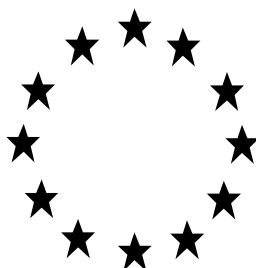


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR THE RENEWAL OF A NATIONAL
AUTHORISATION**



Product identifier in R4BP	AGRORAT BRODI-5 PRO
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-CY019782-13 (NA-RNL) BC-RN033267-24 (NA-ADC)
Asset No. in R4BP	ES-0008700-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00325
Date	February 2018 Updated March 2019

Table of content

1. Conclusion	3
2. Summary of the product assessment	5
2.1 Administrative information	5
2.2 Composition and formulation.....	5
2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008.....	7
2.4 Use(s) appropriate for further authorisation	8
2.5 General directions for use.....	13
3. Assessment of the product	16
3.1 Use(s) considered appropriate for authorisation after former assessment (uses evaluated in SPAIN).....	16
3.2 Physical, chemical and technical properties.....	20
3.3 Physical hazards and respective characteristics.....	20
3.4 Methods for detection and identification.....	20
3.5 Efficacy against target organisms	20
3.6 Risk assessment for human health	25
3.7 Risk assessment for animal health.....	26
3.8 Risk assessment for the environment	27
Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the environment remains valid.	
.....	¡Error! Marcador no definido.
3.9 Assessment of a combination of biocidal products	30
3.10 Comparative assessment	30
4. Confidential annex (Access level: “Restricted” to applicant and authority).....	32
4.1 Full composition of the product	32
4.2 List of studies for the biocidal product (Confidential data)	33

1. Conclusion

The assessment presented in this report has shown that the ready-to-use product, AGRORAT BRODI-5 PRO with the active substance brodifacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) since the conclusions of initial evaluation remain valid.

In the initial evaluation of this biocidal product the trade name is MOSFERTIL RATICIDA BRODIFACOUM, the authorisation holder and the manufacturer of the biocidal product has been changed at the renewal stage and the name of the product has also changed to AGRORAT BRODI-5 PRO.

For clarification, this product is an identical product to AGRORAT BRODI-5 (asset number ES-0008997-0000) in the former authorization which PAR includes full evaluation according to the intended uses.

However, the biocidal product AGRORAT BRODI-5 PRO contains 0.005 %w/w brodifacoum and the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has been applied.

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w brodifacoum only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

Therefore, AGRORAT BRODI-5 PRO is granted as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoors around buildings, outdoor in open areas and waste dumps by trained professional. It is a ready to used grain bait to be used in tamper-resistant bait stations. The specific intended uses of the product are in section 2.4. of this assessment report.

The risk assessment for the environment has been performed for the intended uses in and around buildings since the concentration of the active substance is the same, the evaluation shows that the conclusions for the first evaluation remain valid. For this reason, the use granted for the product AGRORAT BRODI-5 PRO is control of rats and mice indoor, inside industrial, commercial and residential buildings, and rats outdoor around the buildings by trained professional users only.

Please, note that this assessment report includes all uses requested by the applicant and assessed by ES CA, only as information for the concerned Member States.

Spanish CA only grants the use of AGRORAT BRODI-5 PRO according to the table 5 included in this assessment report due to our national risk mitigation measures.

2. Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

AGRORAT BRODI-5 PRO

2.1.2 Manufacturer(s) of the product

Name of manufacturer	LABORATORIOS AGROCHEM S.L.
Address of manufacturer	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN
Location of manufacturing sites	C/ Tres Rieres, 10 08292 - Esparreguera (Barcelona) SPAIN

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

Active substance	BRODIFACOUM
Name of manufacturer	ACTIVA S.r.l. / Dr. TEZZA S.r.l.
Address of manufacturer	ACTIVA S.r.l. Via Feltre, 32 20132 – Milano ITALY
Location of manufacturing sites	Dr. TEZZA S.r.l. Via Tre Ponti, 22 37050 – S. Maria di Zevio (VR) ITALY

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1	Active substance	56073-10-0	259-980-5	0.005

