Summary of product characteristics for a biocidal product

Product name: PROKUM CUB PARAFINAT

Product type(s): PT14 - Rodenticides (Pest control)

PT14 - Rodenticides (Pest control)

Authorisation number: RO/2018/0038/MRA/UK-2012-0612

R4BP 3 asset reference number: RO-0009282-0000

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Administrative information

1.1. Trade names of the product

Prokum Cub Parafinat		

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/2018/0038/MRA/UK-2012-0612

R4BP 3 asset reference number

RO-0009282-0000

Date of the authorisation

27/02/2023

Expiry date of the authorisation

01/07/2024

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

PelGar International Limited

Address of the manufacturer

Unit 13, Newman Lane GU34 2QR Alton, Hants United Kingdom

Location of manufacturing sites

Unit 13, Newman Lane GU34 2QR Alton, Hants United Kingdom

jud. Mures Promedivet SRL, 545500 SOVATA, str. Lunga nr. 46/G jud. Mures Romania

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

Active substance	11 - Brodifacoum
Name of the manufacturer	PelGar International Limited
Address of the manufacturer	Unit 13, Newman Lane GU34 2QR Alton, Hants United Kingdom
Location of manufacturing sites	Prazska 54 280 02 Kolin Czech Republic

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro - 1-napthyl]-4- hydroxycoumarin	Active Substance	56073-10-0	259-980-5	0,005

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	To avoid risks to human health and the environment, comply with the instructions for use.				
	Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.				
Precautionary statements	Keep out of reach of children.				
•	Read carefully and follow all instructions.				
	Keep away from clothing and other combustible materials.				
	Do not get in eyes, on skin, or on clothing.				
	Do no eat, drink or smoke when using this product.				
	Avoid release to the environment.				

Wear protective gloves.

IF SWALLOWED:Immediately call a POISON CENTER.

Store in a closed container.

Store locked up.

Dispose of contents to in accordance with national regulations.

4. Authorised use(s)

4.1 Use description

Use 1 - Professional use in and around buildings and in sewers

Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT14 - Rodenticides (Pest control)

VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)

Scientific name: Rattus norvegicus Common name: Brown rat Development stage: All

Scientific name: Mus musculus Common name: House mouse Development stage: All

Field(s) of use

Indoor

Outdoor

IV.1 Indoor use

IV.2 Outdoor use (around buildings only)

IV.3 Use in sewerage

Application method(s)

Method: Bait application Detailed description:

VI1.1 Open trays (sewer use only)VI.2.1 In bait stations VI.2.2 Other covering

Application rate(s) and frequencies

Application Rate: Rats in and around buildings: 10 to 60 g bait. Mice: 5 to 20 g bait. Rats in accuracy 20 to 200 g bait.

in sewers: 20 to 200 g bait Dilution (%): 100

Number and timing of application:

Rats in and around buildings:Secure 10-60g of blocks in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.Mice:Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation

areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.Rats in sewers:Secure 20-200g of blocks per bait point to available structures to ensure the block is not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.

Category(ies) of users

Professional

Pack sizes and packaging material

Block, Bait, 5, 10, 20, 28, 50, 60, 100 or 200 g

Packaging detailsPack sizes for professional use5g, 10g, 20g, 28g, 50g and 60g blocks (either wrapped in PP or PE or loose) within a PE or PP tub or pail Up to 20 kg Loose 5g, 10g, 20g, 28g. 50g, 60g, 100g or 200g blocks either unlined or within a PP or wiretied PE bag within a double-walled or fibreboard carton Up to 20kg Loose 5g, 10g, 20g, 28g, 50g or 60g blocks in fibreboard carton 'uni-trays' (moulded styrene tray with popout blocks) Up to 12 kg 2, 3 or 4 x 5g blocks packed in a single or multi-use tamperproof 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 Up to 80g 1 or 2 x 10g blocks 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 Up to 80g 1 x 20g blocks 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 heatsealed bag or poly outer heat-sealed with a cardboard topper Up to 80g 2 or 3 x 20g 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 Up to 240g 50g 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 Up to 200g

See PAR

4.1.1 Use-specific instructions for use

For use in and around buildings and in sewers onlyFor professional use onlyThe 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. The product may be applied by professional users when appropriate chemical resistant gloves (EN 374) are used. Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry). Where possible, secure baits so that they cannot be dragged away. In case of using the product in sewers, bait should be placed in a way to protect from flooding or displacement. 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. For further information on disposal contact the Environment Agency (http://www.ANPM.ro). 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 Poison Centre (htpp//www.ms.ro) for further advice.

