

Summary of product characteristics for a biocidal product

Product name: Harmonix Rodent Paste

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

Authorisation number: RO/2022/0338/MRP/DE-0015959-0000

R4BP 3 asset reference number: RO-0028861-0000

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Administrative information

1.1. Trade names of the product

Harmonix Rodent Paste

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Bayer SRL Romania
	Address	Sos. Bucuresti-Ploiesti nr. 1A 40 013681 Bucharest Romania
Authorisation number	RO/2022/0338/MRP/DE-0015959-0000	
R4BP 3 asset reference number	RO-0028861-0000	
Date of the authorisation	10/05/2022	
Expiry date of the authorisation	24/07/2025	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Bayer SAS
Address of the manufacturer	16 rue Jean-Marie Leclair, CS 90106 69266 Lyon (Cedex 09) France
Location of manufacturing sites	INDUSTRIALCHIMICA Srl. Via Sorgaglia 40, I-35020 Arre Italy

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

Active substance	1443 - Cholecalciferol
Name of the manufacturer	Zhejiang Garden Biochemical High-tech Co.,Ltd.
Address of the manufacturer	No. 166, Street 20, Economic & Technological Development Zone, Hangzhou, Zhejiang, China N/A Hangzhou China
Location of manufacturing sites	Zhejiang Garden Biochemical High-tech Co., Ltd. 310018 Hangzhou China

Active substance	1443 - Cholecalciferol
Name of the manufacturer	Dishman Netherlands BV
Address of the manufacturer	P.O. Box 70, 3900 AB Veenendaal Netherlands
Location of manufacturing sites	Pharmaceuticals Works Polpharma S.A. 19, Pelplinska str, 83-200 Starogard Gdanski Poland

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 (%)
Cholecalciferol		Active Substance	67-97-0	200-673-2	0,075

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements

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Precautionary statements

Store in a well-ventilated place.Keep cool.

Keep container tightly closed.

Keep only in original packaging.

Store locked up.

Do not get in eyes, on skin, or on clothing.

Wash hands thoroughly after handling.

Take off immediately all contaminated clothing.And wash it before reuse.

4. Authorised use(s)

4.1 Use description

Use 1 - EU BPD Product type PT 14 Rodenticides (Pest control)

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Harmonix Rodent Paste is a universal bait for mouse and rat control in and around buildings, in waste dumps and in open areas.
Target organism(s) (including development stage)	<p>Scientific name: Rattus norvegicus Common name: Norway rat Development stage: Adults and juveniles</p> <p>Scientific name: Rattus rattus Common name: Roof rat Development stage: Adultes and juveniles</p> <p>Scientific name: Mus musculus Common name: House mouse Development stage: Adults and juveniles</p>
Field(s) of use	<p>Indoor</p> <p>Outdoor</p> <p>The bait is designed for use in and around buildings (residential homes and other places in which people are accommodated, rooms intended for the preparation, processing or storage of food and beverages, empty stores, ships' holds, factories and silos), at waste dumps, on animal husbandry farms (pigs, poultry, cattle, etc.) and in open areas such as airports or leisure areas.</p>
Application method(s)	<p>Method: Bait application</p> <p>Detailed description: Application is recommended on sites either where mice or rats feed or on the rat runways. Baiting points are to be inspected frequently (Subsequent follow-up visits must be no longer than 14 days apart), and bait to be replenished according to consumption. Due to its high fat-content, no application is recommended in places, which may be exposed to direct sunlight.</p>

Application rate(s) and frequencies

Application Rate: For rat infestations: 100g to 200g of bait per baiting point depending upon the infestation level (from low to high infestation, respectively). For mouse infestations: 20g of bait per baiting point.
Dilution (%): 0
Number and timing of application:

Inspect the bait regularly in particular during the first days of the treatment, and renew it as necessary until consumption stops.

Distance between baiting points: Rats:
10-20 linear metres for a low infestation
3-10 linear metres for a heavy infestation

Distance between baiting points: Mice:
5-20 linear metres for a low infestation
2-5 linear metres for a heavy infestation

Subsequent follow up visits must be no more than 14 days apart.

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Bait in individual tea bag sachet - Long fibre paper - 20g

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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5. General directions for use

5.1. Instructions for use

Control of House Mice

Bait stations should be set in place with un-poisoned food a few days prior to the treatment in order to get the mice familiar with these sources of bait. Even for mouse control, a few days of pre-baiting will enhance the effect of the treatment. The bait should be placed at high density where mice are present. The extent of the infestation must be carefully investigated by searching for signs of mouse activity, such as droppings and urine smears, in particular overhead and inside devices. The sachets can be easily fixed using a wire, in bait boxes and in hidden places. But where children or non-target organisms could be present, always secure the bait so it remains in place and in a manner to be inaccessible to children and non-target organisms.

