ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Roban Cut Wheat Bait

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70573

R4BP asset number: IE-0000423-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Roban Cut Wheat Bait
	Doff Super Rat & Mouse Killer

1.2. Authorisation holder

	Name	PelGar International Limited
Name and address of the authorisation holder	Address	18 rue des Remparts d'Ainay 69002 Lyon France
Authorisation number		IE/BPA 70573
R4BP asset number		IE-0000423-0000
Date of the authorisation		09/03/2012
Expiry date of the authorisation		01/07/2026

1.3. Manufacturer(s) of the product

Name of manufacturer	PelGar International Limited
Address of manufacturer	18 rue des Remparts d'Ainay 69002 Lyon France
Location of manufacturing sites	Unit 13 Newman Lane GU34 2QR Alton 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

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs blood through prolonged or repeated exposure
	H360D: May damage the unborn child.
	EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Precautionary statements	P260: Do not breathe dust.
	P280: Wear protective gloves.
	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.
	P202: Do not handle until all safety precautions have been read and understood.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Professional - indoors and outdoors

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: Mus musculus Common name: house mouse Development stage: Adults and juveniles Scientific name: Rattus norvegicus Common name: brown rat 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: Ready-to-use bait to be used in tamper-resistant bait stations
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	professional
Pack sizes and packaging material	1. Loose bait
	Outer packaging type Pack sizes for professional use
	Polypropylene woven sack or multi-ply paper sack. 2.5 to 10 kg
	Polypropylene pail 2.5 to 10 kg
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Polypropylene or polyethylene tub 2.5 to 10 kg

PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch 2.5 to 10 kg

Polypropylene or polyethylene jerry can, with tamper-evident screw-top lid. 2.5 to 10 kg

2. Bait in sachets/place packs

a) Bait in single non-perforated sachets

Packaging type Pack sizes for professional use

Polyethylene sachet, polypropylene/paper sachet, orientated polypropylene sachet, polyethylene/aluminium sachet or polyethylene/paper/aluminium sachet (10 g, 25 g, 30 g, 40 g, 50 g, 100 g or 200 g), with or without cardboard outer 2.5 to 20 kg

b) Bait in 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:

Outer packaging type Pack sizes for professional use

Polypropylene woven sack or multi-ply paper sack. 2.5 to 25 kg

Polypropylene pail 2.5 to 20 kg

Polypropylene or polyethylene tub 2.5 to 20 kg

PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch 2.5 to 10 kg

Jerry can, with tamper-evident screw-top lid. 2.5 to 10 kg

Fibreboard box 2.5 to 10 kg

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:

Outer packaging type Pack sizes for professional use

Cardboard outer 2.5 to 20 kg

Single use or multi-use tamper-proof HDPE or PP bait station, packed in multiples in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper 2.5 to 20 kg

4.1.1. Use-specific instructions

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

4.1.3. Use-specific risk mitigation measures

- Do not apply this product directly in burrows.

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

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

4.1.6. 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 professional - indoors and outdoors (around buildings), in sewers

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: Mus musculus Common name: house mouse Development stage: Adults and juveniles Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	indoor use outdoor use Other Indoors Outdoors - around buildings 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. Loose bait

Outer packaging type Pack sizes for professional use

Polypropylene woven sack or multi-ply paper sack. 2.5 to 10 kg

Polypropylene pail 2.5 to 10 kg

Polypropylene or polyethylene tub 2.5 to 10 kg

PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch 2.5 to 10 kg

Polypropylene or polyethylene jerry can, with tamper-evident screw-top lid. 2.5 to 10 kg

- 2. Bait in sachets/place packs
- a) Bait in single non-perforated sachets

Packaging type Pack sizes for professional use

Polyethylene sachet, polypropylene/paper sachet, orientated polypropylene sachet, polyethylene/aluminium sachet or polyethylene/paper/aluminium sachet (10 g, 25 g, 30 g, 40 g, 50 g, 100 g or 200 g), with or without cardboard outer 2.5 to 20 kg

b) Bait in 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:

Outer packaging type Pack sizes for professional use

Polypropylene woven sack or multi-ply paper sack. 2.5 to 25 kg

Polypropylene pail 2.5 to 20 kg

Polypropylene or polyethylene tub 2.5 to 20 kg

PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch 2.5 to 10 kg

Jerry can, with tamper-evident screw-top lid. 2.5 to 10 kg

Fibreboard box 2.5 to 10 kg

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:

Outer packaging type Pack sizes for professional use

Cardboard outer 2.5 to 20 kg

Single use or multi-use tamper-proof HDPE or PP bait station, packed in multiples in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper 2.5 to 20 kg

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-liable 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. Follow any additional instructions provided by the CRRU Code of Best Practice (or equivalent)
- 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.

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

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 as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- 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.
- 4.2.5. Where specific to the use, the instructions for safe disposal of the product and its packaging
- 4.2.6. 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.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the
- 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 CRRU Code of Best Practice (or equivalent). 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. For non-emptiable sachets:- Do not open the sachets containing the bait.

For loose baits: place the bait in the baiting point by using a dosage device. Specify methods to minimise dust (e.g. wet wiping).

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.
- 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.

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

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.

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

- 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.
- Poison Information: For information or to report a poisoning incident contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), retain the label for reference.
- Please note IRELAND applies a minimum Professional pack size of 2.5 Kg instead of 3.0 kg.

There are a number of errors in the drop-down menus in the hazard statements section. The correct phrases are: 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.