

EN

*ANNEX*

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

RAT CONTROL

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** IT/2013/00108/AUT

**R4BP asset number:** IT-0008224-0000

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	RAT CONTROL
---------------	-------------

### 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	IT/2013/00108/AUT	
<i>R4BP asset number</i>	IT-0008224-0000	
Date of the authorisation	27/06/2013	
Expiry date of the authorisation	31/12/2026	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	ORMA
Address of manufacturer	Via U. Saba 4 10028 Trofarello Italy
Location of manufacturing sites	FERBI Srl-Viale 1 Maggio 64023 Mosciano S Angelo Italy

Name of manufacturer	Gamma international srl
Address of manufacturer	via nettunense km 23400 04011 Aprilia Italy
Location of manufacturing sites	via nettunense km 23400 04011 Aprilia Italy

Name of manufacturer	INDIA INDUSTRIE CHIMICHE spa
Address of manufacturer	Nona Strada 53/57 35100 Padova Italy
Location of manufacturing sites	Nona Strada 53/57 35100 Padova Italy

Name of manufacturer	INDUSTRIALCHIMICA Srl
Address of manufacturer	Via Sorgaglia 25 35020 Arre Italy
Location of manufacturing sites	Via Sorgaglia 25 35020 Arre Italy

Name of manufacturer	VEBI ISTITUTO BIOCHIMICO Srl
Address of manufacturer	Via Desman 43 35010 S Eufemia di Borgoricco Italy
Location of manufacturing sites	Via Desman 43 35010 S Eufemia di Borgoricco Italy

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

Active substance	Bromadiolone
Name of manufacturer	DR TEZZA srl
Address of manufacturer	Via tre ponti 22 87050 Santa Maria de Zevio Italy
Location of manufacturing sites	Via tre ponti 22 87050 Santa Maria de Zevio 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 (%)
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

### 2.2. Type(s) of formulation

PA Paste

---

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.  H372: Causes 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.  P270: Do not eat, drink or smoke when using this product.  P202: Do not handle until all safety precautions have been read and understood.  P280: Wear protective gloves.  P308+P313: IF exposed or concerned: Get medical advice.  P501: Dispose of container to according to the law.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Use in and around buildings**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Use in and around buildings
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 use outdoor use
Application method(s)	Method: in bait boxes  Detailed description: Baits shall be placed in bait boxes
Application rate(s) and frequency	Application rate: Rats 60 100g of pasta bait per 100m <sup>2</sup> of infested area Mice 40 g of pasta bait per 100m <sup>2</sup> of infested area  Dilution (%): 100  Number and timing of application: Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed
Category(ies) of users	industrial ; trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	Sachet, Paper, cardboard , 20g  For non professional use packs with 40 60 80 100 160 200 240 300 400 500 g For professional use packs with 1 3 5 10 20 25 Kg

#### 4.1.1. Use-specific instructions

RAT CONTROL is applied via tamper resistant bait stations

---

Bait is deposited and fixed in the bait stations

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

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

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

#### **4.1.3. Use-specific risk mitigation measures**

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

#### **4.1.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

The active ingredient in the form of bait may be palatable to humans and non target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Bromadiolone interacts with vitamin K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombin activity

Note to doctor the product RAT CONTROL contains an anticoagulant rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non target animals

Bait boxes must always be clearly labelled Do Not Touch and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents

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

Store away from light

Keep container tightly closed in fresh and dry places  
 Keep out of the reach of children  
 Keep away from food drink and animal foodstuffs  
 Store in the original container  
 The product could be conserved 24 months since the manufacturing date  
 To be indicated on bait stations Keep out of the reach of children Keep away from food drink and animal foodstuffs

## 4.2. Use description

**Table 2. Use in open areas**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Use in open areas
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>Rattus norvegicus</i>          Common name: brown rat          Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i>          Common name: roof rat          Development stage: adults</p>
Field(s) of use	outdoor use
Application method(s)	<p>Method: in bait boxes</p> <p>Detailed description: Baits shall be placed in bait boxes</p>
Application rate(s) and frequency	<p>Application rate: Rats 60 100g of pasta bait per 100m<sup>2</sup> of infested area          Mice 40 g of pasta bait per 100m<sup>2</sup> of infested area</p> <p>Dilution (%): 100</p> <p>Number and timing of application:          Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed</p>
Category(ies) of users	industrial ; trained professional ; professional ; general public (non-professional)
Pack sizes and packaging material	<p>Sachet, Paper, cardboard , 20g</p> <p>For non professional use packs with 40 60 80 100 160 200 240 300 400 500 g          For professional use packs with 1 3 5 10 20 25 Kg</p>

---

--	--

#### **4.2.1. Use-specific instructions**

Bait is deposited and fixed in the bait stations

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

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

#### **4.2.2. Use-specific risk mitigation measures**

#### **4.2.3. Use-specific risk mitigation measures**

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

#### **4.2.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

The active ingredient in the form of bait may be palatable to humans and non target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Bromadiolone interacts with vitamine K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombine activity

Note to doctor the product RAT CONTROL contains an anticoagulant rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non target animals

Bait boxes must always be clearly labelled Do Not Touch and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents



---

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

Store away from light

Keep container tightly closed in fresh and dry places

Keep out of the reach of children

Keep away from food drink and animal foodstuffs

Store in the original container

The product could be conserved 24 months since the manufacturing date

To be indicated on bait stations Keep out of the reach of children Keep away from food drink and animal foodstuffs

---

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

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

RAT CONTROL is applied via tamper resistant bait stations

Bait is deposited and fixed in the bait stations

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

Inspect and resupply the bait stations once a week as long as the bait is consumed

Remove all bait points after the end of treatment

The amount of bait per bait point and distances between bait points must be respected

Products have always to be used in accordance with the label

### **5.2. Risk mitigation measures**

The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development

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

The active ingredient in the form of bait may be palatable to humans and non target species in sufficient quantity to produce toxic effects

Effects result from the inhibition of blood coagulation as Bromadiolone interacts with vitamin K1 inducing hemorrhages over the course of several days

If large quantity are ingested induce vomiting perform gastric lavage and monitor prothrombin activity

Note to doctor the product RAT CONTROL contains an anticoagulant rodenticide treatment with vitamin K1 could be needed for a long time

Emergency measures to protect the environment In case of accidental contamination avoid spreading in house drains rainy waters and environment

In case of a release had already occurred the competent authority has to be warned

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

Always read the label before use and follow the instruction provided

Keep out of reach of children

Keep away from food drink and animal feeding stuff

Avoid contact with skin

If swallowed seek medical advice immediately (show the label when possible)

Do not smoke eat or drink while handling this product

Baits must be secured in tamper resistant bait boxes to minimize the risk of consumption and poisoning to children companion animals and other non target animals

Bait boxes must be placed in areas inaccessible to children companion animals and non target animals

Bait boxes must always be clearly labelled Do Not Touch and warn of the contents

In public areas (such as business premises schools hospitals etc) it must be clearly signed that rodenticide control is in operation

Signage must provide information on the risks of interfering with the product and dead rodents

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

Store away from light

---

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

---

Keep container tightly closed in fresh and dry places

Keep out of the reach of children

Keep away from food drink and animal foodstuffs

Store in the original container

The product could be conserved 24 months since the manufacturing date

To be indicated on bait stations Keep out of the reach of children Keep away from food drink and animal foodstuffs

---

## **6. OTHER INFORMATION**