

Summary of product characteristics for a biocidal product

Product name: RODEXION PASTA

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

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Authorisation number: RO/2019/0060/MRA/IT/2013/00103/AUT

R4BP 3 asset reference number: RO-0006336-0000

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Administrative information

1.1. Trade names of the product

RODEXION PASTA

1.2. Authorisation holder

Name and address of the authorisation holder	Name	BIOTUR EXIM SRL
	Address	G-ral Praporgescu no 48 145200 Turnu Magurele Romania
Authorisation number	RO/2019/0060/MRA/IT/2013/00103/AUT	
R4BP 3 asset reference number	RO-0006336-0000	
Date of the authorisation	14/12/2012	
Expiry date of the authorisation	01/07/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	INDUSTRIALCHIMICA S.r.l.
Address of the manufacturer	via Sorgaglia, 40, Arre 35020 Padova Italy
Location of manufacturing sites	via Sorgaglia, 40, Arre 35020 Padova Italy

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

Active substance	12 - Bromadiolone
Name of the manufacturer	ACTIVA S.R.L. / Dr. Tezza s.r.l.
Address of the manufacturer	Via Feltre, 32 20132 Milano Italy
Location of manufacturing sites	Via Tre Ponti 22, S. Maria di Zevio 37050 Verona 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	0,005
Denatonium benzoate	Denatonium benzoate	Non-active substance	3734-33-6	223-095-2	0,001

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	<p>Keep out of reach of children.</p> <p>Do not eat, drink or smoke when using this product.</p> <p>Wear protective gloves.</p> <p>IF SWALLOWED: Immediately call a POISON CENTER.</p> <p>Store in accordance with away from food, drink and animal feeding stuff..</p> <p>Dispose of container to hazardous waste facilities in accordance with national regulations..</p>

4. Authorised use(s)

4.1 Use description

Use 1 - Non professional use

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	MEGALON PASTA for non-professional use can be used in and around buildings, in cellars, garages, closets and gardens.
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: House mouse Development stage: Adults Scientific name: <i>Rattus norvegicus</i> Common name: Brown rat Development stage: Adults Scientific name: <i>Rattus rattus</i> Common name: Roof rat Development stage: Adults
Field(s) of use	Indoor Outdoor
Application method(s)	Method: Bait application Detailed description: MEGALON PASTA is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. Stations and baiting points are controlled in an interval of 7 days and consumed bait is replaced. Method: Bait application Detailed description: MEGALON PASTA is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. Stations and baiting points are controlled in an interval of 7 days and consumed bait is replaced.
Application rate(s) and frequencies	Application Rate: House mouse (<i>Mus musculus</i>): 2 bait stations (containing 20 g pasta bait in a food paper sachet each) per 100 sm of infested area (40 g pasta bait/100 sm). Dilution (%): 0 Number and timing of application: The number of bait points employed is dependent on: the treatment site, the size and severity of the infestation, the user and the user requirements and needs. Consumed baits have to be replaced in regular intervals until consumption stops. If no further consumption of baits is observed for more than three days, it is considered that control has been achieved and the bait boxes are removed from the sites. Application Rate: Brown rat (<i>Rattus norvegicus</i>) and Black rat (<i>R. rattus</i>): 3-5 bait stations (containing 20 g pasta bait in a food paper sachet each) per 100 sm of infested area (60-100 g pasta bait/100 sm). Dilution (%): 0 Number and timing of application: The number of bait points employed is dependent on: the treatment site, the size and

severity of the infestation, the user and the user requirements and needs.
Consumed baits have to be replaced in regular intervals until consumption stops.
If no further consumption of baits is observed for more than three days, it is considered that control has been achieved and the bait boxes are removed from the sites.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

Bag /Sack, Plastic: composite: , 40-100-160-200-260-500 g

Packs with: 40-100-160-200-260-500 g (containing 20 g pasta bait in a food sachet each)

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

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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

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

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

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4.2 Use description

Use 2 - Professional use

Product type

PT14 - Rodenticides (Pest control)

Where relevant, an exact description of the authorised use

MEGALON PASTA for professional use can be used in and around buildings, in cellars, garages, closets and gardens, in and around industrial buildings (warehouses and holds included), farms and civilian buildings.

Target organism(s) (including development stage)

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

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

Scientific name: *Rattus rattus*
Common name: Roof rat
Development stage: Adults

Field(s) of use

Indoor

Outdoor

Application method(s)

Method: Bait application

Detailed description:

MEGALON PASTA is applied via tamper resistant bait stations.