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
	,2,3,4- tetrahydro-1-naphthyl]- 4-hydroxycoumarin				
-	-	Non active substances	-	-	-

- The product contains a bittering agent and a dye.
 - Information on the full composition is provided in the confidential annex (see chapter 4).
- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012

2.2.2 Information on the substance(s) of concern

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

2.2.3 Candidate(s) for substitution

No candidate for substitution was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

Brodifacoum does meet the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

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

And therefore, Brodifacoum does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation


Ready-to-use bait: grain

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008

Table 2

Classification	
Hazard classes, Hazard categories	Hazard statements
Reproductive toxicity; Repr. 1A	H360D May damage the unborn child
Specific target organ toxicity — repeated exposure; STOT RE 2	H373 May cause damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling		
	Code	Pictogram / Wording
Pictograms	GHS08	
Signal word		Danger
Hazard statements	H360D	May damage the unborn child
	H373	May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray
	P264	Wash ... thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product
	P280	Wear protective gloves/ protective clothing/eye protection/face protection
	P314	Get medical advice/attention if you feel unwell.
	P405	Store locked up.
	P501	Dispose of contents and/ or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
Note	-	

2.4 Use(s) appropriate for further authorisation

In order to make proper use of the standard sentences for SPCs for rodenticides it is considered necessary to split the uses currently evaluated in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently evaluated in SPAIN)		Use(s) appropriate for further authorisation	
1	House mice and/or Brown rats – general public – indoor, outdoor around building, outdoor open areas & waste dumps	1	House mice and/or Brown rats – trained professionals - indoor
2	House mice and/or Brown rats – Professionals– indoor, outdoor around building, outdoor open areas & waste dumps	2	House mice and/or Brown rats – trained professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor, outdoor around building, outdoor open areas & waste dumps	3	Brown Rats – trained professionals – outdoor open areas & waste dumps

Uses authorised in Spain according national Risk Mitigation Measures

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)	Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.
House mice and/or brown rats – trained professionals – indoor	House mice and/or Brown rats – trained professionals - indoor
	Brown rats – trained professionals – outdoor around buildings

2.4.1 Use 1 House mice and/or brown rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain
Application rate(s) and	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-100 g per baiting point

frequency	
Category(ies) of users	Trained professionals
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 10 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC</p> <p>Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.</p>

2.4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.1.2 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
- 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.
- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

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

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

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

-See section 2.5.4.

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

-See section 2.5.5

2.4.2 Use 2 – House mice and/or brown rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-100 g per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 10 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.

2.4.2.1 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.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.2.2 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.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

-See section 2.5.4

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

-See section 2.5.5

2.4.3 Use 3 – Brown Rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides

Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rats)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain
Application rate(s) and frequency	Rats: bait boxes with 100-200 g per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 10 kg. Grams/kg of bait per packed bag: individual sachets from 10g to 200g. Packaging material: Bags, Sacks, Buckets, Tubes, bottles and Sachets. Material: Carton or PE or PP or PET or LDPE or PET / PET MET / PE or PET / ALU / PE or PET / PE or PA / PE or HDPE or PVC</p> <p>Furthermore, the product can be supplied as loose grain directly inside the secondary packaging mentioned above.</p>

2.4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the bait stations 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
- Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

See section 2.5.4

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

See section 2.5.5

2.5 General directions for use

2.5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (*see section 2.5.3 for the information to be shown on the label*).
- 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.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Bait in sachets: Do not open the sachets containing the bait
- Loose grains: Place the bait in the bait station by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping)

2.5.2 Risk mitigation measures:

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements [*The method of disposal shall be described specifically in the national SPC and be reflected on the product label*].

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.

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

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

- At the end of the treatment, dispose 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]. Use of gloves is recommended.

2.5.5 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: two years

2.5.6. Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.

3. Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses evaluated in SPAIN)

3.1.1 Use 1 – House mice and/or Brown rats – general public – indoor, outdoor around building, outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	The product is authorised only for use against rats (<i>Rattus norvegicus</i>) and mice (<i>Mus musculus</i>).
Field(s) of use	Indoor, outdoor around building, outdoor open areas & waste dumps
Application method(s)	The biocidal product is ready to use grain bait (in sachets or loose) containing Brodifacoum (0.005%).
Application rate(s) and frequency	For rats, each bait point usually contains up to 100g of bait and it should be placed in 10 m ² depending on the level of infestation. For mice each bait point usually contains up to 50g of bait and it should be placed 10 m ² depending on the level of infestation.
Category(ies) of users	General public
Pack sizes and packaging material	- Loose grain: plastic bag or sachet (PE, PP or LDPE), kraft plastic bucket (HDPE) and cardboard box, of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5kg, 10kg, 15kg 20kg and 25kg, without any other kind of packaging. Additionally, plastic bag or sachet (PE, PP or LDPE) of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg, in four different kinds of packaging: <u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard <u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: HDPE <u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag

	<p>Material: Kraft paper and Polyethylene</p> <p>- Grain in sachets: LDPE, PP and PE sachets of 25g, 50g and 100g, in four different kinds of packaging:</p> <p><u>Plastic bag</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or LDPE Labelling: The principal area label Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: HDPE Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5 kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag Material: Kraft paper and Polyethylene Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g y 500 g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p>
--	---

3.1.2 Use 2 – House mice and/or Brown rats –Professionals– indoor, outdoor around building, outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	The product is authorised only for use against rats (<i>Rattus norvegicus</i>) and mice (<i>Mus musculus</i>).
Field(s) of use	Indoor, outdoor around building, outdoor open areas & waste dumps
Application method(s)	The biocidal product is ready to use grain bait (in sachets or loose) containing Brodifacoum (0.005%).
Application rate(s) and frequency	For rats, each bait point usually contains up to 100g of bait and it should be placed in 10 m ² depending on the level of infestation. For mice each bait point usually contains up to 50g of bait and it should be placed 10 m ² depending on the level of infestation.

Category(ies) of users	Professionals
Pack sizes and packaging material	<p>- Loose grain: plastic bag or sachet (PE, PP or LDPE), kraft plastic bucket (HDPE) and cardboard box, of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5kg, 10kg, 15kg 20kg and 25kg, without any other kind of packaging.</p> <p>Additionally, plastic bag or sachet (PE, PP or LDPE) of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg, in four different kinds of packaging:</p> <p><u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard</p> <p><u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: HDPE</p> <p><u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag Material: Kraft paper and Polyethylene</p> <p>- Grain in sachets: LDPE, PP and PE sachets of 25g, 50g and 100g, in four different kinds of packaging:</p> <p><u>Plastic bag</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: PE or PP or LDPE Contents (Net weight)100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg 20kg and 25kg</p> <p><u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard Contents (Net weight)100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: HDPE Contents (Net weight)100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5 kg,10kg, 15kg, 20kg and 25kg</p> <p><u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag Material: Kraft paper and Polyethylene Contents (Net weight)100g, 150g, 200g, 250g, 300g, 400g y 500 g, 1kg, 2kg, 2.5kg, 3kg, 5kg,10kg, 15kg, 20kg and 25kg</p>

3.1.3 Use 3 – House mice and/or brown rats – trained professionals – indoor, outdoor around building, outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	The product is authorised only for use against rats (<i>Rattus norvegicus</i>) and mice (<i>Mus musculus</i>).
Field(s) of use	Indoor, outdoor around building, outdoor open areas & waste dumps
Application method(s)	The biocidal product is ready to use grain bait (in sachets or loose) containing Brodifacoum (0.005%).
Application rate(s) and frequency	For rats, each bait point usually contains up to 100g of bait and it should be placed in 10 m ² depending on the level of infestation. For mice each bait point usually contains up to 50g of bait and it should be placed 10 m ² depending on the level of infestation.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	<p>- Loose grain: plastic bag or sachet (PE, PP or LDPE), kraft plastic bucket (HDPE) and cardboard box, of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5kg, 10kg, 15kg 20kg and 25kg, without any other kind of packaging.</p> <p>Additionally, plastic bag or sachet (PE, PP or LDPE) of 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg, in four different kinds of packaging:</p> <p><u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard</p> <p><u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: High Density Polyethylene (HDPE)</p> <p><u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag Material: Kraft paper and Polyethylene</p> <p>- Graininsachets: LDPE, PP and PE sachets of 25g, 50g and 100g, in four different kinds of packaging:</p> <p><u>Plastic bag</u> Description: Prefabricated bags or serial production bags, both thermal-welded Material: Polyethylene or Polypropylene or LDPE Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg 20kg and 25kg</p>

