

**EN**

***ANNEX***

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

**RODEX CONTROL PASTA BAIT**

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** RO/2022/0325/MRS/ES/MR (NA) -2018-14-00494

**R4BP asset number:** RO-0029345-0000

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## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Rodex Pasta RATIBROM 2.5 PASTE RODEX CONTROL PASTA BAIT
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	PelGar International Limited
	Address	18 rue des Remparts d'Ainay 69002 Lyon France
Authorisation number	RO/2022/0325/MRS/ES/MR (NA) -2018-14-0 0494	
<i>R4BP asset number</i>	RO-0029345-0000	
Date of the authorisation	19/11/2012	
Expiry date of the authorisation	31/12/2026	

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

Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)  Kollant Via C. Colombo 7-7A 30030 Vigonovo (Ve) Italy

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

Active substance	Bromadiolone
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Prazska 54 280 02 Kolin Czechia

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## 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	0,0025 % (w/w)

### 2.2. Type(s) of formulation

RB Bait (ready for use)

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>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:}.</p> <p>EUH401: To avoid risks to human health and the environment, comply with the instructions for use.</p>
Precautionary statements	<p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P262: Do not get in eyes, on skin, or on clothing.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P273: Avoid release to the environment.</p> <p>P280: Wear protective gloves.</p> <p>P301+P310: IF SWALLOWED: Immediately call a POISON CENTER.</p> <p>P404: Store in a closed container.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to in accordance with local regulations.</p>

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Non-professional**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles  Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles
Field(s) of use	indoor use outdoor use  Indoors Outdoors – around buildings
Application method(s)	Method: bait application  Detailed description: VI.2 Covered application VI.2.1 In bait stations For use against mice, commercially available bait stations (prefilled or refillable) or covered/protected bait points are authorised. For use against rats, commercially available tamper resistant bait stations (prefilled or refillable) only are authorised. For both rats and mice, the bait should be supplied in inner packs or units, each containing at most enough bait for one point (either rat or mouse). The whole pack should contain a maximum of 1.5kg of bait. Bait stations/bait points are manually placed in the rodent infested area. Ideally bait boxes should be fixed to the ground. The product must never be placed indiscriminately.
Application rate(s) and frequency	Application rate: Mice: High infestation – Up to 40g bait in bait stations or covered bait points every 2 metres, Low infestation – Up to 40 g bait in bait stations or covered bait points every 5 metres. Rats: High infestation – Up to 200g bait in bait stations every 5 metres, Low infestation – Up to 200g bait in bait stations every 10 metres.  Dilution (%): 100  Number and timing of application:  <b>Mice</b> High infestation – Up to 40g bait in bait stations or covered bait points every 2 metres Low infestation – Up to 40 g bait in bait stations or covered bait points every 5 metres <b>Rats</b>

	<p>High infestation – Up to 200g bait in bait stations every 5 metres  Low infestation – Up to 200g bait in bait stations every 10 metres</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Tubs, pails or jerry can, PP or PE , Up to 1.5 kg  Cardboard outer, Polythene-lined cardboard outer , Up to 1.5 kg  Pouches sold as they are or in a cardboard outer, Paper/PE/  aluminium, PP, PET/PE or laminated PP , Up to 1.5 kg  Lined carton, Polythene-lined cardboard carton , Up to 1.5 kg</p> <p>Individual edible paper t-bags/sachets of 10, 15 or 20 g packed in  above outer packs.</p> <p>Cardboard outer, Polythene-lined cardboard outer , Up to 1.5 kg  Tubs or pails, PP or PE , Up to 1.5 kg  Pouches, Paper/PE/aluminium, PP, PET/PE or laminated PP , Up  to 1.5 kg</p> <p>Individual edible paper t-bags/sachets of 10, 15 or 20 g packed in  above outer packs.</p> <p>Baitbox, HDPE or PP , Up to 120 g</p> <p>1. 1 or 2 x 10 g t-bags packed in a single or multi-use tamper-  proof mouse HDPE or PP bait station, all packed in multiples of  1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve  or heat-sealed bag or poly outer heat-sealed with a cardboard  topper.  2. 1 or 2 x 15 g t-bags packed in a single or multi-use tamper-  proof mouse HDPE or PP bait station, all packed in multiples of  1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve  or heat-sealed bag or poly outer heat-sealed with a cardboard  topper.</p> <p>Covered bait stations (tamper-resistant)</p> <p>Baitbox, HDPE or PP , Up to 360 g</p> <p>1. 10, 11 or 12 x 15 g blocks packed in a single or multi-use  tamper-proof rat HDPE or PP bait station, all packed in multiples  of 1, 2 or 4 in a cardboard outer or blister pack or cardboard  sleeve or heat-sealed bag or poly outer heat-sealed with a  cardboard topper.</p> <p>Covered bait stations (tamper-resistant)</p> <p>Bait trays with a sealed lid, PVC, PS, PET/PE, PP or PE bait trays  with heat-sealed lid , Up to 1.5 kg</p>

