



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL
SERVIZIO FARMACEUTICO

Ufficio I – Affari generali e prodotti di interesse sanitario diversi dai dispositivi medici
Viale Giorgio Ribotta, 5 - 00144 Roma

Class. : I.5.i.d.2/845

Allegati: 1 decreto + 2 documenti

Ministero della Salute

0051379-15/07/2021-DGDMF-MDS-P

DGDMF

0051379-P-15/07/2021



454798163

Bayer CropScience s.r.l.

Viale Certosa 130
20156 Milano – Italia

OGGETTO: Prodotto biocida Harmonix Rodent Paste - Trasmissione decreto di autorizzazione.

Si trasmette, in allegato, il decreto di autorizzazione, n. **IT/2021/00.150...../MRP** relativa al biocida indicato in oggetto. Si richiama inoltre l'attenzione in merito a quanto previsto dal regolamento 1272/2008 del Parlamento europeo e del Consiglio, e successive modifiche e adeguamenti, relativo alla classificazione, all'etichettatura e all'imballaggio delle sostanze, delle miscele.

IL DIRETTORE GENERALE
dott. Achille IACHINO

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DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO I
I.5.i.d.2/845

IT/2021/00 750 /MRP

IL DIRETTORE

VISTO l'art. 15 della legge 6 agosto 2013, n. 97, recante: "Disposizioni per l'adempimento degli obblighi derivanti dall'appartenenza dell'Italia all'Unione europea – Legge europea 2013";
VISTO il Regolamento (UE) 528/2012 del Parlamento Europeo e del Consiglio del 22 maggio 2012 relativo alla messa a disposizione sul mercato e all'uso dei biocidi, in particolare gli artt.19 e ss.;
VISTO, in particolare, gli articoli 33 e 34 del suddetto Regolamento riguardanti il riconoscimento reciproco delle autorizzazioni e delle registrazioni di prodotti biocidi in sequenza e in parallelo;
VISTA l'istanza NA-MRP, numero BC-CG025957-40 presentata sul Registro R4BP3 in data 14/07/2016;
VISTA la decisione di autorizzazione del prodotto di riferimento, con ASSET NUMBER DE-0015958-0000, ed essendosi verificate le condizioni di cui all'art. 34 paragrafo 5 del Regolamento (UE) 528/2012;
VISTA la documentazione presentata dalla società richiedente a sostegno della suddetta istanza e accertata la conformità della medesima alla normativa vigente in materia di immissione sul mercato di biocidi;
VISTO il parere dell'Istituto Superiore di Sanità, inserito nel registro ECHA in data 20.05.2021;

DECRETA

L'autorizzazione del prodotto biocida

DENOMINAZIONE	Harmonix Rodent Paste
TITOLARE DELL'AUTORIZZAZIONE PER L'IMMISSIONE SUL MERCATO	Bayer CropScience s.r.l. Viale Certosa 130 20156 Milano (Italia)
NUMERO DI AUTORIZZAZIONE	IT/2021/00 750 /MRP
SCADENZA DELL'AUTORIZZAZIONE	24 luglio 2025

A far data dalla notifica del presente decreto, la società è tenuta a produrre e commercializzare il prodotto come biocida esclusivamente alle condizioni riportate nell'allegato 1 (SPC – sommario delle caratteristiche del prodotto) e nell'allegato 2 (ulteriori condizioni dell'autorizzazione).

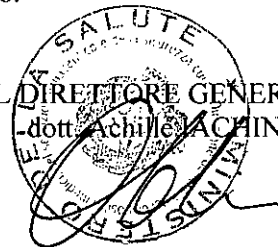
Avverso il presente atto è ammesso ricorso giurisdizionale presso il Tribunale Amministrativo Regionale competente entro il termine di sessanta giorni, ovvero ricorso straordinario al Capo dello Stato entro il termine di centoventi giorni.

Il presente decreto viene redatto in duplice originale, di cui un esemplare è notificato in via amministrativa alla ditta interessata e l'altro è conservato agli atti di questo Ufficio.

