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***ANNEX***

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

Rodex Whole Wheat Bait

**Product type(s)**

PT14: Rodenticides

**Authorisation number:** 2011-06-23-B02b

**R4BP asset number:** MT-0002182-0000

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Rodex Whole Wheat
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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	2011-06-23-B02b	
<i>R4BP asset number</i>	MT-0002182-0000	
Date of the authorisation	19/11/2012	
Expiry date of the authorisation	31/12/2025	

### 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)  Doa Rat Bait Production Center, Mesokeleos street Palouriotissa, Nicosia Cyprus  Promedivet SRL, str. Lunga nr. 46/G 545500 SOVATA Romania

### 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	0,005

### 2.2. Type(s) of formulation

RB Bait (ready for use)

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child.  H372: Causes damage to organs (blood) through prolonged or repeated exposure ..  EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Precautionary statements	P201: Obtain special instructions before use.  P202: Do not handle until all safety precautions have been read and understood.  P260: Do not breathe dust.  P280: Wear protective gloves.  P270: Do not eat, drink or smoke when using this product.  P264: Wash hands thoroughly after handling.  P308+P313: IF exposed or concerned: Get medical advice.  P314: Get medical advice if you feel unwell.  P405: Store locked up.  P501: Dispose of contents to in accordance with national regulations..

#### 4. AUTHORISED USE(S)

##### 4.1. Use description

**Table 1. Professional users with demonstrated competence (equivalent to trained professionals) – indoor**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles  Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	indoor use  Indoor
Application method(s)	Method: bait application  Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations - Covered and protected baiting points
Application rate(s) and frequency	Application rate: Rats: up to 200g of bait per bait point. Mice: up to 40g of bait per baiting point.  Dilution (%): 100  Number and timing of application: Rats: - High infestation: Up to 200 g of bait per baiting point spaced 5m apart. - Low infestation: Up to 200 g of bait per baiting point spaced 10m apart.  Mice: - High infestation: 40 g of bait per baiting point spaced 2m apart. - Low infestation: 40 g of bait per baiting point spaced 5m apart.
Category(ies) of users	trained professional
Pack sizes and packaging material	1. Loose bait in the following packaging:  Polyethylene-lined polypropylene sack or multi-ply paper sack or polyethylene/polypropylene laminated sack - 3kg to 10kg

Polyethylene lined double-walled or fibreboard carton - 3kg to 10kg

Polyethylene/paper bag in a fibre-board carton - 3kg to 10kg.

Polypropylene or polyethylene tub - 3kg to 10kg

Polypropylene or polyethylene pail - 3kg to 10kg

Polypropylene or polyethylene jerrican - 3kg to 10kg

Polyethylene sachets or polypropylene/paper sachets or orientated polypropylene sachets or polyethylene/aluminium sachets or polyethylene/paper/aluminium sachets - 3kg to 10kg

Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack - 3kg to 10kg

Polypropylene pouches or laminated polypropylene pouches or PET/polyethylene pouches or polyethylene/paper/aluminium pouches .

Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack - 3kg to 10kg

## 2. Bait in sachets/place packs

Bait in perforated or non-perforated polypropylene/paper film sachets, PET/polyethylene film sachets, polyethylene/paper film sachets or polyethylene/aluminised film sachets (10 g, 25 g, 30 g, 40 g, 50 g, 100 g or 200 g) supplied in the following outer packs:

Polypropylene woven sack or multi-ply paper sack. - 3kg to 25kg

Polypropylene pail - 3kg to 20kg

Polypropylene or polyethylene tub - 3kg to 10kg.

	<p>PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch - 3kg to 10kg</p> <p>Jerry can, with tamper-evident screw-top lid. - 3kg.</p> <p>Fibreboard box - 3kg to 10 kg</p> <p>3. Bait in trays ((PVC or polystyrene or polypropylene or PET or PET/polyethylene or fibreboard); 25g, 30g, 40g, 50g, 100g or 200g)) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) supplied in the following outer packs:</p> <p>Cardboard outer - 3kg to 6.4kg</p> <p>Single-use or multi-use tamper-proof HDPE or PP bait station, 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. Packed in multipacks of 4, 8, 16, 24, 32, 48, 60, 72, 96, 100, 120, 144 - 3 kg to 20 kg.</p>
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#### **4.1.1. Use-specific instructions**

- Remove the remaining product at the end of treatment period.

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

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product in pulsed baiting treatments.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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**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**

- When placing bait points close to water drainage systems, ensure that bait contact with water is avoided.

