.1	[-]	D
Food intake rate / body weight slug	FIR/BW_{slug}	0.4	[-]	D
Fraction of poisoned rodents in predators' diet	$Frodent_{acute}$	1	[-]	D
Fraction of poisoned slugs in predators' diet	$Fslug_{acute}$	1	[-]	D
Fraction of poisoned rodents in predators' diet	$Frodent_{chronic}$	0.5	[-]	D
Fraction of poisoned slugs in predators' diet	$Fslug_{chronic}$	0.5	[-]	D
Intermediate calculations				
Concentration in food (rodent) after one day	$C_{food,rodent}$	1.71E+00	[mg/kg food/d]	O
Concentration in food (slug) after one day	$C_{food,slug}$	6.84E+00	[mg/kg food/d]	O
Output				
Secondary poisoning – Tier I				
Acute - Predicted environmental concentration of an active substance in food of a predator/scavenger:				
If the food is a rodent	$PEC_{oral,rodent\ acute}$	8.55E+00	[mg/kg food]	O
If the food is slugs	$PEC_{oral,slug,\ acute}$	3.42E+01	[mg/kg food]	O

Chronic - Predicted environmental concentration of an active substance in food of a predator/scavenger:				
If the food is a rodent	$PEC_{oral,rodent\ chronic}$	4.28E+00	[mg/kg food]	O
If the food is slugs	$PEC_{oral,slug,\ chronic}$	1.71E+01	[mg/kg food]	O
Secondary poisoning – Tier II				
Acute - Predicted environmental concentration of an active substance in a rodent predator:				
Barn owl (*Tyto alba*)	$PEC_{oral,rodent,birds,\ acute}$	2.14E+00	[mg/kg bw/d]	O
Kestrel (*Falco tinnunculus*)	$PEC_{oral,rodent,birds,\ acute}$	3.25E+00	[mg/kg bw/d]	O
Carrion crow (*Corvus corone*)	$PEC_{oral,rodent,birds,\ acute}$	2.39E+00	[mg/kg bw/d]	O
Red fox (*Vulpes vulpes*)	$PEC_{oral,rodent,mammals,\ acute}$	8.55E-01	[mg/kg bw/d]	O
Weasel (*Mustela nivalis*)	$PEC_{oral,rodent,mammals,\ acute}$	3.33E+00	[mg/kg bw/d]	O
Domestic cat (*Felix silvestris catus*)	$PEC_{oral,rodent,mammals,\ acute}$	4.28E-01	[mg/kg bw/d]	O
Shrew (*Sorexp ssp*)	$PEC_{oral,slug,mammals,\ acute}$	1.88E+01	[mg/kg bw/d]	O
European starling (*Sturnus vulgaris*)	$PEC_{oral,slug,birds,\ acute}$	2.15E+01	[mg/kg bw/d]	O
Chronic - Predicted environmental concentration of an active substance in a rodent predator:				
Barn owl (*Tyto alba*)	$PEC_{oral,rodent,birds,\ chronic}$	1.07E+00	[mg/kg bw/d]	O
Kestrel (*Falco tinnunculus*)	$PEC_{oral,rodent,birds,\ chronic}$	1.62E+00	[mg/kg bw/d]	O
Carrion crow (*Corvus corone*)	$PEC_{oral,rodent,birds,\ chronic}$	1.20E+00	[mg/kg bw/d]	O
Red fox (*Vulpes vulpes*)	$PEC_{oral,rodent,mammals,\ chronic}$	4.28E-01	[mg/kg bw/d]	O
Weasel (*Mustela nivalis*)	$PEC_{oral,rodent,mammals,\ chronic}$	1.67E+00	[mg/kg bw/d]	O
Domestic cat (*Felix silvestris catus*)	$PEC_{oral,rodent,mammals,\ chronic}$	2.14E-01	[mg/kg bw/d]	O
Shrew (*Sorexp ssp*)	$PEC_{oral,slug,mammals,\ chronic}$	9.41E+00	[mg/kg bw/d]	O

European starling (*Sturnus vulgaris*)	$PEC_{oral,slug,birds,\ chronic}$	1.08E+01	[mg/kg bw/d]	O

- Secondary poisoning via the environment

Secondary poisoning via the food chain earthworms-non target mammals or birds is calculated considering PEC values of scenarios where soil compartment exposure are foreseen (scenarios 1.a, 1.b, 2 and 3). Secondary poisoning via the food chain fish-non target mammals or birds is calculated considering PEC values of scenarios where aquatic compartment exposure are foreseen (scenario 4). For these scenarios, $PEC_{oral,predator}$ for soil and surface water are calculated according to Volume IV Part B+C (2017) equations and it is considered that 50% of the diet comes from a local area and 50% comes from the regional area. Thus, when the $PEClocal_{soil}$ is used in calculation, the $PEC_{oral,predator,soil}$ to be used in risk assessment is x 0.5.

