ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

PRODIORAT - G

Product type(s)

PT14: Rodenticides

Authorisation number: RO/2018/0039/MRA/UK-2012-0635

R4BP asset number: RO-0004782-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Prodiorat G

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		RO/2018/0039/MRA/UK-2012-0635
R4BP asset number		RO-0004782-0000
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 King dom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	PelGar International Limited, Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
	Promedivet SRL, 545500 SOVATA, str. Lunga nr. 46/ G 545500 jud. Mures Romania

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

Active substance	Bromadiolone
Name of manufacturer	PelGar International Limited
	Unit 13 Newman Lane GU34 2QR Alton United King dom 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 (%)
Bromadiolone	3-[3-(4'-Bromo[1 ,1'-biphenyl]-4-yl)-3-hydroxy-1-ph enylpropyl]-4-hy droxy-2H-1-benz opyran-2-one		28772-56-7	249-205-9	0,005 % (w/w)

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	EUH401: To avoid risks to human health and the envir onment, comply with the instructions for use.
	EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.
Precautionary statements	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P220: Keep away from clothing or other combustible materials.
	P262: Do not get in eyes, on skin, or on clothing.
	P270: Do not eat, drink or smoke when using this product.
	P273: Avoid release to the environment.
	P280: Wear protective gloves.
	P301+P310: IF SWALLOWED: Immediately call a P OISON CENTER.
	P404: Store in a closed container.
	P405: Store locked up.
	P501: Dispose of contents to in accordance with local r egulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. In/around buildings - amateurs

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	For use indoors and outdoors around buildings. 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 sachets, 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.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and juveniles
	Scientific name: Mus musculus Common name: house mouse Development stage: Adults and juveniles
Field(s) of use	indoor use For use indoors and outdoors around buildings. Baits are manually placed in the rodent infested area. The bait product can potentially be used under many different circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Methods of deployment for amateur users are bait stations (tamper proof boxes) or - for mice only - covered/protected bait points. Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. The product may also be placed on trays under a tile or located in such a way that access by nontarget organisms is restricted. These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used. The product must never be placed indiscriminately.
Application method(s)	Method: bait application Detailed description: Method of application: bait application; in bait boxes (rats or mice); Covered/protected bait points (mice only). Detailed description of the method: Place bait where there are signs of rodent activity, like fresh droppings, inside or near nests and burrows, runways and rodent feeding places. Place bait points throughout the infested area. For rat infestations use bait points of up to 200g. Place bait points 10 m apart reducing to 5

m in high infestations. For mouse infestations use bait points of up to 40g. Place bait points 5 m apart reducing to 2 m in high infestations. 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 no signs of rat activity are seen near a bait point after 7-10 days, move it to an area of higher activity. Mice are very inquisitive. It may help the control programme to move bait points when they are inspected/ topped up. Protect bait points from non-target animals and from water, preferably using commercially available bait stations. For rat control, commercially available tamper resistant bait stations must be used. For mice, if these are not available, place the bait on bait trays inside pieces of drainage pipe or under sections of slate, board or corrugated iron which are firmly propped against a wall and suitably weighted. 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. Sachets can be wired or nailed in place. 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. It is generally much more efficient to use a larger number of small bait points compared to a smaller number of large bait points. Large bait points increase the risk to wild-life and to other non-target animals. 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. Application rate: For rat infestations use bait points of up to 200g. Application rate(s) and frequency Place bait points 10 m apart reducing to 5 m in high infestations. For mouse infestations use bait points of up to 40g. Place bait points 5 m apart reducing to 2 m in high infestations. Dilution (%): 100 Number and timing of application: The treatment frequency is typically 2-4 applications per year, 3-6 months apart. Baiting programmes are repeated as necessary, due to reinfestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks. Category(ies) of users general public (non-professional) Pack sizes and packaging material Single non-perforated sachets, PE or PP/paper or oreintated PP or PE/aluminium or PE/paper/aluminium, 10, 25, 30, 40, 50, 100 or 200 g Sachets with or without cardboard outer. Tamper-evident packaging Pail, PP, Up to 1.5 kg Tub, PP or PE, Up to 1.5 kg

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Pouch, PET/PE, PP/PE or paper/PE, Up to 1.5 kg Box, Fibreboard, Up to 1 kg

Bait in perforated or non-perforated polypropylene/paper or PET/polyethylene or polyethylene/paper or polyethylene/aluminised film sachets (10, 25, 30, 40, 50, 100 or 200g) in the above outer packaging.