	<p><u>Cardboard box</u> Description: Self-assembly cardboard box with flap and seal or glued flaps Material: Cardboard Contents (Net weight) 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Plastic bucket</u> Description: Rectangular or conical bucket sealed Material: High Density Polyethylene (HDPE) Contents (Net weight) 100g, 150g, 200g, 250g, 300g, 400g, 500g, 1kg, 2kg, 2.5 kg, 3kg, 5 kg, 10kg, 15kg, 20kg and 25kg</p> <p><u>Kraft sacks</u> Description: Kraft paper sack with internal Polyethylene bag Material: Kraft paper and Polyethylene Contents (Net weight): 100g, 150g, 200g, 250g, 300g, 400g y 500 g, 1kg, 2kg, 2.5kg, 3kg, 5kg, 10kg, 15kg, 20kg and 25kg</p>
--	--

3.2 Physical, chemical and technical properties

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

The conclusion from the former assessment regarding efficacy against target organisms remains valid. However, the applicant has provided two new field studies, one of them against rats (*Rattus norvegicus*)

and the other one against mice (*Mus musculus*). These studies have been performed with the same formulation but with different content in active substance (0.0027 ppm).

ES CA considers that the different between both formulations are negligible and as the formulation has proven the efficacy with the content of active substance lower these studies complete the assessment of the efficacy for this product.

Please, see the summary of field trials submitted by the applicant.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Rodenticide	Semi-field test	Brodifacoum 0.0027% w/w grain bait	Brown rat (<i>Rattus norvegicus</i>) 5 females 5 males Weight between 150 and 230g.	Semi-field test: Mortality and palatability. According to TNG for PT 14 and Transitional Guidance for PT14	Rats placed by sex in a circular conditioned space with three rectangular surfaces at 20.30-24.30°C of temperature with an air exchange of 20-35 rph and a relative humidity between 57% and 74%. The total area of the habitat per sex was 2.7414 m ² (0.548m ² / rat). Photoperiod: 12 h light/12 h dark Food, drink and test item were placed in vessels ad libitum. Acclimation period (3 days) Pre-feeding period (4 days), Administration period (Brodifacoum grain bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 42.11% (304.9g) Average mortality occurrence: 100% at day 6.1 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7
Rodenticide	Semi-field test	Brodifacoum 0.0027% w/w grain bait	House mouse (<i>Mus musculus</i>) 5 females 5 males Weight between 25 and 40g.	Semi-field test: Mortality and palatability. According to TNG for PT 14 and Transitional Guidance for PT14	Mice placed by sex in a circular conditioned space with two rectangular surfaces at 19.61-24.52°C of temperature with an air exchange of 20-35 rph and a relative humidity between 60% and 73%. The total area of the habitat per sex was 1.8145 m ² (0.363m ² / mouse). Photoperiod: 12 h light/12 h dark. Food, drink and test item were placed in vessels ad libitum. Acclimation period (3 days), Pre-feeding period (4 days), Administration period (Brodifacoum grain bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 40.58% (53.2 g) Average mortality occurrence: 100% at day 7.4 Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7
Rodenticide	Field test (Indoor/Outdoor)	Brodifacoum 0.0027% w/w grain bait	Brown rat (<i>Rattus norvegicus</i> Berk)	Field test. According to Transitional Guidance for	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses).	-Pre-treatment: consumption (on the last 4 days): 768.8 g/day and	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
				PT14, ECHA Guidance on the Biocidal Products Regulation. Volume II Efficacy - Assessment and Evaluation (Parts B+C). Version 1. February 2017 and OEPP/EPPO principles: PP 1/114(2)	-Pre-treatment census (5 days): census bait stations (100 g) and tracking patches -Lag phase: 4 days -Treatment (17 days) : 100 g of poisoned test bait were daily put down in each station -Lag phase: 5 days -Post-treatment census (5 days): census bait stations (100 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	average tracking score values of 17-24. Estimate of a population size of a minimum of 35-45 rats. -Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according TNG for PT 14)	
Rodenticide	Field test (Indoor)	Brodifacoum 0.0027% w/w grain bait	House mouse (<i>Mus musculus</i> L.)	Field test. According to Transitional Guidance for	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait	-Pre-treatment: consumption (on the last 4 days) of 467.8 g/day	IUCLID 6.7