Input parameters for calculating the PEC values (Secondary poisoning via the environment)			
Input	**Symbol**	**Value**	**Unit**
Secondary poisoning *via* surface water contamination:			
Bioconcentration factor for fish on wet weight basis	BCF fish	35645	[L/kg wet fish]]
Biomagnification factor in fish	BMF	10	[-]
Fraction of diet sourced locally	$F_{diet,local}$	0.5	[-]
Secondary poisoning *via* soil contamination:			
Bioconcentration factor for earthworms on net weight basis	BCF worms	15820	[L/kg wet earthworms]
Conversion factor for soil concentration wet-dry weight soil	CONVsoil	1.13	[kg ww/kg dw]
Fraction of gut loading in worm	Fgut	0.1	[kg dw/kg ww]
Fraction of diet sourced locally	$F_{diet,local}$	0.5	[-]
Output for Secondary poisoning via soil/water contamination:			
Scenarios		**$PEC_{oral,predator,SW}$** [mg/kg $_{wet\ fish}$]	**$PEC_{oral,predator,soil}$** [$mg/kg_{ww\ earthworms}$]
EMISSIONS TO SOIL			
Scenario 1.a: In and around building (Outdoor application)	Direct emissions	n.r	1.97E-01
	Indirect emissions	n.r	2.90E-02
	Total Tier I	n.r	2.26E-01

	Total Tier II	n.r	2.93E-02
Scenario 1.b: In and around building (Indoor application)		n.r	2.16E-02
Scenario 2: Open areas		n.r	3.13E+00
EMISSIONS TO SURFACE WATER			
Scenario 4: Bank slopes		4.38E+01	n.r

n.r: not relevant

2.2.8.4 Risk characterisation

Atmosphere

Brodifacoum is a non-volatile substance (vapour pressure <1.E-06 Pa and Henry's Law constant <2.18E-03 Pa.m^3/mol) presenting a half-life of 0.276 days in air. Therefore, it is not expected to contaminate air and no PNEC value were calculated as according to the AR, it is not considered to be an environmental compartment of concern.

Thus, emissions to air from biocidal uses are not relevant.

Aquatic (including sediment compartment, STP), terrestrial, groundwater compartments and secondary poisoning via the environment

A summary of the calculated PEC/PNEC values and PEC_{GW} values estimated with $FOCUS_{GW}$ for each scenario and all other environmental compartments are indicated in the following table. For secondary poisoning via the environment, only birds are presented as they present the worst-case and PEC_{oral} birds are compared with $PNEC_{oral}$ birds Tier I (in mg/kg food

PEC_{GW} and RCR for aquatic, terrestrial compartments and secondary poisoning via the environment calculations							
		RCR water	**RCR sediment***	**RCR soil**	**PEC_{GW}* * [µg/l]**	**Secondary poisoning via the environment**	
						RCR predator,SW	**RCR predator,soil**
						Birds as worst case	Birds as worst case
DIRECT EMISSIONS TO SOIL							
Scenario 1.a: In and around building (Outdoor application)	Direct emissions	-	-	5.08E-03	0	-	**1.55E+03**
	Indirect emissions	-	-	7.48E-04	0	-	**2.28E+02**
	Total Tier I	-	-	5.83E-03	0	-	**1.78E+03**
	Total Tier II	-	-	7.56E-04	0	-	**2.31E+02**
Scenario 1.b: In and around building (Indoor application)		-	-	5.59E-04	0	-	**1.70E+02**
Scenario 2: Open areas		-	-	8.09E-02	0	-	**2.47E+04**
DIRECT EMISSIONS TO SURFACE WATER							
Scenario 4: Bank slopes		**6.14E+00**	**6.14E+01**	-	-	**3.45E+05**	-

* RCRsediment: A $PNEC_{sediment}$ was derived through the Equilibrium Partitioning Method in the AR of Brodifacoum. According to the Guidance of BPR Volume IV Part B+C (2017) and considering the log Kow > 5, the PEC/PNEC ratio for the aquatic compartment is increased by a factor of 10 to take into account the possible additional uptake via sediment ingestion. Therefore, the PEC values are not calculated and the risk ratios for surface water are used to derive the risk for sediment using a factor of 10.

