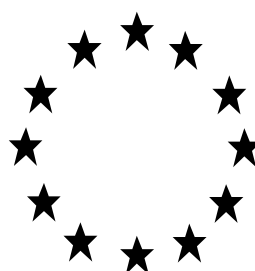


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product identifier in R4BP	AGRORAT BD-5 PRO
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-TC014257-48 (NA-RNL)
Asset No. in R4BP	ES-0005466-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00178
Date	February 2018 (updated December2018)

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1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, AGRORAT BD-5 PRO with the active substance bromadiolone, 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 BROM RATICIDA, 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 BD-5 PRO.

For clarification, this product AGRORAT BD-5 PRO (old MOSFERTIL BROM RATICIDA) is an identical product to AGRORAT BD-5 (asset number ES-0003204-0000) in the former authorization which PAR includes full evaluation according to the intended uses.

However, the biocidal product AGRORAT BD-5 PRO contains 0.005 %w/w bromadiolone 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 bromadiolone 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 BD-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.

According to the renewal of anticoagulant active substance for trained professional users the product may be authorised for use in covered and protected bait points other than tamper resistant bait stations.

The applicant has not submitted any additional information to include these application methods, so the ES CA does not authorise other use different to tamper resistant bait stations.

The risk assessment for the environment has been performed for the intended uses in and around buildings, sewer system, open areas, and waste dumps since the concentration of the active substance is the same, the new evaluation shows that the conclusions for the first evaluation remain valid.

The overall conclusion is that the intended uses of AGRORAT BD-5 PRO do not pose an unacceptable risk to the sewage treatment plant, soil, air, surface water, sediment, and groundwater compartments.

However, an unacceptable risk is however identified for the primary and secondary poisoning of non-target vertebrates, and specific risk mitigation measures on the use of the product are required to reduce the risk for the environment. The risk for primary poisoning can be significantly reduced by deploying baits so that they cannot be reached by the non-target animals, using the baits in tamper-resistant bait stations, and applying the granulate formulations only inside buildings. The risk for secondary poisoning is more difficult to control, as poisoned rodents may be available for predators for several days after intake of Bromadiolone. One way to reduce the risk is to limit the field of use of grain baits and pellets to indoor use only. Carcasses and unconsumed baits must be collected during and after the control campaign to reduce the secondary poisoning.

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 BD-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 BD-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	Bromadiolone
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

2.2 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 (%)
Bromadiolone	3-[(1RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxycoumarin	Active substance	28772-56-7	249-205-9	0.005
-	-	Non-active substance	-	-	-

- 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:

- Bromadiolone.

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

- toxic for reproduction category 1B
- persistent, bioaccumulative and toxic

And therefore, Bromadiolone 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. 1B	H360D May damage the unborn child
Specific target organ toxicity — repeated exposure; STOT RE 1	H372 Causes 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
	H372	Causes 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.
	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 authorised in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)		Use(s) appropriate for further authorisation	
1	House mice and/or rats –general public – indoor	1	House mice and/or brown rats – trained professionals – indoor
2	House mice and/or rats – professional– indoor	2	Mice and/or brown rats – trained professionals – outdoor around buildings
3	House mice and/or rats –trained professional– indoor	3	Brown rats – trained professionals – Outdoor open areas & waste dumps

Uses authorized in Spain according national Risk Mitigation Measures

Table 5

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

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	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
Field(s) of use	Indoor

Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	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. Grain in sachets: Individual sachets of 10, 15, 20, 25, 50, 75, 90, 100 and 200 grams in packs of sachets up to 30kg. Loose grains: Packs of loose grains up to 30kg. Package is restricted to separately packed bags with a maximum of 10kg per packed bag. Packaging material: Paper or Sachets of: PP or PE or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. Plastic bottles or buckets: HDPE or PE or PP or PET or PVC. Carton bags of: PET or LDPE or Paper Kraft. Carton boxes

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 [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.
- 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 - Mice and/or brown rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	<i>Mus musculus</i> (house mice) <i>Rattus norvegicus</i> (brown rat)
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.