Roma,

14 LUG. 2021

IL DIRETTORE GENERALE
-dott. Achille ACCHINO



Summary of product characteristics for a biocidal product

1. Administrative information

1.1. Trade names of the product

Market area Trade name(s)
Italy Harmonix Rodent Paste

1.2. Authorisation holder

Authorisation number

Not defined

Date of the authorisation

Not defined

Expiry date of the authorisation

Not defined

Name and address of the
authorisation holder

Name
Address

Not defined
Not defined

1.3. Manufacturers of the product

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)

BAS number: 1443

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

BAS number: 1443

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 product

BAS number	EC number	CAS number	Common name	IUPAC name	Function	Content (%)
1443	200-673-2	67-97-0	Cholecalciferol		Active Substance	0.075

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements

Not defined

Precautionary statements

Store in a
well-ventilated place.Keep cool.

Keep container tightly
closed.

Keep only in
original container.

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. 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.

Field(s) of use Indoor, Outdoor

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.

Category(ies) of users Trained professional, Professional

Target organisms	Scientific name	Common name	Development stage
	Rattus norvegicus	Norway rat	Adults and juveniles
	Rattus rattus	Roof rat	Adults and juveniles
	Mus musculus	House mouse	Adults and juveniles

Application method(s)

Method Bait application

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.

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%

Timing:

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.

Pack sizes and packaging material

Type	Material	Size
Bait in individual tea bag sachet	Long fibre paper	20g

Description

Primary bait packaging : tea bag (cellulose), 20 g

Type of packaging: Bucket

Up to 5kg

Description: Inner LDPE plastic sachet in a plastic PP Bucket

Type of packaging: Box

Up to 2,5kg

Description: Inner PE/PES plastic sachet in a cardboard box

Type of packaging: Bag

5 kg

Description: PE Plastic bag, with handle and reclosable zip

Type of packaging: Bucket

Size/volume of the packaging: up to 1500g

Material of the packaging: Other: PP

Safety
See above

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 pesticial 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 feedings stuffs

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

Ulteriori condizioni dell'autorizzazione

ETICHETTATURA

- L'etichetta del prodotto biocida oggetto della presente autorizzazione dovrà essere redatta, integralmente in lingua italiana, nel rispetto delle disposizioni di cui all'articolo 69 del Regolamento (UE) n.528/2012 riportando le informazioni di cui al sommario delle caratteristiche del prodotto riportato in Allegato 1.
- Tutte le etichette del prodotto biocida devono riportare il numero di autorizzazione attribuito dal presente decreto, con la seguente dicitura:
**"*PRODOTTO BIOCIDA (PT14)*
*AUTORIZZAZIONE DEL MINISTERO DELLA SALUTE n. IT/2021/00...⁷⁵⁰...../MRP"***
- Per ogni categoria di utilizzatore autorizzata (Professionisti/ Professionisti formati/ Utilizzatori non professionisti) deve essere predisposta una etichetta distinta.
- L'etichetta dovrà contenere l'indicazione dell'officina di produzione e sito produttivo del formulato autorizzato.
- Nell'etichetta l'esatta denominazione del biocida dovrà comunque essere individuabile attraverso una colorazione e un carattere unici in contrasto con le altre eventuali colorazioni e caratteri usati nel testo degli stampati autorizzati.
- L'etichetta del prodotto non contiene le formule «biocida a basso rischio», «non tossico», «innocuo», «naturale», «rispettoso dell'ambiente», «rispettoso degli animali» o indicazioni analoghe comportanti una sottovalutazione degli effetti potenziali del prodotto da parte dell'utilizzatore e non devono riportare indicazioni riferite al prodotto che possano generare confusione per quanto concerne i rischi che il prodotto comporta per l'uomo o l'ambiente.

N.B. E' consentita l'immissione sul mercato dei biocidi a condizione che le indicazioni dell'etichetta siano redatte in lingua italiana.