Bait is deposited and fixed in the bait stations.

Stations and baiting points are controlled in an interval of 7 days and consumed bait is replaced.

Method: Bait application

Detailed description:

MEGALON PASTA is applied via tamper resistant bait stations.

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Stations and baiting points are controlled in an interval of 7 days and consumed bait is replaced.

Application rate(s) and frequencies

Application Rate: House mouse (*Mus musculus*): 2 bait stations (containing 20 g pasta bait in a food paper sachet each) per 100 sm of infested area (40 g pasta bait/100 sm).

Dilution (%): 0

Number and timing of application:

The number of bait points employed is dependent on: the treatment site, the size and severity of the infestation, the user and the user requirements and needs.

Consumed baits have to be replaced in regular intervals until consumption stops.

If no further consumption of baits is observed for more than three days, it is considered that control has been achieved and the bait boxes are removed from the sites.

Application Rate: Brown rat (*Rattus norvegicus*) and Black rat (*R. rattus*): 3-5 bait stations (containing 20 g pasta bait in a food paper sachet each) per 100 sm of infested area (60-100 g pasta bait/100 sm).

Dilution (%): 0

Number and timing of application:

The number of bait points employed is dependent on: the treatment site, the size and severity of the infestation, the user and the user requirements and needs.

Consumed baits have to be replaced in regular intervals until consumption stops.

If no further consumption of baits is observed for more than three days, it is considered that control has been achieved and the bait boxes are removed from the sites.

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Bag /Sack, Plastic: composite: , 40-100-160-200-260-500 g
Box, Paper, cardboard , 1-3-5-10-20-25 kg

Packs with 40-100-160-200-260-500 g, 1-3-5-10-20-25 kg (containing 20 g pasta bait in a food sachet each).

4.2.1 Use-specific instructions for use

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4.2.2 Use-specific risk mitigation measures

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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

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

In a professional use, containers, even if completely empty, must be clean up before to be disposed.

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

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5. General directions for use

5.1. Instructions for use

MEGALON PASTA is used for the control of brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and house mouse (*Mus musculus*). The active substance Bromadiolone is an anticoagulant rodenticide/Vitamin K antagonist. MEGALON PASTA can be used in and around buildings, in cellars, garages, closets and gardens. For professional use also in and around industrial buildings (warehouses and holds included), farms and civilian buildings. MEGALON PASTA is applied via tamper resistant bait stations. Bait is deposited and fixed in the bait stations. Stations and baiting points are controlled in an interval of 7 days and consumed bait is replaced. Bait points should be removed, in a typical campaign, 6 weeks after initial placement.

5.2. Risk mitigation measures

The product must be placed into an appropriate container, protected from weather. Containers should be placed securely to minimize the risk of tampering and accidental ingestion by children or non-target animals. Avoid treatments in the presence of not protected food or feed. Always be sure that containers are adequately secured and that baits could not be dragged away by rodents. While handling bait material and/or dead rodents, wear rubber gloves. In case of contamination wash hands thoroughly with soap and plenty of water. In case of suspected ingestion consult a poison control center.

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

MECHANISM OF ACTION: the active ingredient of MEGALON PASTA is a long lasting anticoagulant chemical and decreases the hepatic synthesis of k-dependent factors.
SYMPTOMS: Severe poisoning by ingestion causes Vitamin K inhibition, causing dermal and mucous haemorrhages. Symptoms to occur in other systems is mainly haemorrhagic.
THERAPY: if large quantities are ingested, induce vomiting, perform gastric lavage and monitor prothrombin activity, if decreased Vitamin K1 should be administered. Follow the appropriate medical protocol.

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

Keep out of the reach of children.
Keep container tightly closed.
Keep away from food, drink and animal feed stuffs. Store in original container, tightly closed, in a safe place.
The product should not be re-used or recycled.
Unconsumed product should be collected and disposed in accordance with local requirements.
Arrange disposal of the dead rodents by incineration or with other approved suitable treatments.
Elimination or recycling according with the local Authority Regulations.

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

Keep container tightly closed in cool and dry places, far from unauthorized people, far from foods and domestic animals.
Protect from direct solar rays.
Keep far from combustion fonts.
Accurate ventilation/aspiration in work places.
The provisional shelf-life of the product is two years.

6. Other information

Non professionals baits should be supplied as inner packs or units containing at most enough bait for one bait point (either rat or mouse) and used only in refillable tamper-resistant bait stations. Individual packs for non-professional use should not exceed 500 g. MEGALON PASTA for professional use should not be available to the general public.