	<p>Grain in sachets: Individual sachets of 10, 15, 20, 25, 50, 75, 90, 100 and 200 grams in packs of sachets up to 30kg.</p> <p>Loose grains: Packs of loose grains up to 30kg. Package is restricted to separately packed bags with a maximum of 10kg per packed bag.</p> <p>Packaging material: Paper or Sachets of: PP or PE or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. Plastic bottles or buckets: HDPE or PE or PP or PET or PVC. Carton bags of: PET or LDPE or Paper Kraft. Carton boxes</p>
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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 [*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 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	Rodenticide
Target organism(s) (including development stage)	<i>Rattus norvegicus</i> (brown rat)
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 only
Pack sizes and packaging material	Minimum pack size of 3 kg. Grain in sachets: Individual sachets of 10, 15, 20, 25, 50, 75, 90, 100 and 200 grams in packs of sachets up to 30kg

	<p>Loose grains: Packs of loose grains up to 30kg. Package is restricted to separately packed bags with a maximum of 10kg per packed bag.</p> <p>Packaging material: Paper or Sachets of: PP or PE or PET or LDPE or PET/PET MET/PE or PET/ALU/PE or PET/PE or PA/PE. Plastic bottles or buckets: HDPE or PE or PP or PET or PVC. Carton bags of: PET or LDPE or Paper Kraft. Carton boxes.</p>
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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 [in accordance with the applicable code of good practice, if any].
- 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.

2.4.3.6 Use-specific instructions for use

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

2.4.3.7 Use-specific risk mitigation measures

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

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

See section 2.5.3.

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

See section 2.5.4.

2.4.3.10 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 baiting point by using a dosage device. 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 [in accordance with the applicable code of good practice, if any]".

- 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 [unless authorised for permanent baiting treatments].
- 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, always check for and remove contact lenses, 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 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].

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: 2 years.

2.5.6 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.

3 Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)

3.1.1 Use 1 – House mice and/or brown rats – general public– indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
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)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats , each bait point should be placed each 10 m ² and usually contains: · up to 100g of product using sachets of 10, 20, 25 or 50g For the control of mice , each bait point should be placed each 10 m ² and usually contains up to 50 g.
Category(ies) of users	General public
Pack sizes and packaging material	Individual sachets of 10, 20, 25 o 50g in containers of 100, 200, 250 and 500g and 1kg.

3.1.2 Use 2 – House mice and/or brown rats – professional– indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
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)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats , each bait point should be placed each 10 m ² and usually contains: · up to 100g of product using sachets of 10, 20, 25 or 50g For the control of mice , each bait point should be placed each 10 m ² and usually contains up to 50 g.
Category(ies) of users	Professional
Pack sizes and packaging material	Individual sachets of 10, 20, 25 o 50g in containers of 100, 200, 250 and 500g and 1kg.

3.1.3 Use 3 – House mice and/or brown rats – trained professional– indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
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)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats , each bait point should be placed each 10 m ² and usually contains: · up to 100g of product using sachets of 10, 20, 25 or 50g For the control of mice , each bait point should be placed each 10 m ² and usually contains up to 50 g.
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Individual sachets of 10, 20, 25 o 50g in containers of 500g and 1, 2, 2.5, 5, 10, 15, 20 and 25kg.

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 organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Rodenticide	Semi-field test	Bromadiolone 0.0027% w/w grain bait	Brown rat (<i>Rattus norvegicus</i>) 5 females 5 males Weight between 230 and 385g.	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 21.1-25.4°C Of temperature with an air exchange of 20-35 rph and a relative humidity between 56% and 70%. 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) and Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 69.26% (655.1g) Average mortality occurrence: 100% at day 5.2 after the introduction of the test item. Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7
Rodenticide	Field test (Indoor/ Outdoor)	Bromadiolone 0.0027% w/w grain bait	Brown rat (<i>Rattus norvegicus</i> Berk)	Field test. According to Transitional Guidance for PT14, ECHA Guidance on the Biocidal Products Regulation. Volume II Efficacy - Assessment and Evaluation (Parts B+C). Version 1. February 2017	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (100 g) and tracking patches -Lag phase: 4 days -Treatment (16 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.	-Pre-treatment: consumption (on the last 4 days): 795 g/day and average tracking score values of 17-24. Estimate of a population size of a minimum of 40-50 rats. -Post-treatment: no bait takes was recorded. Tracking	IUCLID 6.7