** Worst-case concentrations in groundwater calculated with FOCUS v4.4.4

If secondary poisoning via the environment is not taken into account, all scenarios lead to acceptable risks for all environmental compartments except Scenario 4 – Bank slopes, for which unacceptable risks are foreseen for the sediment compartment for which a RMM should be applied
Concerning secondary poisoning via the environment, unacceptable risks are foreseen for every scenarios.

Primary and Secondary Poisoning Tier I and II

Acute/chronic poisoning:
In the revised ESD for PT14 (2018), a quantitative approach is proposed for acute and chronic exposure of non-target organisms. Since the PNECoral is generally based on chronic effect concentrations, another threshold values were defined for the acute poisoning situation, named "NAET", or "No acute Effect Threshold".
Therefore, NAET values are compared with $PEC_{oral,acute}$ and PNECoral are compared with $PEC_{oral,chronic}$.

Tier I/Tier II calculations:
In Tier I, the PEC_{oral} represents the concentration of the active substance in bait (for primary poisoning) or the concentration in the rodent/slug eaten by the predator/scavenger (for secondary poisoning) in mg/kg food.
Therefore, this value should be compared with a NAET (for acute poisoning) or $PNEC_{oral}$ (for chronic poisoning) converted in mg/kg food.
In Tier II, the PEC_{oral} are in mg/kg bw, therefore, they can be compared with NAET/PNECoral calculated in mg/kg bw.

A summary of the calculated PEC/PNEC values for primary and secondary poisoning (Tier I and II) are indicated in the following table.

RCR calculations (Primary and Secondary poisoning Tier I and II)				
	Acute		**Chronic**	
	Birds	**Mammals**	**Birds**	**Mammals**
Primary poisoning Tier I and II, Acute/Chronic RCR calculations:				
Primary poisoning – Tier I				
RCR	**2.07E+03**	**6.40E+02**	**1.35E+05**	**7.70E+04**
Primary poisoning – Tier II				
RCR - House sparrow	**3.82E+03**	n.r	**1.54E+06**	**n.r**
RCR - Shrew	n.r	**7.07E+03**	**n.r**	**4.28E+06**
RCR - Woodpigeon	**1.66E+03**	n.r	**6.68E+05**	**n.r**
RCR - Dogs	n.r	**7.71E+02**	**n.r**	**4.66E+05**
RCR - Young Pigs	n.r	**3.09E+02**	**n.r**	**1.87E+05**
Secondary poisoning Tier I and II, Acute/Chronic RCR calculations:				
Secondary poisoning – Tier I				

RCR calculated with the active substance in food (=rodent) of a predator/scavenger	**1.03E+03**	**3.20E+02**	**3.37E+04**	**1.93E+04**
RCR calculated with the active substance in food (=slug) of a predator/scavenger	**4.14E+03**	**1.28E+03**	**1.35E+05**	**7.70E+04**
Secondary poisoning – Tier II				
RCR - Barn owl (*Tyto alba*)	**2.08E+03**	n.r	**8.35E+04**	n.r
RCR - Kestrel (*Falco tinnunculus*)	**3.15E+03**	n.r	**1.27E+05**	n.r
RCR - Carrion crow (*Corvus corone*)	**2.32E+03**	n.r	**9.35E+04**	n.r
RCR - Red fox (*Vulpes vulpes*)	n.r	**6.43E+02**	n.r	**3.89E+04**
RCR - Weasel (*Mustela nivalis*)	n.r	**2.51E+03**	n.r	**1.52E+05**
RCR - Domestic cat (*Felix silvestris catus*)	n.r	**3.21E+02**	n.r	**1.94E+04**
RCR - Shrew (*Sorexp ssp*)	n.r	**1.41E+04**	n.r	**8.55E+05**
RCR - European starling (*Sturnus vulgaris*)	**2.09E+04**	n.r	**8.42E+05**	n.r

Unacceptable risks are foreseen with very high RCRs for primary and secondary poisoning (Tier I and II). In order to mitigate the risk of poisoning, specific use instructions and risk mitigation measures must be put in place.

Conclusion

Claimed uses	Field of use	Targets	Covered by	Acceptable risks for the environment
Use 1	Indoor	Mice	Use 2	**YES (except for poisoning)**
Use 2	Indoor	Rats	Scenario 1.b (on rats)	
Use 3	Outdoor - Around building	Rats	Use 7	**YES (except for poisoning, surface water and sediment compartments)**
Use 4	Indoor	Mice/rats	Use 2	**YES (except for poisoning)**
Use 5	Indoor	Mice	Use 2	**YES (except for poisoning)**
Use 6	Outdoor - Around building	Rats	Use 7	**YES (except for poisoning, surface water and sediment compartments)**
Use 7	Indoor	Mice/rats	Use 2	**YES (except for poisoning)**

Use 8	Outdoor - Around building	Mice/rats	Scenario 1.a (on rats) / Scenario 2 / Scenario 3	**YES (except for poisoning, surface water and sediment compartments)**

Mixture toxicity

As no substance of concern was identified in the product, mixture toxicity assessment is not relevant.