4.1.2 Use-specific risk mitigation measures

For use in and around buildings and in sewers only For professional use only 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. The product may be applied by professional users when appropriate chemical resistant gloves (EN 374) are used Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry). Where possible, secure baits so that they cannot be dragged away. In case of using the product in sewers, bait should be placed in a way to protect from flooding or displacement. 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. For further information on disposal contact the Environment Agency (http://www.ANPM.ro).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 Poison Centre (htpp://www.ms.ro) for further advice.

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

Oral:In case of ingestion or if swallowed seek medical advice immediately. Eyes: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. Dermal:In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing. General:In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) Brodifacoum 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 μ g/kg body weight for a child). Treatment with phytomenadione (orally or intravenously) may be required for several weeks. The advice of the National Poison Centre (htpp://www.ms.ro) should be sought, particularly if active bleeding occurs.

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. For information on disposal contact the Environment Agency (http://www.ANPM.ro)

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

Store in original container. Keep in a cool, dry, well ventilated area Shelf life of up to 2 years. Store away from light.

4.2 Use description

Use 2 - Non-professional use in and around buildings

Product type

PT14 - Rodenticides (Pest control)

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: Rattus norvegicus Common name: Brown rat Development stage: All

Scientific name: Mus musculus Common name: House mouse Development stage: all

Field(s) of use

Indoor

Outdoor

IV.1 Indoor use

IV.2 Outdoor use (around buildings only)

Application method(s)

Method: Bait application Detailed description:

For use against mice, commercially available bait stations (prefilled or refillable) or covered 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 enough bait for at most 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 frequencies

Application Rate: Rats: 10 to 60 g bait; mice: 5 to 20 g bait

Dilution (%): 100

Number and timing of application:

Rats: Secure 10-60g of blocks in covered tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.Mice:Secure 5-20g of blocks in covered tamper resistant baiting stations or covered bait points spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice are very inquisitive and it may help the control program to move baits every 2-3 days at the time when bait points are inspected or topped up. Make frequent inspections of the bait points during the first 10-14 days and replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt. If all the bait has been eaten from certain areas, increase the quantity of bait by placing more bait points. Do not increase the bait point size. Replace any bait eaten by rodents or that has been damaged by water or contaminated by dirt.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

Block, Bait , 5, 10, 20, 28, 50 or 60 $\ensuremath{\text{g}}$

Packaging detailsPack sizes for non-professional use5g, 10g, 20g, 28g, 50g and 60g

blocks (either wrapped in PP or PE or loose) within a PE or PP tub or pail Up to 1.5 kg2, 3 or 4 x 5g blocks 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 Up to 80g 1 or 2 x 10g blocks 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 Up to 80g 1 x 20g blocks packed in a single or multiuse 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 Up to 80g 2 or 3 x 20g 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 Up to 240g 50g blocks packed in a single or multiuse 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 Up to 200g

See PAR

4.2.1 Use-specific instructions for use

For non-professional use onlyFor use in and around buildings onlyWash hands and exposed skin before meals and after useFor use only in areas that are inaccessible to infants, children, companion animals and non-target animalsPrevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry). 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. 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. 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 Poison Centre (htpp://www.ms.ro) for further advice.

4.2.2 Use-specific risk mitigation measures

For non-professional use onlyFor use in and around buildings onlyWash hands and exposed skin before meals and after useFor use only in areas that are inaccessible to infants, children, companion animals and non-target animalsPrevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry). 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. 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. 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 Poison Centre (htpp://www.ms.ro) for further advice.

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

In case of ingestion or if swallowed seek medical advice immediately. Eyes: 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. Dermal: In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing. General: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) Brodifacoum 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 Poison Centre (htpp://www.ms.ro) should be sought, particularly if active bleeding occurs.

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. In the UK: Waste bait should be double bagged in plastic bags and disposed of in a household waste bin with a secure lid to prevent access of wildlife or pets or taken to a civic amenity site. For information on civic amenity sites contact the local authority.

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

Store in original containerKeep in a cool, dry	, well-ventilated areaShelf life o	of up to 2 years.	Store away from light.
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5. General directions for use

5.1. Instructions for use

See authorised uses tab

5.2. Risk mitigation measures

See authorised uses tab

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

See authorised uses tab

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

See authorised uses tab

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

See authorised uses tab			
6. Other information			
6. Other information			

N/A