Summary of product characteristics for a biocidal product

Product name: Ratimor Plus Grain Bait

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

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Authorisation number: SI-0017955-0000

R4BP 3 asset reference number: SI-0017955-0000

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Administrative information

1.1. Trade names of the product

Ratimor Plus Grain Bait		
Ratimor Plus žitna vaba		

1.2. Authorisation holder

Name and address of the	Name	Unichem d.o.o.	
authorisation holder	Address	Sinja Gorica 2 SI 1360 Vrhnika Slovenia	
Authorisation number	SI-0017955-0000		
R4BP 3 asset reference number	SI-0017955-0000		
Date of the authorisation	04/02/2014		
Expiry date of the authorisation	27/01/2026		

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Unichem d.o.o.
Address of the manufacturer	Sinja Gorica 2, 1360 Vrhnika, Slovenia
Location of manufacturing sites	Sinja Gorica 2, 1360 Vrhnika, Slovenia

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

Active substance	12 - Bromadiolone
Name of the manufacturer	Activa s.r.l.
Address of the manufacturer	Via Feltre 32, 20132 Milano, Italy
Location of manufacturing sites	Tezza S.r.l., 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 biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3-hydroxy- 1-phenylpropyl]-4- hydroxy-2H-1- benzopyran-2-one	Active Substance	28772-56-7	249-205-9	0,0029

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	May cause damage to organs (blood) through prolonged or repeated exposure . Contains octhilinone (ISO) and 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
Precautionary statements	Keep out of reach of children. Do not breathe dust.
	Get medical advice if you feel unwell. Get medical attention if you feel unwell. Dispose of contents to in accordance with local regulations.

Dispose of container to in accordance with local regulations.

4. Authorised use(s)

4.1 Use description

Use 1 - House mice - general public - indoor

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Where relevant, an exact description of the authorised use

Not relevant for rodenticides.

Target organism(s) (including development stage)

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

Field(s) of use

Indoor

Application method(s)

Method: In bait boxes Detailed description:

Ready-to-use bait [in sachets for loose bait] to be used in tamper-resistant bait stations.

Application rate(s) and frequencies

Application Rate: For mouse infestations use 10 g up to 40 g per bait point. Dilution (%):

Number and timing of application:

Place bait stations 5 m apart reducing to 2 m in case of high infestations.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

- 1. Edible paper tea-bag sachets (10 g 20 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g
- polyethylene (PE) or polypropylene (PP) packs up to 50 g
- natron bag up to 50 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g
- PE or PP buckets with lid up to 50 g
- cardboard or fibre-board boxes with PE or PP bag or liner up to 50 g
- cardboard or fibre-board boxes up to 50 g
 pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 50 g

- 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g 50 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g
- PE or PP packs up to 50 g
- HDPE container up to 50 g
- Natron bag up to 50 g
- Packs up to 50 g
- PP woven sack or multi-ply paper sack up to 50 g
- Pail (PP) or bucket (PP or PE) with lid up to 50 g
- PP or PE tub up to 50 g
- Prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 50 g
- PET/PE, PP/PE or paper/PE pouch up to 50 g
- Cardboard or fibre-board pack with PE or PP bag or liner up to 50 g
- Cardboard or fibre-board box up to 50 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g
- 3. Other packaging:
- loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 50g
- loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to $50~\rm g$

4.1.1 Use-specific instructions for use

The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.1.2 Use-specific risk mitigation measures

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 5.3
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See 5.4

See 5.2

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

See 5.5			

4.2 Use description

Use 2 - Rats - general public - indoor

Product type

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: all

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Scientific name: Rattus rattus Common name: Roof rat Development stage: all

Field(s) of use

Indoor

Application method(s)

Method: In bait boxes Detailed description:

Ready-to-use bait [in sachets for loose bait] to be used in commercially available tamper-resistant bait stations.