Aggregated exposure (combined for relevant emission sources)

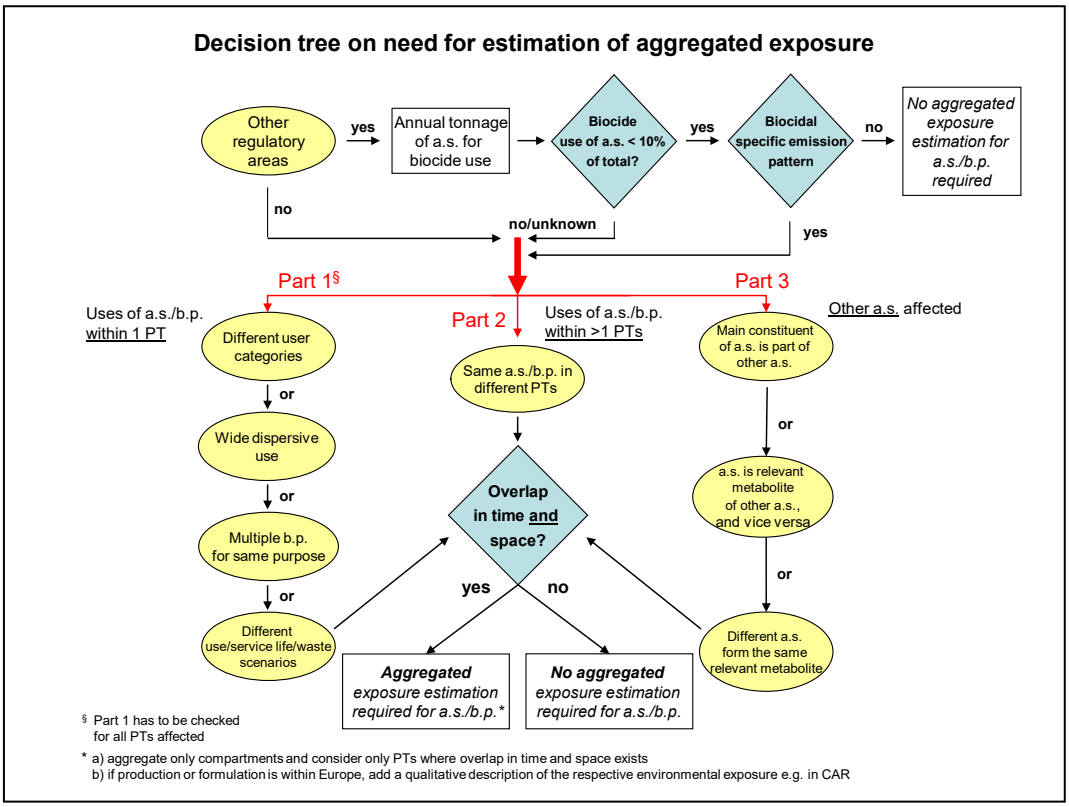


Figure 1: Decision tree on the need for estimation of aggregated exposure

Conclusion: Emission *via* the STP is the only way that could lead to combined exposure of the different uses. However, no uses leads to emission to the STP, aggregated exposure is not relevant.

Overall conclusion on the risk assessment for the environment of the product
The risk assessment has been conducted for the active substance only. No substance of concern has been defined for the environment. For the indoor uses (uses 1, 2, 4, 5, 7), the estimated risks are acceptable for all the environmental compartments (surface water, sediment, soil and groundwater). For the outdoor uses around building (uses 3, 6, 8), unacceptable risks are foreseen for the sediment compartment if baits are used near water bodies. The following risk mitigation measure must be applied: "*Do not use the product close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches).*" Moreover, for all uses, the risk for primary and secondary poisoning of non-target animals cannot be excluded. Specific use restrictions must be applied to mitigate these risks.

For professionals and trained professionals:

- 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 open the sachets containing the bait

For professionals, trained professionals and non-professionals:

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

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

- Store in places prevented from the access of children, birds, pets and farm animals.
- Remove the remaining bait or the bait stations at the end of the treatment period.

