

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ROEDOFIN

Product type(s)

PT14: Rodenticides

Authorisation number: ES/APP(NA)-2018-14-00324

R4BP asset number: ES-0008989-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ROEDOFIN
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	QUIMICA DE MUNGUIA S.A.
	Address	DERIO BIDEA 51 48100 MUNGUIA Spain
Authorisation number	ES/APP(NA)-2018-14-00324	
<i>R4BP asset number</i>	ES-0008989-0000	
Date of the authorisation	11/09/2015	
Expiry date of the authorisation	31/12/2025	

1.3. Manufacturer(s) of the product

Name of manufacturer	QUÍMICA DE MUNGUÍA, S.A.
Address of manufacturer	C/ Derio Bidea 51 48100 Munguía (Vizcaya) Spain
Location of manufacturing sites	C/ Derio Bidea 51 48100 Munguía (Vizcaya) Spain

1.4. Manufacturer(s) of the active substance(s)

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

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,005

2.2. Type(s) of formulation

Ready-to-use: grain

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H373: May cause damage to organs (blood through prolonged or repeated exposure ..
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. P260: Do not breathe fume. P260: Do not breathe gas. P260: Do not breathe mist. P260: Do not breathe vapours. P260: Do not breathe 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 if you feel unwell. P314: Get medical attention if you feel unwell. P405: Store locked up. P501: Dispose of contents to as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.. P501: Dispose of container to as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1- House mice and/or brown rats – trained professionals – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles Scientific name: Mus musculus Common name: house mouse Development stage: adults Scientific name: Mus musculus Common name: house mouse Development stage: juveniles
Field(s) of use	indoor use Indoor
Application method(s)	Method: in bait boxes Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain
Application rate(s) and frequency	Application rate: Rats: bait boxes with 100-200 g per baiting point; Mice: bait boxes with 60-100 g per baiting point Dilution (%): 0 Number and timing of application: 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 professional
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.
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4.1.1. Use-specific instructions

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

4.1.2. Use-specific risk mitigation measures

4.1.3. 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.

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

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

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

See section Directions for use

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

See section Directions for use

4.2. Use description

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

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides

Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: adults</p> <p>Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles</p> <p>Scientific name: Mus musculus Common name: house mouse Development stage: adults</p> <p>Scientific name: Mus musculus Common name: house mouse Development stage: juveniles</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor around buildings</p>
Application method(s)	<p>Method: in bait boxes</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain</p>
Application rate(s) and frequency	<p>Application rate: Rats: bait boxes with 100-200 g per baiting point ; Mice: bait boxes with 60-100 g per baiting point</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Rats: bait boxes with 100-200 g per baiting point Mice: bait boxes with 60-100 g per baiting point</p>
Category(ies) of users	trained professional
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>

4.2.1. Use-specific instructions

- 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.

4.2.2. Use-specific risk mitigation measures

4.2.3. 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.

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

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

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

See section Directions for use

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

See section Directions for use

4.3. Use description

Table 3. Use 3 – Brown rats – trained professionals – Outdoor open areas & waste dumps

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults

	<p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p>
Field(s) of use	<p>outdoor use</p> <p>Outdoor open areas Outdoor waste dumps</p>
Application method(s)	<p>Method: in bait boxes</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations, in sachets or as loose grain.</p>
Application rate(s) and frequency	<p>Application rate: Rats: bait boxes with 100-200 g per baiting point.</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Rats: bait boxes with 100-200 g per baiting point.</p>
Category(ies) of users	<p>trained professional</p>
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>Number of packed bags per packaging: up to 10 kg.</p> <p>Grams/kg of bait per packed bag: individual sachets from 10 g to 200g.</p> <p>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>

4.3.1. Use-specific instructions

- 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.

4.3.2. Use-specific risk mitigation measures

4.3.3. 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.

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

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

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

See section Directions for use

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

See section Directions for use

5. GENERAL DIRECTIONS FOR USE¹

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 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 device. Specify the methods to minimise dust (e.g. wet wiping).

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.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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- 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].

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.

5.4. Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

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.