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
				and OEPP/EPPO principles: PP 1/114(2)	*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).	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	Semi-field test	Bromadiolone 0.0027% w/w grain bait	House mouse (<i>Mus musculus</i>) 5 females 5 males Weight between 22 and 33g.	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 19.93-26.35°C of temperature with an air exchange of 20-35 rph and a relative humidity between 54% and 76%. 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) and Administration period (Bromadiolone fresh bait vs. EPA STANDARD, 4 days) and Observation period.	Mean consumption test item: 56.18% (69.5 g) Average mortality occurrence: 100% at day 5.2 Palatability: Acceptable (≥20%) Mortality: Acceptable (≥90%)	IUCLID 6.7

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
Rodenticide	Field test (Indoor)	Bromadiolone 0.0027% w/w grain bait	House mouse (<i>Mus musculus</i> L.)	Field test. According to Transitional Guidance for 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)	The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses). -Pre-treatment census (5 days): census bait stations (60 g) and tracking patches -Lag phase: 4 days -Treatment (16 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).	-Pre-treatment: consumption (on the last 4 days) of 478.3 g/day and average tracking score values of 12-16. 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)	IUCLID 6.7

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 bound to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w bromadiolone 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 revised “open areas” scenario and 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).

Use in Open areas

In the last authorization for the scenario “open areas” a PNEC soil of 0.918mg/kg was used resulting in no unacceptable risk for the soil compartment. However, the correct PNEC soil is 0.0099mg/kgwwt, using this PNEC soil results in an unacceptable risk for the soil compartment for the use in open areas. The ES –CA has undertaken the calculated emissions from the use of bromadiolone in open area following the new ESD for PT14 (ESD PT14, 2018).According the information submitted by the applicant the dose for a rat hole is 100-200g grain/hole and normally application is repeated twice with an interval of 5-6 days. As conservative default this assessment has assumed that a Tier 1 value of 200g and a more typical Tier 2 value of 100g bait is applied per hole.

Rodenticide emissions to soil due to burrow baiting with solid baits.

Input Parameters	Nomenclature	Value	Value	Unit	Origin
		Tier-1	Tier-2		
Amount of product used at each refill for one rodent hole	Qprod	200	100	[g]	S
Fraction of active substance in the product	FCproduct	0,00005	0,00005	[-]	S
Number of application sites	Nsites	1	1	[-]	D
Number of applications	Nappl	2	2	[-]	S
Fraction of active ingredient released directly during application	Freleases-Dsoil-appl	0,05	0,05	[-]	D
Fraction of active ingredient released directly during use	Freleases-Dsoil-use	0,2	0,2	[-]	D

Output						
Local direct emission rate to soil from a campaign	Elocalsoil-D	5,00E-03	2,50E-03	[g]	O	
Soil Volume exposed to rodenticide	Vsoilexposed	0,0085	0,0085	[m3]	D	
Bulk density of wet soil	RHosoil	1700	1700	[kgwwt·m3]	D	
Output		Tier-1	Tier-2			
Local concentration of active ingredient in soil resulting from direct exposure	Clocalsoil-D	3,46E-01	1,73E-01	[mg·kgwwt-1]	O	

The PNEC_{soil} was determined through a test with earthworms, conducted according to the guideline OECD 207, with soil concentration ranging up to 1331 (mg/kg dwt). When corrected for soil humidity, the resulting NOEC was 918 mg/kg wet soil. Thereafter an assessment factor of 1000 was used in accordance with TGD part II, section 3.6, table 20, which gave a PNEC of 918 mg/kg dwt/1000 = 0.918 (mg/kg dwt). However, as only one soil organism was tested an EPM calculation was also made for PNEC_{soil} giving a value of 9.90E-02 (mg/ kg wwt). It was decided in the AR to use the EPM derived value for risk assessment due to the difference between measured and EPM values, and also as a separate notifier had presented a PNEC_{soil} value much closer to 9.90E-02 mg/ kg in a separate bromadiolone CAR. Hence following the approach taken in the AR, the PNEC_{soil} value from the equilibrium partitioning calculations of 0.099 mg/kg wwt, has been used in this risk assessment.

A summary of the calculated PECs is given in the following Table:

Scenario Open areas	PEC soil mg/kg	PNEC soil mg/kg	PEC/PNEC
Tier -1	3,46E-01	0,099	3,50
Tier-2	1,73E-01	0,099	1,75

An unacceptable risk for soil has been identified for open areas, when wax blocks are used directly into rat holes. However, this risk is acceptable when wax blocks are used inside tamper-resistant bait stations.

