

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

MASTERBRODY PASTA

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2024/0391/MRS/IT/2016/00327/AUT

R4BP asset number: RO-0033043-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	MASTERBRODY PASTA RATT ON
---------------	------------------------------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Orma S.r.l.
	Address	Via A. Chiribiri 2 10028 Trofarello Italy
Authorisation number	RO/2024/0391/MRS/IT/2016/00327/AUT	
<i>R4BP asset number</i>	RO-0033043-0000	
Date of the authorisation	05/02/2014	
Expiry date of the authorisation	31/12/2026	

1.3. Manufacturer(s) of the product

Name of manufacturer	ORMA Srl
Address of manufacturer	Via A. Chiribiri 2 10028 Trofarello (TO) Italy
Location of manufacturing sites	Ferbi S.r.l. - Via 1° Maggio snc 64023 Mosciano S. Angelo (TE) Italy ORMA Srl - Via Molino della Splua 22 10028 Trofarello (TO) Italy

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

Active substance	Brodifacoum
Name of manufacturer	dr. Tezza S.r.l.
Address of manufacturer	Via Tre Ponti, 22 37050 Santa Maria di Zevio (VR) Italy
Location of manufacturing sites	dr. Tezza S.r.l. - Via Tre Ponti, 22 37050 Santa Maria di Zevio (VR) Italy

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,005 % (w/w)

2.2. Type(s) of formulation

PA Paste

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H373: May cause damage to organs blood through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P102: Keep out of reach of children. P202: Do not handle until all safety precautions have been read and understood. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice/attention. P501: Dispose of contents to according to national rules.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Rodenticide

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	<p>For use in and around buildings only. Application in bait boxes. Bait box is applied via refillable tamper resistant bait station. Bait is deposited and fixed in the bait station.</p> <p>For use against mice and rats, commercially available tamper resistant bait stations (prefilled or refillable) are authorised. For both rats and mice, bait should be supplied in inner packs or units, each containing 20 grams. Bait stations/bait points are manually placed in the rodent infested area, wearing appropriate gloves. Ideally bait boxes should be fixed to the ground. The product must never be placed indiscriminately. For use indoor and around buildings by professional and non-professional users.</p>
Target organism(s) (including development stage)	<p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles</p>
Field(s) of use	<p>indoor use Other</p> <p>For use in and around buildings only by professional and non-professional users. Non-professional users can apply the product for mice and rats control in and around buildings: homes, basements, garages, closets, home gardens. Professional users are allowed to apply in and around civil and industrial buildings (including warehouses and ships cargo), farms, basements, garages, closets, home gardens.</p>
Application method(s)	Method: bait application

	<p>Detailed description: Application in bait boxes. Bait box is applied via refillable tamper resistant bait station. Bait is deposited and fixed in the bait station. For use against mice and rats, commercially available tamper resistant bait stations (prefilled or refillable) are authorised. For both rats and mice, bait should be supplied in inner packs or units, each containing 20 grams. The whole pack should contain a maximum of 0.5kg of bait for non professional users and 25 kg for professional users. Bait stations/bait points are manually placed in the rodent infested area, wearing appropriate gloves. Ideally bait boxes should be fixed to the ground. The product must never be placed indiscriminately.</p>
Application rate(s) and frequency	<p>Application rate: For mice 40 grams in 100 square meters; for rats 60 to 100 grams in 100 square meters</p> <p>Dilution (%): 0</p> <p>Number and timing of application: For rat infestations use bait points of up to 100g/100m² according to the infestation. Do not move or disturb bait points for several days after laying bait. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or damaged/contaminated by water or dirt. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. For mouse infestations use bait points of 40g/100m². Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or damaged/contaminated by water or dirt. If no signs of mouse activity are seen near the bait after 7-10 days, move the bait to an area of higher mouse activity.</p> <p>The number of bait points used is dependent on the site of treatment and severity of the infestation: - For rats, place bait points at 5 to 10 metres apart. - For mice, place bait points at 1 to 2 metres apart.</p>
Category(ies) of users	<p>trained professional ; professional ; general public (non-professional)</p>
Pack sizes and packaging material	<p>Rodenticide baits of 20 g of fresh pasta in food sachet, ready to use. Bag /Sack, Paper, cardboard , up to 500; Bag /Sack, Plastic: composite: , up to 3 kilograms (for professional use only); Can /Tin, Plastic: HDPE , up to 25 kilos (for professional use only); Box, Paper, cardboard , up to 25 kilos (for professional use only).</p>

4.1.1. Use-specific instructions

Baits are manually placed in the rodent infested area. A priority is always to exclude non target exposure as much as possible. Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. Product must never be placed at random.

