

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

MURIBROM DIFENACOUM FRESH BAIT

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2019/0189/MRA/IT/2012/00005 AUT

R4BP asset number: RO-0017755-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	AGRORAT DIFE-5 PASTA MURIBROM DIFENACOUM FRESH BAIT MURIBROM DIFENACOUM RÁGCSÁLÓIRTÓ PÉ P MURIBROM DIFENACOUM FRESH BAIT MURIBROM DIFENACOUM FRESH BAIT
---------------	--

1.2. Authorisation holder

Name and address of the authorisation holder	Name	QUIMICA DE MUNGUÍA S.A.
	Address	DERIO BIDEA 51 48100 MUNGUÍA Spain
Authorisation number	RO/2019/0189/MRA/IT/2012/00005 AUT	
<i>R4BP asset number</i>	RO-0017755-0000	
Date of the authorisation	05/05/2010	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

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

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

Active substance	Difenacoum
Name of manufacturer	Activa s.r.l. / Dr. Tezza s.r.l.
Address of manufacturer	Via Feltre, 32 20132 Milano Italy
Location of manufacturing sites	Via Tre Ponti 22 37050 S.Maria di Zevio 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 (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	active substance	56073-07-5	259-978-4	0,005 % (w/w)

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	<p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P233: Keep container tightly closed.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P280: Wear protective clothing.</p> <p>P301+P310: IF SWALLOWED: Immediately call a doctor.</p> <p>P273: Avoid release to the environment.</p> <p>P201: Obtain special instructions before use.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. For PROFESSIONAL users

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready to use rodenticide bait based on an anticoagulant active substance known as Difenacoum, effective against House mouse (<i>Mus musculus</i>), Brown rat (<i>Rattus norvegicus</i>), Black rat (<i>Rattus rattus</i>) after a single ingestion by professional and non professional users.</p> <p>The product contains a bittering agent to prevent accidental ingestion by children.</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults and juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: Adults and juveniles</p>
Field(s) of use	<p>indoor use outdoor use Other</p> <p>The product can be used in and around industrial buildings (warehouses and holds included), farms, civilian buildings, houses, cellars, garages, closets and its gardens or open areas.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Avoid touching the product with bare hands, use protective gloves. The rodenticide bait must be placed in an appropriate box, protected from the atmospheric agents, the ingestion of nontarget species and in order to avoid dispersion in the environment. Observe the area of infestation and place the bait box that contains the bait at the rodents dens, along their routes and places of major attendance. Bait boxes should be placed 5-10 m far from each other.</p>
Application rate(s) and frequency	<p>Application rate: House mouse: 2 baits X 10 m; Brown rat: 3-5 baits X 10 m; Black rat: 3-5 baits X 10 m</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Replace weekly the bait boxes, if necessary. Remove daily possible dead animals and dispose of them according to local rules. The product is not intended for permanent use, organize treatments lasting up to 6 weeks. At the end of treatment dispose of bait boxes containing the bait remained, according to current rules.</p>

Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	<p>paper/carton, Bag /Sack, 1, 3, 5, 10, 20, 25 kg Packages: 1-3-5-10-20-25 g (containing rodenticide baits in fresh pasta, weight 20 g each, in paper bags suitable for food)</p> <p>Bait boxes should be placed in a secure manner, in order to minimize the risk of tampering and accidental ingestion of the bait by children or non-target animals. Always ensure that bait boxes are secured properly and that the bait cannot be dragged away by rodents. Avoid treatments in the presence of not protected food or feed. Not to use in agriculture. In case of contamination wash hands thoroughly with soap and plenty of water. Do not reuse the bait box and do not release it to the environment, but dispose of it in accordance with current rules. In case of suspected ingestion consult a Poison Control Centre. The product can be dangerous if ingested by pets or other nontarget animals. If swallowed, induce vomiting. Contact your veterinarian immediately and show the container or label.</p>

4.1.1. Use-specific instructions

Please refer to section "Application methods"

4.1.2. Use-specific risk mitigation measures

Please refer to section "Directions for use"

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

Please refer to section "Directions for use"

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

Please refer to section "Directions for use"

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

Please refer to section "Directions for use"

