Summary of product characteristics for a biocidal product

Product name: Protect wax block extruded

Product type(s): PT14 - Rodenticides (Pest control)

PT14 - Rodenticides (Pest control)

Authorisation number: RO/2019/0045/MRA / HU-2013-MA-14-00039-0000

R4BP 3 asset reference number: RO-0009680-0000

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Administrative information

1.1. Trade names of the product

Rodenticid sub forma de bloc cerat extrudat Protect	

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Bábolna Bioenvironmental Centre Private Limited Company
Address	Szállás u. 6. H-1107 Budapest Hungary

Authorisation number

RO/2019/0045/MRA / HU-2013-MA-14-00039-0000

R4BP 3 asset reference number

RO-0009680-0000

Date of the authorisation

22/07/2013

Expiry date of the authorisation

01/07/2024

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Babolna Bio Ltd

Address of the manufacturer

Szallas u 6 1107 Budapest Hungary

Location of manufacturing sites

Dr Köves János 2943 Bábolna Hungary

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

Active substance	12 - Bromadiolone
Name of the manufacturer	Dr Tezza SrL
Address of the manufacturer	Via Tre Ponti 22 37050 St. Maria di Zevio Italy
Location of manufacturing sites	Via Tre Ponti 22 37050 St. Maria di Zevio Italy

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal 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 of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	May cause damage to organs through prolonged or repeated exposure .				
Precautionary statements	Keep out of reach of children.				
	Do not get in eyes, on skin, or on clothing.				
	Do no eat, drink or smoke when using this product.				
	Wear protective gloves.				
	IF SWALLOWED:Immediately call a doctor.				
	Dispose of contents to local requirement.				

4. Authorised use(s)

4.1 Use description

Use 1 - PCO

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

used against mouse or rats in and around of buildings

Target organism(s) (including development stage)

Scientific name: Mus musculus Common name: House mouse Development stage: Adults

Scientific name: Mus musculus Common name: House mouse Development stage: Juveniles

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles

Field(s) of use

Indoor

Outdoor

Place out the bait according to the dosage instruction in and around of building

Application method(s)

Method: Bait application Detailed description: bait station or bait points

Application rate(s) and frequencies

Application Rate: For rat infestations use bait points of up to 200 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations. For mouse infestations use bait points of up to 40g to 50 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations.

Dilution (%): 100

Number and timing of application: Depends on the rate of infestation

Category(ies) of users

Professional

Trained professional

Industrial

Pack sizes and packaging material

Packet - Plastic: composite: - 20g or 25g or 50 g block

4.1.1 Use-specific instructions for use						
NA						
4.1.2 Use-specific risk mitiga	4.1.2 Use-specific risk mitigation measures					
NA						
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment					
NA						
4.1.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its					
NA						
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage						
NA	NA NA					
4.2 Use description						
Use 2 - Non-professional						
Product type	PT14 - Rodenticides (Pest control)					
Where relevant, an exact description of the authorised use	used against mouse or rats in and around of buildings					
Target organism(s) (including development stage)	Scientific name: Mus musculus Common name: House mouse Development stage: Adults					
	Scientific name: Mus musculus Common name: House mouse Development stage: Juveniles					
	Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Adults					
Scientific name: Rattus norvegicus Common name: Brown rat Development stage: Juveniles						

Field(s) of use	Indoor
riciu(3) oi use	Outdoor
	Place out the bait according to the dosage instruction in and around of building
Application method(s)	Method: Bait application Detailed description: bait box or covered baiting point
Application rate(s) and frequencies	Application Rate: For rat infestations use bait points of up to 200 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations. For mouse infestations use bait points of up to 40g to 50 g. Place bait points 10-metres apart for low infestations and 4-metres apart for high infestations. Dilution (%): 100 Number and timing of application: Depends on the rate of infestation
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Packet - Paper, cardboard - 20g or 25g or 50 g block Packet - Plastic: composite: - 20g or 25g or 50 g block

4.2.1 Use-specific instructions for use

For mouse infestations use bait points of up to 40 to 50 g blocks in bait stations (mouse boxes) or covered bait points. Bait may also be placed on trays under a tile or located, where accessby non-target organisms is restricted. In this case – as far aspossible – fix the blocks (with a nail or wire) so that they cannot be draggedaway (or dispersed) by rodents.

Baitbox - Plastic: composite: - 20 g or 25 g

4.2.2 Use-specific risk mitigation measures

NA NA

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

NA			

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

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

5. General directions for use

5.1. Instructions for use

Place baits manually in the rodent infested area. The method of deployment is dependant on the particular circumstances, however a priority should be to exclude non-target exposure as much as possible.

Bait may be deployed in bait stations (tamperproof baiting boxes), at bait points (a makeshift arrangement using materials and/or the local environment to restrict access to the bait), and loose butinaccessible (using the local environment only to restrict access to the bait).

These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non-targetorganisms) of a particular site must be assessed in the decision for thedeployment method to be used.

Bait can be placed in bait boxes, which may be fixed to the ground. Suchbait should be secured in place on the built-in spikes, to minimise removal anddispersal by rodents. Bait may also beplaced on trays under a tile, or located in such a way that access bynon-target organisms is restricted.

The product must never be placed indiscriminately.

The resistance status of the target populationshould be taken into account when considering the choice of rodenticide to beused. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primaryor secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside thebaits.

When tamper resistant bait stations are used, they should be clearlymarked to show that they contain rodenticides and that they should not be disturbed.

Rate of use:

For rat infestations use bait points of up to 200 g. Place bait points10-metres apart for low infestations and 4-metres apart for high infestations

For mouse infestations use bait points of up to 40g to 50 g. Place bait points10-metres apart for low infestations and 4-metres apart for high infestations.

Death of the rodents starts after 3-5 days from the beginning ofconsumptions. Make regular inspections of the bait points (regularly every 7 –10 days) and replace any bait that has been eaten by rodents, damaged by wateror contaminated by dirt. If bait is totally consumed then the quantity of the bait at each bait point should be replenished.

5.2. Risk mitigation measures

The rodenticide wax block extruded bait contains denatonium benzoate - an extremely bitter substance - which helps preventing incidental consumption by humans.

Prevent access to bait by children, birds and non-target animals(particularly dogs, cats, pigs and poultry).

Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined.

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

Bromadiolone is an anticoagulant which may produce bleeding; the onset of bleeding may be delayed for several days after exposure. If there is no active bleeding the INR(prothrombin time) should be measured on presentation and 48-72 hours after exposure. If the INR is greater than 4,administer Vitamin K1 (phytomenadione) 5-10 mg by slow intravenous injection(100 µg/kg body weight for a child). Treatment with phytomenadione (orally or intravenously) may be required for several weeks. Antidote Vitamin K1(under medical supervision)

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

Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances. Dispose of dead rodents in accordance with local requirements.

Remove all baits after treatment and disposeof them in accordance with local requirements.

ļ	5.5. Conditions o	f storage and	shelf-life of the	product und	ler normal d	conditions of	storage

Keep in a cool, dry, well-ventilated area. Shelf life of up to 24 months .	
6. Other information	