	<p>Loose bait packed in bait trays with a heat-sealed lid, 25g, 30g, 50g, 75g, 100g, 150g or 200g.  The trays are to be packed in:  Multiples of 2/4/8/12/16/20/24/32 packed in cardboard outers.  Single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.</p> <p>Tamper-evident packs.  Maximum pack size 1.5 kg.</p> <p>'Sausage' for use in rat or mouse boxes, Polyethylene film  'sausage' in a collagen or PE outer casing , 30g or 200g</p> <p>30 g for use in mouse bait boxes  200 g for use in rat bait boxes  Packed in units up to 1.5 kg in a fibreboard outer.</p> <p>Tamper-evident packs.</p>
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#### 4.1.1. Use-specific instructions

Do not open sachets

Wash hands and exposed skin before meals and after use.

Keep locked up and out of reach of children.

For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.

Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry).

Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined.

Search for and remove dead rodents at frequent intervals during treatment, at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.

Dispose of dead rodents in accordance with local requirements. Poisoned rodents should be double-bagged using plastic bags and either disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or collected by a specialist waste contractor or the local authority.

For products to be used in public areas the following safety precaution shall be carried on the label, packaging or accompanying leaflet:

\* When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

\* When tamper resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Antidote vitamin K1 (under medical supervision). Medical professionals should contact the National Poisons Centre for further advice.

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

None

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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

Bromadiolone is an anticoagulant which may produce bleeding; this may be delayed for several days after exposure. If there is no active bleeding the INR (prothrombin time) should be measured on presentation and 48-72 hours after exposure. If the INR is greater than 4, administer Vitamin K1 (phytomenadione) 5-10 mg by slow intravenous injection (100 µg/kg body weight for a child). Treatment with phytomenadione (orally or intravenously) may be required for several weeks. The advice of the National Poisons Centre should be sought, particularly if active bleeding occurs. In case of accident, or if you feel unwell, seek medical advice immediately (show the label where possible).

In case of accident, or if you feel unwell, seek medical advice immediately (show the label where possible).

In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing.

In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek medical advice immediately.

In case of ingestion or if swallowed seek medical advice immediately.

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

Remove all baits after treatment and dispose of them in accordance with local requirements.

Dead rodents and bait found outside bait stations should be disposed of using protective gloves.

Non-Professionals: Waste bait should be disposed of 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 in a cool, dry, well ventilated area.

Keep away from oxidising agents.

Store only in original container.

Shelf life of up to 2 years supported.

### 4.2. Use description

**Table 2. Professional**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles  Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles
Field(s) of use	indoor use



	<p>outdoor use</p> <p>Indoors Outdoors – around buildings In sewers</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: VI.2 Covered application VI.2.1 In bait stations</p>
Application rate(s) and frequency	<p>Application rate: Mice: High infestation – Up to 40g bait in bait stations or covered bait points every 2 metres, Low infestation – Up to 40g bait in bait stations or covered bait points every 5 metres. Rats: High infestation – Up to 200g bait in bait stations or covered bait points every 5 metres, Low infestation – Up to 200g bait in bait stations or covered bait points every 10 metres. Rats (in sewers): Up to 200g bait per bait point.</p> <p>Dilution (%): 100</p> <p>Number and timing of application:</p> <p><b>Mice</b>  High infestation – Up to 40g bait in bait stations or covered bait points every 2 metres  Low infestation – Up to 40g bait in bait stations or covered bait points every 5 metres</p> <p><b>Rats</b>  High infestation – Up to 200g bait in bait stations or covered bait points every 5 metres  Low infestation – Up to 200g bait in bait stations or covered bait points every 10 metres</p> <p><b>Rats (in sewers)</b>  Up to 200g bait per bait point</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Tubs, pails or jerry can, PP or PE , Up to 20 kg  Cardboard outer, Polythene-lined cardboard outer , Up to 2 kg  Lined carton, Polythene-lined cardboard carton , Up to 20 kg  Pouches, paper/PE/aluminium or PP or laminated PP or PET/PE , Up to 20 kg</p> <p>Individual edible paper t-bags/sachets of 10, 15 or 20 g packed in above outer packs.</p> <p>Tamper-evident packs.</p> <p>Cardboard outer, Polythene-lined cardboard outers , Up to 1.65 kg</p> <p>Tubs or pails, PP or PE , Up to 1.65 kg  Pouches, Paper/PE/aluminium, PP, PET/PE or laminated PP , Up to 1.65 kg</p> <p>Individual edible paper t-bags/sachets of 10, 15 or 20 g packed in above outer packs.</p> <p>Tamper-evident packs</p>