4.2. Use description

Table 2. For NON PROFESSIONAL users

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>The product is a ready to use rodenticide bait based on an anticoagulant active substance known as Difenacoum, effective against House mouse (<i>Mus musculus</i>), Brown rat (<i>Rattus norvegicus</i>), Black rat (<i>Rattus rattus</i>) after a single ingestion by professional and non professional users.</p> <p>The product contains a bittering agent to prevent accidental ingestion by children.</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: Adults and juveniles</p>
Field(s) of use	<p>indoor use</p> <p>The product can be used in houses, cellars, garages, closets and gardens of property.</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Avoid touching the product with bare hands, use protective gloves. The rodenticide baits must be placed in an appropriate bait box, tamper resistant and marked, available on the market. Bait boxes must be securely deposited in a way so as to minimize the risk of tampering and of accidental ingestion by children or non-target animals. Always ensure that the bait boxes are secured properly and that the bait cannot be dragged away by rodents. Product must be used according to the doses written below. Observe the area of infestation and place the bait box that contains the bait at the rodents dens, along their routes and places of major attendance. Bait boxes should be placed 5-10 m far from each other.</p>
Application rate(s) and frequency	<p>Application rate: House mouse: 2 baits X 10 m; Brown rat: 3-5 baits X 10 m; Black rat: 3-5 baits X 10 m</p> <p>Dilution (%): 0</p> <p>Number and timing of application: Regularly check containers with baits and replenish baits. Perform controls at frequent intervals to remove dead rodents and dispose of them according to local rules. Do not dispose of carcasses with garbage or in landfills. Use suitable gloves when handling dead animals. The product is not intended for permanent use, organization treatments lasting up to 6 weeks. At the end of treatment dispose of bait boxes containing the bait remained, according to current rules.</p>

Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Paper, cardboard, Bag /Sack, 40, 100, 160, 200, 260 and 500g Packages: 40-100-160-200-260-500 g (containing rodenticide baits in fresh pasta, weight 20 g each, in paper bags suitable for food)</p> <p>Avoid treatments in the presence of not protected food or feed. Not to use in cultivated areas. In case of contamination wash hands thoroughly with soap and plenty of water. Do not reuse the bait box and do not release it to the environment, but dispose of it in accordance with current rules. In case of suspected ingestion consult a Poison Control Centre. The product can be dangerous if ingested by pets or other nontarget animals. If swallowed, induce vomiting. Contact your veterinarian immediately and show the container or label.</p>

4.2.1. Use-specific instructions

Please refer to section "Application Methods"

4.2.2. Use-specific risk mitigation measures

Please refer to section "Directions for use"

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

Please refer to section "Application Methods"

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

Please refer to section "Application Methods"

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

Please refer to section "Application Methods"

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Please refer to section "Application Methods"

5.2. Risk mitigation measures

Please refer to section "Application Methods"

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

Intoxication may cause:

- Haemorrhagic diathesis, derivated from antiprothrombin effect – prolonged prothrombin time – that may become evident at minimum term of 24 hours and a maximum of 72 hours (A normal prothrombine time on admittance does not exclude the diagnosis) Symptoms: the ingestion of significant quantities of product may cause maximum inhibition of vitamin K resulting in haemorrhage of the skin, mucosa, organs and parenchyma.

First aid:

- Take the person out of the contaminated zone and remove stained or splashed clothing.
- Rinse the eyes with plenty of water for 15 minutes. Do not forget remove the contact lenses.
- Wash off the skin with soap and plenty of water, without rubbing.
- If swallowed, do not make him/her vomit - Keep the patient warm and at rest. Mantain body temperature.
- Check the breath. If necessary, give artificial respiration If the person is unconscious, make him/her lie on his/her side, with the head at lower level than the rest of the body, bending the legs.
- Take person to a hospital and show the label or packaging where possible.

DO NOT LEAVE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff

- If less than 2 hours has passed from the intake, gastric emptying must be performed, and activated carbon dispensed (25 g)

- Antidote: Vitamin K
- Check the prothrombine time
- Treat symptomatically

IN CASE OF ACCIDENT, CONSULT THE TOXICOLOGICAL INFORMATION MEDICAL SERVICE.

Telephone: 91 562 04 20

Emergency measures to protect the environment:

- Prevent accidental exposure of the product to the environment.
- Clean up accidental spillage promptly by sweeping or vacuum.
- If the product gets into water or soil, it should be removed mechanically. Transfer to a suitably labelled container and dispose of as hazardous waste according to local legislation. Subsequently, wash the contaminated area with water, taking care to prevent the washing entering sewers or drains.

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

Do not throw the product on the ground, into a water course, into the sink or down the drain.

For professional users: Remove all packaging, uneaten baits and bait boxes after treatment and dispose of them in accordance with current regulations through registered establishment or undertaking carrying out waste management operations.

For non-professional users: Packaging, uneaten baits and bait boxes must be deposited at collection points or points established by the local authority in accordance with their respective ordinances.

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

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

- Store in the original container in dry, well-ventilated place.
- Store original container tightly closed.
- Keep away from sun radiation and all other heat sources. Protect against frost
- Keep away from strong smelling stuff.
- Keep/store out of reach of children and companion animals.
- Keep/store away from food, drink and animal feedstuffs.
- The product is stable for 2 years.

6. OTHER INFORMATION

Not defined