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

See "Directions for use"

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

See "Directions for use"

**4.2. Use description**

**Table 2. Professional users with demonstrated competence (equivalent to trained professionals) – outdoor around buildings**

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles  Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	outdoor use  Outdoors around buildings
Application method(s)	Method: bait application  Detailed description: - Ready-to-use bait to be used in tamper-resistant bait stations . - Covered and protected baiting points - Direct application of ready-to-use bait into the burrow
Application rate(s) and frequency	Application rate: Rats: up to 200g of bait per bait point. Mice: up to 40g of bait per baiting point.  Dilution (%): 100  Number and timing of application:



	<p>Rats:</p> <ul style="list-style-type: none"> <li>- High infestation: Up to 200 g of bait per baiting point spaced 5m apart.</li> <li>- Low infestation: Up to 200 g of bait per baiting point spaced 10m apart.</li> </ul> <p>Mice:</p> <ul style="list-style-type: none"> <li>- High infestation: 40 g of bait per baiting point spaced 2m apart.</li> <li>- Low infestation: 40 g of bait per baiting point spaced 5m apart.</li> <li>- Burrow baiting: 20-200 g of bait per burrow.</li> </ul>
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>1. Loose bait in the following packaging:</p> <p>Polyethylene-lined polypropylene sack or multi-ply paper sack or polyethylene/polypropylene laminated sack - 2.5kg to 10kg  Polyethylene lined double-walled or fibreboard carton - 2.5kg to 10kg  Polyethylene/paper bag in a fibre-board carton - 2.5kg to 10kg.  Polypropylene or polyethylene tub - 2.5kg to 10kg  Polypropylene or polyethylene pail - 2.5kg to 10kg  Polypropylene or polyethylene jerrican - 2.5kg to 10kg  Polyethylene sachets or polypropylene/paper sachets or orientated polypropylene sachets or polyethylene/aluminium sachets or polyethylene/paper/aluminium sachets - 2.5kg to 10kg  Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack - 2.5kg to 10kg  Polypropylene pouches or laminated polypropylene pouches or PET/polyethylene pouches or polyethylene/paper/aluminium pouches .  Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack - 2.5kg to 10kg</p> <p>2. Bait in sachets/place packs  Bait in perforated or non-perforated polypropylene/paper film sachets, PET/polyethylene film sachets, polyethylene/paper film sachets or polyethylene/aluminised film sachets (10 g, 25 g, 30 g, 40 g, 50 g, 100 g or 200 g) supplied in the following outer packs:</p> <p>Polypropylene woven sack or multi-ply paper sack. - 2.5kg to 25kg  Polypropylene pail - 2.5kg to 20kg  Polypropylene or polyethylene tub - 2.5kg to 10kg.  PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch - 2.5kg to 10kg  Jerry can, with tamper-evident screw-top lid. 2.5 - 3kg.  Fibreboard box - 2.5kg to 10 kg</p>

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<p>3. Bait in trays ((PVC or polystyrene or polypropylene or PET or PET/polyethylene or fibreboard); 25g, 30g, 40g, 50g, 100g or 200g)) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) supplied in the following outer packs:</p>
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Cardboard outer - 2.5kg to 6.4kg

Single-use or multi-use tamper-proof HDPE or PP bait station, 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. Packed in multipacks of 4, 8, 16, 24, 32, 48, 60, 72, 96, 100, 120, 144 - 2.5 kg to 20 kg.

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

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-labile to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period (except when directly applied into burrows).
- Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled. Follow any additional instructions provided by the relevant code of best practice.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

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

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

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product in pulsed baiting treatments.
- Permanent baiting is strictly limited to sites with a high potential for reinvasion when other methods of control have proven insufficient
- The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

#### **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**

- When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

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

See "Directions for use"

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

See "Directions for use"

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

### 5.1. Instructions for use

Professional users with demonstrated competence (equivalent to trained professionals)

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- Sites where burrow baiting is used should be visited more frequently than those where secure bait boxes are employed
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Bait in non-emptiable sachets: Do not open the sachets containing the bait.
- Loose grains: Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

### 5.2. Risk mitigation measures

Professional users with demonstrated competence (equivalent to trained professionals)

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment (unless permanent baiting)
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.

- Antidote: Vitamin K1 administered by medical/veterinary personnel only.

- In case of:

- Dermal exposure, wash skin with water and then with water and soap.

- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.

- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.

Poison Centre:

MCCAA, Standards and Metrology Institute. Mizzi House,  
National Road, Blata L-Bajda Hmr9010, Malta. Tel: +356 2395 2000.

- Contact a veterinary surgeon in case of ingestion by a pet.

- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of accident, call a poison centre".

- Hazardous to wildlife.

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

Professional users with demonstrated competence (equivalent to trained professionals)

- At the end of the treatment, dispose uneaten bait and the packaging in accordance with local requirements.

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

- Store in places prevented from the access of children, birds, pets and farm animals.

- Shelf life: 2 years.

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## **6. OTHER INFORMATION**

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- This product contains a bittering agent and a dye.
- Use Biocides Safely and Sustainably
- It is illegal to use this product for uses or in a manner other than that prescribed on this label.