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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

ROBAN VAXKUBBAR

Product type(s)

PT14: Rodenticides

Authorisation number: IS-2014-0001

R4BP asset number: IS-0006759-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	ROBAN VAXKUBBAR
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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		IS-2014-0001
<i>R4BP asset number</i>		IS-0006759-0000
Date of the authorisation		04/07/2014
Expiry date of the authorisation		01/07/2025

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) Overley Hill, B5061, Wellington TF6 5HD Telford United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Difenacoum
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

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 (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	active substance	56073-07-5	259-978-4	0,005 % (w/w)

2.2. Type(s) of formulation

RB Bait (ready for use)

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>H360D: May damage the unborn child.</p> <p>H317: May cause an allergic skin reaction.</p> <p>EUH208: Contains 1,2-benzisothiazolin-3-one and 2-oxyl-2H-isothiazol-3-one. May produce an allergic reaction.</p>
Precautionary statements	<p>P280: Wear protective gloves.</p> <p>P308+P313: IF exposed or concerned: Get medical advice.</p> <p>P314: Get medical advice if you feel unwell.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to in accordance with national regulations.</p> <p>P201: Obtain special instructions before use.</p> <p>P202: Do not handle until all safety precautions have been read and understood.</p> <p>P301+P310: IF SWALLOWED: Immediately call a POISON CENTER.</p> <p>P404: Store in a closed container.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Professional - indoors and outdoors (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>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 Indoor Outdoor (around buildings)
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Application rate: RATS: Up to 200 g of bait per bait station. MICE: Up to 40 g of bait per bait station. Dilution (%): 100 Number and timing of application: Mice High infestation – Up to 40g bait in bait stations every 2 metres Low infestation – Up to 40g bait in bait stations 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
Category(ies) of users	professional
Pack sizes and packaging material	1 or 2 x 20 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg. 1 or 2 x 15 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg. 1 or 2 x 10 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg. 10 x 15 g blocks secured on a fixed metal bar in tamper-resistant HDPE or polypropylene rat bait station (refillable or single use).

	<p>Bait stations packed in units of 1 or 2 in cardboard outer - Up to 300 g. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>4, 5, 6, 7, 8, 9 or 10 x 20 g blocks in tamper-resistant HDPE or polypropylene rat bait station (refillable or single use). Bait stations packed in units of 1, or 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>Loose 10 g, 15 g or 20 g blocks in HDPE or polypropylene bucket: 3 to 10 kg.</p> <p>20 g blocks packed in uni-trays packed in fibre-board carton: 3 to 12 kg.</p> <p>10 g, 15 g or 20 g blocks packed on cardboard trays with cellophane wrap, then packed into cardboard cartons. Supplied in multiples in a cardboard box: 3 to 20 kg.</p> <p>10 g, 15 g or 20 g blocks in PP or PP laminate sachets or PP/card 'blister packs': 3 to 10 kg.</p> <p>10 g, 15 g or 20 g blocks packed in polyethylene, PET/polyethylene, PP/polyethylene or paper/polyethylene pouches: 3 to 10 kg.</p>
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4.1.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas non-labile to flooding.

- The bait stations should be visited [for mice - at least every 2 to 3 days at] [for rats - only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

- [When available] Follow any additional instructions provided by the relevant code of best practice.

4.1.2. Use-specific risk mitigation measures

- Do not apply this product directly in burrows.

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

- 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.

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

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

4.2. Use description

Table 2. Trained professionals - indoors and outdoors (around buildings), in sewers, in open areas and in waste dumps

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>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 Other Indoors Outdoors - around buildings Outdoors - in open areas Outdoors - in waste dumps In sewers
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. Ready-to-use bait in sewers to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Application rate: RATS: 20 to 200 g of bait per bait station. MICE: 10 to 40 g of bait per bait station. Dilution (%): 100 Number and timing of application: Mice High infestation – 10 to 40g bait in bait stations every 2 metres Low infestation – 10 to 40g bait in bait stations every 5 metres Rats High infestation – 20 to 200g bait in bait stations every 5 metres Low infestation – 20 to 200g bait in bait stations every 10 metres
Category(ies) of users	trained professional
Pack sizes and packaging material	1 or 2 x 20 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg.