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
				PT14, ECHA Guidance on the Biocidal Products Regulation. Volume II Efficacy - Assessment and Evaluation (Parts B+C). Version 1. February 2017 and OEPP/EPPO principles: PP 1/114(2)	stations (60 g) and tracking patches -Lag phase: 4 days -Treatment (14 days) : 60 g of poisoned test bait were daily put down in each station -Lag phase: 4 days -Post-treatment census (5 days): census bait stations (60 g) and tracking patches. *Each bait station will be spaced out 5-10 m from each other (5 m in case of strong infestation; 10 m in case of weak infestation).	and average tracking score values of 12-15. Estimate of a population size of a minimum of 110-120 rats. -Post-treatment: no bait takes was recorded. Tracking patches score= 0 Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according TNG for PT 14)	

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

3.6.2 Assessment of effects of the product on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the product on human health remains valid.

3.6.3 Exposure assessment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the exposure remains valid.

3.6.4 Risk characterisation for human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the risk characterisation for human health remains valid.

3.6.4.1 Risk for trained professional users

The conclusion from the former assessment regarding the risk characterisation for trained professional user remains valid.

3.6.4.2 Risk for professional users

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w brodifacoum only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this

legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

3.6.4.3 Risk for the general public

According to the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, the biocidal product containing anticoagulant active substance cannot be authorised by general public if the concentration in the biocidal product is above the specific limit concentration ($\geq 0.003\%$).

3.6.4.4 Risk for consumers via residues in food

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

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

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

3.6.4.6 Summary of risk characterisation

The conclusion from the former assessment regarding risk characterisation remains valid, except to the authorisation for general public and professional user which have been removed to the authorisation in order to comply with the requirements laid down in Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

3.7 Risk assessment for animal health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

Neither new data was not provided, however a refinement for PECgroundwater with FOCUS PEARL 4.4.4. has been included due to exceed the trigger value of 0.1 µg/L (BPR Annex VI point 68).

PECgroundwater was calculated according to ECHA guidance on environmental risk assessment, Volume IV, part B (2017) using equation 70, and the values has been summary for the different scenarios (worst case) in the following table:

Summary table Groundwater values

Parameter	Sewer	In/ around buildings	Open areas	Waste dumps
PECgroundwater [µg/L]	0.003	0.103	0.107	0.011

Values > 0.1 µg/L has been calculated for “In & Around buildings” and “open areas”. The ES –CA has applied the new Revised Emission Scenario Document for product Type 14 (August 2018) in order to calculate the application rate per hectare for the worst case “Open areas”.

For open areas, burrow baiting as well as the application of baits in stations/boxes are relevant application modes to be considered with respect to groundwater. The number of application sites per ha is dependent on the rodent infestation. As a reference value, an estimation of 100 bait points per ha is proposed for rat control. For mice control, the number of treated burrows is expected to be 2-fold higher, i.e. 200 bait points/ha.

Rodenticide emissions to soil for groundwater calculations arising from burrow baiting and application in bait stations/boxes in open areas.