Read the label before use and follow instructions.

The product must not be placed indiscriminately.

Wash hands and directly exposed skin after use of product and before eating, drinking, smoking.

While handling bait material and/or dead rodents, wear rubber gloves.

Place the bait points where the rodents are seen: in or near their burrows and harbourages, on their runs and the places where they find food or gnaw.

The bait should be placed inside bait points out of reach of children, birds, pets and other non-target animals.

Baits should be secured so that they cannot be dragged away.

Bait boxes must be clearly marked to show that they contain rodenticides and must not be disturbed.

Remove all baits after treatment.

When control has been achieved, consider control measures (plug holes, remove potential food, etc.) to reduce the likelihood of reinvasion.

4.1.2. Use-specific risk mitigation measures

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. Wash hands and exposed skin after use and before meals. Baits must be secured in tamper resistant stations to minimize the risk of consumption by other animals or children. Where possible, secure bait stations so that they cannot be dragged away. Prevent access to bait by children, birds and non-target animals. Do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 6 weeks. Search for and remove dead rodents at frequent intervals during treatment, at least as often as when bait points are checked and/or replenished. Daily inspection may be required in some circumstances. Dispose of dead rodents in accordance with local requirements.

Do not place bait points near water drainage systems where they can come into contact with water.

Do not use the product where it can come into contact with food, drinking water, animal feeding stuffs, utensils that have contact with food.

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

MECHANISM OF ACTION: the active ingredient of the product is a second generation anticoagulant chemical and decreases the hepatic synthesis of k-dependent factors. **SYMPTONS:** Severe poisoning by ingestion causes Vitamin K inhibition, causing dermal and mucous haemorrhages. Symptoms to occur in other systems is mainly haemorrhagic. **TERAPY:** 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. Call a POISON CENTER. Contraindications: anticoagulants.

In case of animal accidental consumption immediately contact a veterinary doctor.

Collect and dispose left baits and dead rodents in accordance with local requirements to avoid accidental consumption from childer and non-target animals.

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

Dispose unconsumed baits and empty packages in accordance with local requirements.

The container should not be re-used or recycled.

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

Keep out of the reach of children and non-target animals. Store in original container, tightly closed, in a safe place. Keep container tightly closed. Keep away from food, drink and animal feed stuffs. The container should not be re-used or recycled.

Shelf-life: 24 months

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Baits are manually placed in the rodent infested area. A priority is always to exclude non target exposure as much as possible. Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. Product must never be placed at random.

Read the label before use and follow instructions.

The product must not be placed indiscriminately.

Wash hands and directly exposed skin after use of product and before eating, drinking, smoking.

While handling bait material and/or dead rodents, wear rubber gloves.

Place the bait points where the rodents are seen: in or near their burrows and harbourages, on their runs and the places where they find food or gnaw.

The bait should be placed inside bait points out of reach of children, birds, pets and other non-target animals.

Baits should be

secured so that they cannot be dragged away.

Bait boxes must be clearly marked to show that they contain rodenticides and must not be disturbed.

Remove all baits after treatment.

When control has been achieved, consider control measures (plug holes, remove potential food, etc.) to reduce the likelihood of reinvasion.

5.2. Risk mitigation measures

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. Wash hands and exposed skin after use and before meals.

Baits must be secured in tamper resistant stations to minimize the risk of consumption by other animals or children. Where possible, secure bait stations so that they cannot be dragged away. Prevent access to bait by children, birds and non-target animals. Do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 6 weeks. Search for and remove dead rodents at frequent intervals during treatment, at least as often as when bait points are checked and/or replenished. Daily inspection may be required in some circumstances. Dispose of dead rodents in accordance with local requirements.

Do not place bait points near water drainage systems where they can come into contact with water.

Do not use the product where it can come into contact with food, drinking water, animal feeding stuffs, utensils that have contact with food.

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 the product is a second generation 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. **TERAPY:** 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. Call a POISON CENTER. Contraindications: anticoagulants.

In case of animal accidental consumption immediately contact a veterinary doctor.

Collect and dispose unconsumed baits and dead rodents in accordance with local requirements .

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

Dispose unconsumed baits and empty packages in accordance with local requirements.

The container should not be re-used or recycled.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

Keep out of the reach of children and non-target animals. Store in original container, tightly closed, in a safe place. Keep container tightly closed. Keep away from food, drink and animal feed stuffs. The container should not be re-used or recycled.

Shelf-life: 24 months

6. OTHER INFORMATION