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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

TOXIRAT PLUS

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2019/0158/MRA/ES/APP(NA)2013-14-00111

R4BP asset number: RO-0013862-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	TOXIRAT PLUS
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorios Agrochem S.L.
	Address	C/Tres Rieres, 10 - Pol. Ind. Sud 08292 Esparreguera Spain
Authorisation number	RO/2019/0158/MRA/ES/ APP(NA)2013-14-00111	
<i>R4BP asset number</i>	RO-0013862-0000	
Date of the authorisation	30/10/2013	
Expiry date of the authorisation	01/07/2024	

1.3. Manufacturer(s) of the product

Name of manufacturer	SC AGROSEM ZAHIU ECOFITOPLANT L.T.D.
Address of manufacturer	Sat Pitulicea, Comuna Godeanu Sarat, Pitulicea, nr. 200. 127258 Judet Buzau Romania
Location of manufacturing sites	Sat Pitulicea, Comuna Godeanu Sarat, Pitulicea, nr. 200. 127258 Judet Buzau Romania

Name of manufacturer	Laboratorios Agrochem S.L.
Address of manufacturer	Tres Rieres, 10 (Pol. Ind. Sud) 08292 Esparreguera (Barcelona) Spain
Location of manufacturing sites	Tres Rieres, 10 (Pol. Ind Sud) 08292 Esparreguera (Barcelona) Spain

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

Active substance	Bromadiolone
Name of manufacturer	Laboratorios Agrochem S.L.
Address of manufacturer	C/ Tres Rieres, 10 - Pol. Ind. Sud 08292 Esparreguera Spain
Location of manufacturing sites	C/ Tres Rieres, 10 - Pol. Ind. Sud 08292 Esparreguera Spain

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 (%)
Bromadiolone		active substance	28772-56-7	249-205-9	0,005

2.2. Type(s) of formulation

Pellet (granule) bait

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P280: Wear protective gloves. P301: IF SWALLOWED: P310: Immediately call a a POISON CENTER. P310: Immediately call a doctor or physician.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. For TRAINED PROFESSIONAL, PROFESSIONAL and NON-PROFESSIONAL users

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	The product is an anticoagulant rodenticide (Vitamin K antagonists) intended to control <i>Mus musculus</i> and <i>Rattus norvegicus</i> by trained professional, professional and non-professional users in buildings.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles
Field(s) of use	indoor use Inside buildings and fixed or mobile installation (e.g. residential buildings, farming operations...)
Application method(s)	Method: bait application Detailed description: Ready-to-use bait (pellets) placed in bait boxes, correctly labelled.
Application rate(s) and frequency	Application Rate: Mice: baits up to 50g of product should be placed each 10m ² / Rats: baits up to 100g of product should be placed each 10m ² Dilution (%): 0 Number and timing of application: Check the baits and replace the consumed ones daily. Replace weekly the bait boxes, if necessary. Remove daily possible dead animals and discarded according to local rules. The product is not intended for permanent use, organize treatments lasting up to 6 weeks. At the end of the treatment eliminate bait boxes containing the bait remained, according to current rules.
Category(ies) of users	trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	The product is placed on the market in individual polypropylene or polyethylene sachets each containing 10, 20, 25 or 50g according to the current authorisation. They are delivered inside paper, plastic or carton bags/sacks of:

- For professional and non-professional users: 100, 200, 250, 500g and 1 kg
- For trained professional users: 500g and 1, 2, 2.5, 5, 10, 15, 20 or 25kg.
- The use of protective gloves is recommended during the handling of the product and dead rodents in all cases for hygiene reasons.
- Wash hands and exposed skin after use and before meals.
- Place the bait station in areas inaccessible to infants, children, companion animals and non-target animals.
- Baits should not be placed where food, feedingstuffs or drinking water could be contaminated.
- Do not use anticoagulant rodenticides as permanent baits.
- Alternate the use of bromadiolone baits with other active substance baits, in order to avoid resistances.
- Use tamper-resistant bait stations and place them in inaccessible areas to prevent the access non-target species, children and companion animals.
- Collect dead rodent during all control operations to minimise the risk of consumption and poisoning to children, companion animals and other non target animals.
- For professional users: remove all dead rodents 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: dead rodents must be deposited at collections points or points established by the local authority in accordance with their respective ordinances.

4.1.1. Use-specific instructions for use

See point 5, directions for use.

4.1.2. Use-specific risk mitigation measures

See point 5, 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

See point 5, directions for use.

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

See point 5, 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

See point 5, directions for use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

The product is ready-to-use and must be used according to the doses below.

The bait has to be placed in tamper resistant bait stations, correctly labelled.

The rodenticide bait is placed in an appropriate bait box protected from the atmospheric agents, the ingestion of non-target species and dispersion in the environment.

Observe the area of infestation and place the bait box that contains the bait at the dens, along their routes and places of major attendance.

Avoid touching the product with bare hands and use appropriate gloves.

Do not use anticoagulant rodenticides as permanent baits. Alternate the use of bromadiolone baits with other active substance baits, in order to avoid resistances.

Bait points have to be checked every 2-3 days during the first 14 days of treatment. Bait points should be removed, in a typical campaign, 6 weeks after initial placement.

Collect dead rodent during all control operations to minimise the risk of consumption and poisoning to children, companion animals and other non target animals.

For professional users: remove all dead rodents 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: dead rodents must be deposited at collections points or points established by the local authority in accordance with their respective ordinances.

Recommended doses as follows:

Mice: baits up to 50g of product should be placed each 10m²

Rats: baits up to 100g of product should be placed each 10m²

5.2. Risk mitigation measures

The Risk Mitigation Measures are not harmonised in EU yet. They are applied in different ways by the Competent Authority of each concerned Member State.

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

First aid instructions: Intoxication may cause: - Haemorrhagic diathesis, derived from antiprothrombin effect – prolonged prothrombin time – that may become evident at minimum term of 24 hours and a maximum of 72 hours (A normal prothrombin time on admittance does not exclude the diagnosis).

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. Maintain 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 prothrombin 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.

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

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

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 more than 2 years.

6. OTHER INFORMATION