#### **ANNEX**

#### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

#### MASTERBRODY BLOCK

**Product type(s)** 

PT14: Rodenticides

Authorisation number: RO/2024/0392/MRS/IT/2015/00317/AUT

**R4BP asset number:** RO-0033044-0000

#### 1. ADMINISTRATIVE INFORMATION

## 1.1. Trade name(s) of the product

Trade name(s) MASTERBRODY BLOCK
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#### 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/2024/0392/MRS/IT/2015/00317/AUT
R4BP asset number		RO-0033044-0000
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
	VEBI Istituto Biochimico S.r.l Via Desman, 43 35010 S Eufemia di Borgoricco (PD) 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) It aly
Location of manufacturing sites	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'-bromobi phenyl- 4-yl)-1,2 ,3,4-tetrahydro -1 -napthyl]-4-hydr oxycoumarin		56073-10-0	259-980-5	100 % (w/w)

## 2.2. Type(s) of formulation

RB Bait (ready for use)

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.
	H373: May cause damage to organs blood through pro longed 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 b een read and understood.
	P280: Wear protective gloves.
	P308+P313: IF exposed or concerned: Get medical att ention.
	P501: Dispose of contents to national regulation.
	P270: Do not eat, drink or smoke when using this product.

## 4. AUTHORISED USE(S)

## 4.1. Use description

Table 1. Rodenticide

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	For use against mice and rats, commercially available tamper resistant bait stations(prefilled or refillable) are authorised. For both rats and mice, bait shouldbe supplied in inner packs or units, each containing 20 grams. Baitstations/bait points are manually placed in the rodent infested area, wearingappropriate gloves. Ideally bait boxes should be fixed to the ground. The productmust never be placed indiscriminately. For use indoor and outdoor (aroundbuildings) by professional and non-professional users
Target organism(s) (including development	Scientific name: Mus musculus
stage)	Common name: house mouse
	Development stage: adults
	Scientific name: Mus musculus
	Common name: house mouse
	Development stage: juveniles
	Scientific name: Rattus norvegicus
	Common name: brown rat
	Development stage: adults
	Scientific name: Rattus norvegicus
	Common name: brown rat
	Development stage: juveniles
	Scientific name: Rattus rattus
	Common name: roof rat
	Development stage: adults
	Scientific name: Rattus rattus
	Common name: roof rat
	Development stage: juveniles
Field(s) of use	indoor use outdoor use
	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 units, each containing 20 grams. The whole pack should contain a maximum of 0.5 kg 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. For use indoor and outdoor (around buildings) 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
Application method(s)	Method: bait application
	Detailed description: For use againstmice and rats, commercially available tamper resistant bait stations (prefilledor refillable) are authorised. Bait points are manually placed in the rodent infested area, wearing appropriate gloves. Ideally bait boxesshould be fixed to the ground
Application rate(s) and frequency	Application rate: For mice 40 grams in 100 square meter; for rats 60 to 100 grams in 100 square meters
	Dilution (%): 100
	Number and timing of application: Forrat
	infestations use bait points of up to 100g/100m2 according to theinfestation.
	Do not move or disturb bait points for several days after layingbait. Make
	frequent inspections of the bait points during the first 10-14 daysand 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 thebait 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 first10-14 days and replace
	any bait eaten by rodents or damaged/contaminated bywater or dirt. If no signs
	of mouse activity are seen near the bait after 7-10days, move the bait to an
	area of higher mouse activity.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	Bag /Sack, Paper, cardboard, up to 500 grams
	Bag /Sack, Plastic: composite: , up to 3 kilos Can /Tin, Plastic: HDPE , up to 25 kilos

#### 4.1.1. Use-specific instructions

Baits are manually placed in the rodent infested area. The bait product canpotentially be used under many different circumstances and can be deployed using various means. A priority is always to exclude non target exposure asmuch 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 minimiser emoval and dispersal by rodents. Product must never be placed at random.

#### 4.1.2. Use-specific risk mitigation measures

Theresistance status of the target population should be taken into account when considering the choice of rodenticide to be used. Wash hands and exposed skinbefore meals and after use. Baits must be secured in

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

# 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

MECHANISMOF ACTION: the active ingredient of MASTERBRODY PASTA is a second generationanticoagulant 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 gastriclavage and monitor prothrombin activity, if decreased Vitamin K1 should be administered. Follow the appropriate medical protocol. 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.

# 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

# 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. Keep container tightly closed. Keep away fromfood, drink and animal feed stuffs. Store in original container, tightlyclosed, in a safe place. The container should not be re-used or recycled. Unconsumed baits and empty packages in accordance with local requirements

#### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### **5.1.** Instructions for use

Baitsare manually placed in the rodent infested area. The bait product canpotentially be used under many different circumstances and can be deployedusing various means. A priority is always to exclude non target exposure asmuch 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 minimiseremoval and dispersal by rodents. Product must never be placed at random.

#### 5.2. Risk mitigation measures

Theresistance status of the target population should be taken into account whenconsidering the choice of rodenticide to be used. Wash hands and exposed skinbefore meals and after use. Baits must be secured in tamper resistant stationsto minimize the risk of consumption by other animals or children. Wherepossible, secure bait stations so that they cannot be dragged away. Preventaccess to bait by children, birds and non-target animals. Do not useanticoagulant rodenticides as permanent baits. In most cases, anticoagulantbait should have achieved control within 6 weeks. Search for and remove deadrodents at frequent intervals during treatment, at least as often as when baitpoints are checked and/or replenished. Daily inspection may be required in somecircumstances. Dispose of dead rodents in accordance with local requirements

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

MECHANISMOF ACTION: the active ingredient of MASTERBRODY PASTA is a second generationanticoagulant chemical and decreases the hepatic synthesis of k-dependentfactors. SYMPTONS:Severe poisoning by ingestion causes Vitamin K inhibition,causing dermal andmucous haemorrhages. Symptoms to occur in other systems ismainly haemorrhagic.TERAPY: if large quantities are ingested, induce vomiting,perform gastriclavage and monitor prothrombin activity, if decreased Vitamin K1 should be administered. Follow the appropriate medical protocol.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.

<sup>&</sup>lt;sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

Dispose unconsumed baits and empty packages in accordance with local requirements

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

Keep out of the reach of children. Keep container tightly closed. Keep away fromfood, drink and animal feed stuffs. Store in original container, tightlyclosed, in a safe place. The container should not be re-used or recycled. Unconsumed baits and empty packages in accordance with local requirements

### 6. OTHER INFORMATION