For professionals and non professionals:

- use in tamper resistant bait stations only

- **Minor change application (2024)**

The minor change implying a replacement of a non-active substance intentionally incorporated has no impact on the risk assessment for the environment.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title. Report No.	Type of publication	Owner of data	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Nichetti S.	2019	Brodifacoum 0.0017% w/w pasta: Determination of the Physico-Chemical Properties Report No. CH – 0503/2019	study report	Zapi S.p.A.	Yes	Yes
Nichetti S.	2019	Brodifacoum 0.0017% w/w pasta: Validation of the Analytical Method for the Determination of the Active Ingredient Content Report No. CH – 0504/2019	study report	Zapi S.p.A.	Yes	Yes
Nichetti S.	2019	Brodifacoum 0.0017% w/w pasta: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No. CH – 0505/2019	study report	Zapi S.p.A.	Yes	Yes
Nichetti S.	2022	Brodifacoum 0.0017% w/w pasta: Three Years Storage Stability and Corrosion Characteristics Report No. CH – 0506/2019	study report	Zapi S.p.A.	Yes	Yes
Halbwachs P.	2019	Determination of exothermic reactions by DSC method on BRODIFACOUM 0.0017% W/W PASTA Report No. 19-926005-001	study report	Zapi S.p.A.	Yes	Yes

Author(s)	Year	Title. Report No.	Type of publication	Owner of data	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Gledhill I. (2022),	2022	Relative Self-Ignition Testing on a Sample of Brodifacoum 0.0017% w/w Pasta Report No. GLP3016012347R1/2022	study report	Zapi S.p.A.	Yes	Yes
XXX	2020	EVALUATION OF THE EFFICACY OF THE BAIT 'BRODIFACOUM 0.0017% W/W PASTA' FOR THE CONTROL OF BLACK RAT INFESTATION IN AND AROUND AGRICULTURAL BUILDINGS. ONE FIELD TRIAL: RHONE; FRANCE, 2020.	study report	XXX	No	Yes
XXX	2020	EVALUATION OF THE EFFICACY OF THE BAIT 'BRODIFACOUM 0.0017% W/W PASTA' FOR THE CONTROL OF BROWN RAT INFESTATION IN AND AROUND BUILDINGS. ONE FIELD TRIAL: RHONE; FRANCE, 2020.	study report	XXX	No	Yes
XXX	2020	EVALUATION OF THE EFFICACY OF THE BAIT 'BRODIFACOUM 0.0017% W/W PASTA' FOR THE CONTROL OF HOUSE MOUSE INFESTATION IN AND AROUND BUILDINGS. ONE FIELD TRIAL: RHONE; FRANCE, 2020.	study report	XXX	No	Yes
XXX	2019	RODENTICIDE PALATABILITY AND EFFICACY STUDY OF THE AGED BAIT 'BRODIFACOUM 0.0017% W/W PASTA' IN BLACK RAT (Rattus rattus)	study report	XXX	No	Yes
XXX	2019	RODENTICIDE PALATABILITY AND EFFICACY STUDY OF THE AGED BAIT 'BRODIFACOUM	study report	XXX	No	Yes

Author(s)	Year	Title. Report No.	Type of publication	Owner of data	GLP (Yes/No)	Data Protection Claimed (Yes/No)
		0.0017% W/W PASTA' IN BROWN RAT (Rattus norvegicus)				
XXX	2019	RODENTICIDE PALATABILITY AND EFFICACY STUDY OF THE AGED BAIT 'BRODIFACOUM 0.0017% W/W PASTA' IN HOUSE MOUSE (Mus musculus)	study report	XXX	No	Yes
De Servi, B.	2020	PERCUTANEOUS ABSORPTION STUDY (OECD TG 428) ON HUMAN SKIN EXPLANTS OF BRODIFACOUM 0,0017% w/w in PASTA	study report	Zapi S.p.A.	No	Yes
Granata, A.	2019	Determination of solubility of Brodifacoum in three solvents (Purified Water, Methanol and Purified Water:Methanol 80:20 v/v) Report No. BPL-STUDY-19-000112	study report	Zapi S.p.A.	Yes	Yes
Kluxen M. et al. (2019)	2019	Dermal absorption study OECD TG 428 mass balance recommendations based on the EFSA database from Regulatory Toxicology and Pharmacology 108 (2019) 104475	Article	Open access	n.a.	No

3.2 Output tables from exposure assessment tools

HUMAN HEALTH EXPOSURE ASSESSMENT:

Expo_human health_BRODITECH

3.3 Confidential annex

See the confidential PAR.