Application rate(s) and frequencies

Application Rate: For rat infestations use 10 g up to 200 g per bait point. Dilution (%):

Number and timing of application:

Place bait stations 10 m apart reducing to 5 m in case of high infestations.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

- 1. Edible paper tea-bag sachets (10 g 20 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to $150 \mathrm{g}$
- polyethylene (PE) or polypropylene (PP) packs up to 150 g
- natron bag up to 150 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g
- PE or PP buckets with lid up to 150 g
- cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g
- cardboard or fibre-board boxes up to 150 $\ensuremath{\text{g}}$
- pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150 g

- 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10g - 150 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g
- PE or PP packs up to 150 g
- HDPE container up to 150 g
- Natron bag up to 150 g
- Packs up to 150 g
- PP woven sack or multi-ply paper sack up to 150 g Pail (PP) or bucket (PP or PE) with lid up to 150 g
- PP or PE tub up to 150 g
- Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up
- PET/PE, PP/PE or paper/PE pouch up to 150 g
- Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g
- Cardboard or fibre-board box up to 150 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g
- 3. Other packaging:
- loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 150g
- loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

4.2.1 Use-specific instructions for use

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.2.2 Use-specific risk mitigation measures

See 5.2

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

See 5.3

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

See 5.4

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

See 5.5

4.3 Use description

Use 3 - Rats - general public - outdoor around buildings

Product type

description of the authorised

Target organism(s) (including

Where relevant, an exact

development stage)

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Not relevant for rodenticides.

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

Scientific name: Rattus rattus Common name: Roof rat Development stage: all

Field(s) of use

Outdoor

Outdoor around buildings

Application method(s)

Method: In bait boxes Detailed description:

Ready-to-use bait [in sachets for loose bait] to be used in commercially available tamper-resistant bait stations.

Application rate(s) and frequencies

Application Rate: For rat infestations use 10 g up to 200 g per bait point.

Dilution (%):

Number and timing of application:

Place bait stations 10 m apart reducing to 5 m in case of high infestations.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

- 1. Edible paper tea-bag sachets (10 g 20 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g
- polyethylene (PE) or polypropylene (PP) packs up to 150 g
- natron bag up to 150 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g
- PE or PP buckets with lid up to 150 g
- cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g
- cardboard or fibre-board boxes up to 150 g
- pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150 g

- 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 150 g) packed in:
- polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g
- PE or PP packs up to 150 g
- HDPE container up to 150 g
- Natron bag up to 150 g
- Packs up to 150 g
- PP woven sack or multi-ply paper sack up to 150 g Pail (PP) or bucket (PP or PE) with lid up to 150 g
- PP or PE tub up to 150 g
- Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up
- PET/PE, PP/PE or paper/PE pouch up to 150 g
- Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g
- Cardboard or fibre-board box up to 150 g
- sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g
- 3. Other packaging:
- loose bait in prefilled or refillable tamper-resistant mouse or rat bait station, packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 150g
- loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

4.3.1 Use-specific instructions for use

Place the bait stations in areas not liable to flooding.

Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.3.2 Use-specific risk mitigation measures

See 5.2

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

See 5.3

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

See 5.4	

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

See 5.5

5. General directions for use

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.

Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

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. Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

Where possible, bait stations must be fixed to the ground or other structures.

Do not open the sachets containing the bait.

Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. Do not place bait stations near water drainage systems where they can come into contact with water.

When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

Remove the remaining bait or the bait stations at the end of the treatment period.

5.2. Risk mitigation measures

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.

Do not use anticoagulant rodenticides as permanent (e.g. for prevention of rodent infestation or to detect rodent activity) or pulsed baits.

The product information (i.e. label and/or leaflet) shall clearly show that:

- the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
- users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

Using this product should eliminate rodents within 35 days.

The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

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, 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, get medical attention or 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]. Use of gloves is recommended.

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. Store locked up.

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

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.

In case of common packaging for mice and rats, for non-professional users, maximum packaging size is 150 g.