Inspect the bait regularly in particular during the first days of the treatment, and renew it as necessary until consumption stops. For mouse infestations place from 20g of Harmonix D3 per baiting point. An amount of 20g of product must be added when bait has been totally consumed within one control interval.

Subsequent follow up visits must be no more than 14 days apart.

Distance between baiting points:

5-20 linear metres for a low infestation

2-5 linear metres for a heavy infestation

Due to its high fat-content, no application is recommended in places, which may be exposed to direct sunlight.

At the end of the treatment, collect surplus bait and, if possible, dead animals and dispose of safely.

When rodent control is achieved, all remaining baits must be collected and disposed of as pesticidal waste.

Control of Rats

Because sub-lethal doses can cause anorexia in rats, pre-baiting and intense surplus baiting during the first three days of the treatment will enhance the chance of lethal doses ingested by rats within short time, preventing prolonged bait replenishment. The bait should be placed where rats are present, near to burrows and along runs. A careful investigation of the infested site therefore is required.

Put the bait in rat holes and on rat runs protected from the weather and domestic animals by placing inside a length of drainpipe or in a suitable bait box. Alternatively the bait can be covered by a piece of wood or slate. But where children or non-target organisms could be present, always secure the bait so it remains in place and in a manner to be inaccessible to children and non-target organisms.

Inspect the bait regularly in particular during the first days of the treatment, and renew it as necessary until consumption stops.

Used under damp conditions, bait should be monitored and mouldy / decayed baits identified and replaced.

For rat infestations place from 100g to 200g of Harmonix D3 per baiting point depending upon the infestation level (from low to high infestation, respectively). An amount of 200g of product must be added when bait has been totally consumed within one control interval.

Subsequent follow up visits must be no more than 14 days apart.

Distance between baiting points:

10-20 linear metres for a low infestation

3-10 linear metres for a heavy infestation

Due to its high fat-content, no application is recommended in places, which may be exposed to direct sunlight.

At the end of the treatment, collect surplus bait and, if possible, dead animals and dispose of safely.

When rodent control is achieved, all remaining baits must be collected and disposed of as pesticidal waste.

5.2. Risk mitigation measures

For outdoor and indoor uses where children or non-target organisms could be present:
The bait sachets must be placed in a tamper-proof or lockable, secured bait stations, or placed, secured with wire or nail and covered, in a manner to be inaccessible to children and non-target organisms.
For indoor uses where no children or non-target organisms could be present:
The baits can be placed and fixed in a bait station, covered baiting point or applied loose in hidden places.

Rat and mouse control measures should continue until no more bait consumption is apparent, but not exceeding five weeks. A normal bait campaign lasts 2 to 3 weeks. Spoiled bait and carcasses have to be collected during every inspection of the site. When rodent control is achieved, all remaining baits must be collected and disposed of as pesticidal waste.

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

In case of accident or if you feel unwell seek medical advice immediately (show label where possible).
General advice:
The nature of this product, when contained in commercial packs, makes spillage unlikely. However, if significant amounts are spilled nevertheless, the following advice is applicable. Move out of dangerous area. When symptoms develop and persist, seek medical advice.
Skin contact:
Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
Eye contact:
Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.
Ingestion:
Do NOT induce vomiting. Rinse mouth. Call a physician or poison control centre immediately.
Environmental Protection:
Do not allow to get into surface water, drains and ground water.

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

Do not clean the bait stations between two applications.
This material and its container must be disposed of in a safe way.
Do not dispose of the product in environment or pipings.
Packaging, unconsumed baits, unused baits and ejected baits outside bait stations must be collected and disposed in accordance with local regulation.

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

Keep containers tightly closed in a dry, cool and well-ventilated place.
Store in original container.
Store in a place accessible by authorized persons only.
Keep away from direct sunlight.
Keep away from food, drink and animal feedingstuffs.
Store out of reach of children and non-target animals like dogs.
Store in a closed room, dry and at maximum 40°C.
When stored in a dry place at room temperature Harmonix Rodent Paste has a shelf-life of 3 years.

6. Other information

General claims
The best profile for limiting the adverse effects on humans, companions animals, farm animals, wildlife
No toxicological nor environmental classification
Contribute to responsible use of rodenticides
Non classified formulation
Due to cumulative action, it reduces the risk of adverse effects on non-target species with one single ingestion

Specific claims
Harmonix Rodent Paste AI cholecalciferol has a higher end point than 2nd generation and most of the anticoagulants for Acute Oral
Toxicity to non-target mammals and birds
Contain a bittering agent
Harmonix Rodent Paste reduces secondary poisoning risk compared to 2nd generation and most of anticoagulant Rodenticides
Harmonix Rodent Paste reduces secondary poisoning risk for birds compared to 2nd generation and most of anticoagulant Rodenticides