	<p>1 or 2 x 15 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>1 or 2 x 10 g blocks in tamper-resistant HDPE or polypropylene mouse bait station (refillable or single use). Bait stations packed in units of 1, 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>10 x 15 g blocks secured on a fixed metal bar in tamper-resistant HDPE or polypropylene rat bait station (refillable or single use). Bait stations packed in units of 1 or 2 in cardboard outer - Up to 300 g. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>4, 5, 6, 7, 8, 9 or 10 x 20 g blocks in tamper-resistant HDPE or polypropylene rat bait station (refillable or single use). Bait stations packed in units of 1, or 2, 3 or 4 in cardboard outer. Sold in multiples in a cardboard box: 3 to 20 kg.</p> <p>Loose 10 g, 15 g or 20 g blocks in HDPE or polypropylene bucket: 3 to 10 kg.</p> <p>20 g blocks packed in uni-trays packed in fibre-board carton: 3 to 12 kg.</p> <p>10 g, 15 g or 20 g blocks packed on cardboard trays with cellophane wrap, then packed into cardboard cartons. Supplied in multiples in a cardboard box: 3 to 20 kg.</p> <p>10 g, 15 g or 20 g blocks in PP or PP laminate sachets or PP/card 'blister packs': 3 to 10 kg.</p> <p>10 g, 15 g or 20 g blocks packed in polyethylene, PET/polyethylene, PP/polyethylene or paper/polyethylene pouches: 3 to 10 kg.</p>
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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.
 - 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.
 - Remove the remaining product at the end of treatment period (except when directly applied into burrows)
 - For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
 - Where possible, it is recommended that the treated area is revisited every 4 weeks at the latest in order to avoid any selection of a resistant population.
 - [When available] Follow any additional instructions provided by the relevant code of best practice.
- Use in sewers: - Baits must be applied in a way so that they do not come into contact with water and are not washed away.

4.2.2. 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.
- 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.
- Do not use this product in pulsed baiting treatments.

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

- 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.

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

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- 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)
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- 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. 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.
 - Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after consumption of the bait.
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- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing of them.
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- This product contains a bittering agent and a dye.

5.2. Risk mitigation measures

- 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.

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

- Dispose dead rodents in accordance with local requirements.

To be used only by professional users holding certification from the Environment Agency of Iceland.

When this product is supplied to a user for the control of rodents, it shall only be supplied to a professional user holding certification from the Environment Agency of Iceland.

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.

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 center".

- Hazardous to wildlife.

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

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

For information on disposal in Iceland contact the Environment Agency of Iceland (<http://www.ust.is>).

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

6. OTHER INFORMATION

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label in accordance with Article 32 of the Chemicals Act No 61/2013.

Signal word:

Hætta

The hazard statements:

H317 Getur valdið ofnæmisviðbrögðum í húð.

H360D Getur haft skaðleg áhrif á börn í móðurkviði.

H373 Getur skaðað líffæri (blóð) við langvinn eða endurtekin váhrif.

EUH 208 Inniheldur 1,2-bensísópíasólín-3-ón og 2-oktýl-2H-ísópíasól-3-ón. Getur framkallað ofnæmisviðbrögð.

The precautionary statements:

P201 Aflið sérstakra leiðbeininga fyrir notkun.

P202 Nauðsynlegt er að lesa og skilja allar viðvaranir áður en efnið er notað.

P280 Notið hlífðarhanska.

P308 + P313 EF um váhrif eða hugsanleg váhrif er að ræða: Leitið lækni.

P314 Leitið lækni ef lasleika verður vart.

P301 + P310 EFTIR INNTÖKU: Hringið umsvifalaust í EITRUNARMÍÐSTÖÐ; s. 543 2222

P405 Geymist á læstum stað.

P404 Geymist í lokuðu íláti.

P501 Fargið innihaldi í samræmi við landsbundnar reglur.