Parameters	Nomenclature	Value	Unit	Origin
Input				
Amount of product used per application for one application site	Q_{prod}	100	[g]	S
Fraction of active substance in the product	F_{Cproduct}	0,00005	[-]	S
Number of application sites	Rat control	N_{sites}	[ha ⁻¹]	D
	Mice control			

Fraction of active ingredient released directly, burrow baiting		$F_{\text{release-D,soil_burrow}}$	0,25	[-]	D
Fraction of active ingredient released directly, bait station	bagged baits	$F_{\text{release-D,soil_bait station}}$	0,01	[-]	D
	loose baits		0,05		
Output					
Local direct emission rate to soil from one application per ha, burrow baiting	Rat control	$E_{\text{local soil-D,oneappli,burrow}}$	0.13	[g·ha ⁻¹]	O
	Mice control		0.25		
Local indirect emission rate to soil from one application per ha, bait station	Rat control bagged baits	$E_{\text{localsoil-D,one appl,bait station}}$	0,01	[g·ha ⁻¹]	O
	Rat control loose baits		0,03		
Local indirect emission rate to soil from one application per ha, bait station	Mice control bagged baits	$E_{\text{localsoil-D,one appl,bait station}}$	0,01	[g·ha ⁻¹]	O
	Mice control loose baits		0,05		
Application rate to soil from one application per ha, burrow baiting	Rat control	$\text{App_rate}_{\text{burrow}}$	1.25E-04	[kg·ha ⁻¹]	O
	Mice control		2.50E-04		
Application rate to soil from one application per ha, bait station	Rat control bagged baits	$\text{App_rate}_{\text{bait station}}$	5.00E-06	[kg·ha ⁻¹]	O
	Rat control		2.50E-05		

	loose baits				
Application rate to soil from one application per ha, bait station	Mice control bagged baits	App_rate _{bait station}	1,00E-05	[kg·ha ⁻¹]	0
	Mice control loose baits		5,00E-04		

A refinement has been performed by FOCUS models for the Application rate to soil from one application per ha, burrow baiting of 2.50E-04 as worst case and the following input parameters has been taken from the brodifacoum Assessment Report:

Summary of chemical parameters used for FOCUS PEARLS simulations

Parameter	Value
Molar Mass[g·mol ⁻¹]	523.4
Vapour pressure [Pa] at 25°C	1.0·10 ⁻⁶
Solubility in water [mg·L ⁻¹] at 25°C	0.0621
K _{oc} [L·kg ⁻¹]	9155
K _{om} (coeff. for sorption on organic matter) [L·kg ⁻¹]	5310
Freundlich Sorption Exponent [1/n]	1
Half life [d] at 20°C	1000000

The following table describes the application and crop parameter and values to be used for the modelling of groundwater concentrations with FOCUS PEARL. (ESD PT14, 2018).

Input parameter	Direct exposure via direct (+ indirect) emissions
	Open areas
Application type	Surface application
Application time	On day 1, 3 and 8 of control campaign, two campaigns per year: March: 15th, 17th, 22th September: 15th, 17th, 22th
Crop type	Grass/alfalfa
Plant uptake factor	0

The results of the groundwater modelling investigation conducted using FOCUS PEARL are shown in the following Table for all 9 representative locations (FOCUS scenarios).

FOCUS Scenarios	
	Concentration closest to the 80 th percentile [$\mu\text{g}\cdot\text{L}^{-1}$]
	Alfalfa (grassland)
Châteaudun	0.0000
Hamburg	0.0000
Jokioinen	0.0000
Kremsmünster	0.0000
Okehampton	0.0000
Piacenza	0.0000
Porto	0.0000
Sevilla	0.0000
Thiva	0.0000

From the results it can be seen that the average concentration of brodifacoum closest to the 80th percentile is $0.00 \mu\text{g}\cdot\text{L}^{-1}$ and thus the predicted concentrations in groundwater are significantly below the threshold criteria of $0.1 \mu\text{g}\cdot\text{L}^{-1}$ for all crops and locations. Accordingly, the conclusion from the former assessment regarding the environment remains valid and the risk to groundwater will be acceptable.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As brodifacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The decision states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Decision forms the basis of the 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.

On the basis of this comparative assessment, the authorisation of rodenticide products containing brodifacoum is justified.