Rodenticide emissions to soil due to the use in open areas in bait boxes.

Parameters		Nomenclature	Value	Value	Unit	Origin
Input			Tier-1	Tier-2		
Amount of product used at each refill for one rodent hole		Qprod	200	100	[g]	S
Fraction of active substance in the product		FCproduct	0,00005	0,00005	[-]	S
Number of application sites		Nsites	1	1	[-]	D
Number of applications		Nappl	5	5	[-]	D
Fraction of active ingredient released directly, bait station	bagged baits	Frelease-D,soil_bait station	0,01	0,01	[-]	D
	loose baits		0,05	0,05		
Output						
Local direct emission rate to soil from a campaign	bagged baits	Elocalsoil-D	5,00E-04	2,50E-04	[g]	O
	loose baits	Elocalsoil-D	2,50E-03	1,25E-03	[g]	O
Soil area exposed directly		AREAexposed	0,14	0,14	[m ²]	D
Soil Volume exposed to rodenticide		DEPTHsoil	0,1	0,1	[m]	D
Bulk density of wet soil		RHOsoil	1700	1700	[kgwwt·m ³]	D
Output						
Local	bagged	Clocalsoil-D	2,10E-02	1,05E-02	[mg·kgwwt ⁻¹]	O

concentration of active ingredient in soil resulting from direct exposure	baits					
	loose baits	Clocalsoil-D	1,05E-01	5,25E-02	[mg·kgwwt-1]	0

A summary of the calculated PECs is given in the following Table:

	Scenario Open areas	PEC soil mg/kg	PNEC soil mg/kg	PEC/PNEC
Bagged baits	Tier -1	2,10E-02	0,099	0,21
	Tier-2	1,05E-02	0,099	0,11
Loose Baits	Tier -1	1,05E-01	0,099	1,06
	Tier-2	5,25E-02	0,099	0,53

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 in the following table:

Summary table Groundwater values

Parameter	Sewer	In/ around buildings	Open areas	Waste dumps
PECgroundwater [µg/L]	0.003	0.177	1.33	0.020

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}	200	[g]	S
Fraction of active substance in the product		F_{Cproduct}	0,00005	[-]	S
Number of application sites	Rat control	N_{sites}	100	[ha ⁻¹]	D
	Mice control		200		
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	$E_{\text{local soil-D,oneappli,burrow}}$	0,25	[g·ha ⁻¹]	O
	Mice control		0,50		
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		0,05		
Local indirect emission rate to soil from one application per ha, bait station	Mice control bagged baits	$E_{\text{localsoil-D,one appl,bait station}}$	0,02	[g·ha ⁻¹]	O

	Mice control loose baits		0,10		
Application rate to soil from one application per ha, burrow baiting	Rat control	App_rate _{burrow}	2,50E-04	[kg·ha ⁻¹]	O
	Mice control		5,00E-04		
Application rate to soil from one application per ha, bait station	Rat control bagged baits	App_rate _{bait station}	1,00E-05	[kg·ha ⁻¹]	O
	Rat control loose baits		5,00E-05		
Application rate to soil from one application per ha, bait station	Mice control bagged baits	App_rate _{bait station}	2,00E-05	[kg·ha ⁻¹]	O
	Mice control loose baits		1,00E-04		

A refinement has been performed by FOCUS models for the Application rate to soil from one application per ha, burrow baiting of 5.00E-04 as worst case and the following input parameters has been taken from the bromadiolone Assessment Report:

Summary of chemical parameters used for FOCUS PEARLS simulations

Parameter	Value
Molar Mass[g·mol ⁻¹]	527.4
Vapour pressure [Pa] at 25°C	2.13·10 ⁻⁸
Solubility in water [mg·L ⁻¹] at 25°C	18.4
K _{oc} [L·kg ⁻¹]	14770
K _{om} (coeff. for sorption on organic matter) [L·kg ⁻¹]	8567
Freundlich Sorption Exponent [1/n]	1

Half life [d] at 20°C	1000000
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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 [µg·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 bromadiolone closest to the 80th percentile is 0.00 µg·L⁻¹ and thus the predicted concentrations in groundwater are significantly below the threshold criteria of 0.1 µg·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 bromadiolone 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 bromadiolone is justified.