Baitbox, HDPE or PP , Up to 120 g

1. 1 or 2 x 10 g t-bags packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

2. 1 or 2 x 15 g t-bags packed in a single or multi-use tamper-proof mouse HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Covered bait stations (tamper-resistant)

Baitbox, HDPE or PP , Up to 360 kg

1. 10, 11 or 12 x 15 g blocks packed in a single or multi-use tamper-proof rat HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Covered bait stations (tamper-resistant)

Bait trays with a sealed lid, PVC, PS, PET/PE, PP or PE bait trays with heat-sealed lid , Up to 6.4 kg

Loose bait packed in bait trays with a heat-sealed lid, 25g, 30g, 50g, 75g, 100g, 150g or 200g.

The trays are to be packed in:

Multiples of 2/4/8/12/16/20/24/32 packed in cardboard outers. Single or multi-use tamper-proof HDPE or PP bait station, all packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper.

Tamper-evident packaging

'Sausage' for use in rat or mouse boxes, Polyethylene film 'sausage' in a collagen or PE outer casing , Up to 10 kg

30 g for use in mouse bait boxes

200 g for use in rat bait boxes

Packed in units of 1, 2, 5 and 10 kg in a fibreboard outer.

Tamper-evident pack

Tub or pail, HDPE or PP , Up to 5 kg

Loose paste in the above packs for application by decorator's knife or spatula.

Tamper-evident pack

	<p>Cartridge, PE or PP , Up to 3.6 kg</p> <p>Cartridge (for use in a caulking gun) stored in cardboard outer packaging of 6 to 12 cartridges. Can be sold as individual cartridges or in outer packaging units.</p> <p>Tamper-evident pack</p>
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#### **4.2.1. Use-specific instructions**

The product may be applied by professional users only when appropriate chemical resistant gloves (EN 374) are used.

Keep locked up and out of reach of children.

When used in sewers, bait should be placed in a way to protect from flooding or displacement.

The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use. To control the spreading of resistance, it is advisable to alternate baits containing different anticoagulant active ingredients.

Wash hands and exposed skin before meals and after use.

Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry).

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. In most cases, anticoagulant bait should have achieved control within 35 days. Should activity continue beyond this time, the likely cause should be determined. Search for and remove dead rodents at frequent intervals during treatment (unless used in sewers), at least as often as when baits are checked and/or replenished. Daily inspection may be required in some circumstances.

Dispose of dead rodents in accordance with local requirements. Poisoned rodents may be disposed of by the waste producer at an incinerator or landfill permitted to accept that type of waste, or collected by a registered waste carrier and taken for disposal at a suitably permitted site. For further information on disposal contact the local authorities.

For products to be used in public areas the following safety precaution shall be carried on the label, packaging or accompanying leaflet:

\* When the product is being used in public areas and tamper-resistant bait stations are not used, the areas treated must be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

\* When tamper resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Antidote vitamin K1 (under medical supervision). Medical professionals should contact the National Poisons Centre for further advice.

For caulking gun cartridge packs and loose paste packs for application by decorator's knife/spatula: Use a spatula for post-application (cleaning/disposal) of bait. To be used only by professional users.

Read the label before use.

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

None

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

Bromadiolone is an anticoagulant which may produce bleeding; this may be delayed for several days after exposure. If there is no active bleeding the INR (prothrombin time) should be measured on presentation and 48-72 hours after exposure. If the INR is greater than 4, administer Vitamin K1 (phytomenadione) 5-10 mg by slow intravenous injection (100 µg/kg body weight for a child). Treatment with phytomenadione (orally or intravenously) may be required for several weeks. The advice of the National Poisons Centre should be sought, particularly if active bleeding occurs. In case of accident, or if you feel unwell, seek medical advice immediately (show the label where possible).

In case of accident, or if you feel unwell, seek medical advice immediately (show the label where possible).

In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing.

In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek medical advice immediately.

In case of ingestion or if swallowed seek medical advice immediately.

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

Remove all baits after treatment and dispose of them in accordance with local requirements.

Dead rodents and bait found outside bait stations should be disposed of using protective gloves.

Professionals: For information on disposal contact the local authorities.

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

Keep in a cool, dry, well ventilated area.

Keep away from oxidising agents.

Store only in original container.

Shelf life of up to 2 years supported.

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

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

See authorised uses.

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

See authorised uses.

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

See authorised uses.

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

See authorised uses.

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

See authorised uses.

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

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## **6. OTHER INFORMATION**

There are a number of errors in the drop-down menus in the hazard statements section. The correct phrases are:  
P220 Keep / Store away from foodstuffs, beverages and animal feeding stuffs.

P262 Do not get on skin.

P280 Wear protective gloves [Professional users only]

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P501 Dispose of contents/container in accordance with local regulations.