Tamper-evident packs

Outer, Cardboard outer , Up to 1.5 kg Single-use or multi-use tamper-proof bait station packed in multiples of 1, 2 or 4, HDPE or PP bait stations in a cardboard outer or blister pack or a cardboard sleeve or heat-sealed bag or poly outer heat-sealed with cardboard topper , Up to 0.8 kg $\,$

Bait in trays (PVC or polystyrene or PP or PET or PET/PE or fibreboard) - 25, 30, 40, 50, 100 or 200 g - with heat-sealed lid (PET/PP or PET/PE or PP) supplied in the above outer packs.

Tamper-evident pack

4.1.1. Use-specific instructions

None

4.1.2. Use-specific risk mitigation measures

None

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

None

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

None

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

None

4.2. Use description

Table 2. In/around buildings - professionals

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	For use indoors and outdoors around buildings, in open areas and in waste dumps.
	Baits are manually placed in the rodent infested area. The bait product can potentially be used under many different circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait). Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. The product may also be placed on trays under a tile or located in such a way that access by non-target organisms is restricted. These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used. The product must never be placed indiscriminately.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat
suge	Development stage: Adults and juveniles
	Scientific name: Mus musculus Common name: house mouse
	Development stage: Adults and juveniles
Field(s) of use	indoor use outdoor use
	For use indoors and outdoors around buildings. Baits are manually placed in the rodent infested area. The bait product can potentially be used under many different circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Methods of deployment for professional users are bait stations (tamper proof boxes), bait points (a makeshift arrangement which uses materials and/or the local environment to restrict access to the bait), loose but inaccessible (an arrangement which uses the local environment only to restrict access to the bait). Baits can be placed in bait boxes which may be fixed to the ground. The bait in such bait boxes can also be secured in place to minimise removal and dispersal by rodents. The product may also be placed on trays under a tile or located in such a way that access by non-target

	organisms is restricted. These methods, in themselves, represent a scale of potential access. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used. The product must never be placed indiscriminately.
Application method(s)	Detailed description: Method of application: bait application; in bait boxes; Covered/protected bait points. Detailed description of the method: Place bait where there are signs of rodent activity, like fresh droppings, inside or near nests and burrows, runways and rodent feeding places. Place bait points throughout the infested area. For rat infestations use bait points of up to 200g. Place bait points 10 m apart reducing to 5 m in high infestations. For mouse infestations use bait points of up to 40g. Place bait points 5 m apart reducing to 2 m in high infestations. 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 no signs of rat activity are seen near a bait point after 7-10 days, move it to an area of higher activity. Mice are very inquisitive. It may help the control programme to move bait points when they are inspected/topped up. Protect bait points from non-target animals and from water, preferably using commercially available bait stations. For rat control, commercially available, place the bait on bait trays inside pieces of drainage pipe or under sections of slate, board or corrugated iron which are firmly propped against a wall and suitably weighted. 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. Sachets can be wired or nailed in place. 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. It is generally much more efficient to use a larger number of small bait points compared to a smaller number of large bait points. Large bait points increase the risk to wild-life and to other nontarget animals. 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 req
Application rate(s) and frequency	Application rate: For rat infestations use bait points of up to 200g. Place bait points 10 m apart reducing to 5 m in high infestations. For mouse infestations use bait points of up to 40g. Place bait points 5 m apart reducing to 2 m in high infestations.
	Dilution (%): 100 Number and timing of application: The treatment frequency is typically 2-4 applications per year, 3-6 months apart. Baiting programmes are repeated as necessary, due to reinfestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks.

Category(ies) of users	trained professional; professional
Pack sizes and packaging material	Carton, Double-walled or fibreboard carton lined with polyethylene , Up to 25 kg
	Carton, Polyethylene/paper bag in a fibreboard carton, Up to 2 kg
	Bag /Sack, Polyethylene-lined polypropylene sack or multi-ply paper sack or polyethylene/polypropylene laminated sack, Up to 25 kg
	Tub, pail or jerrican, PP or PE, Up to 20 kg
	Loose bait
	Tamper-evident packs
	Sachets, PE or PP/paper or orientated PP or PE/aluminium or PE/paper/aluminium, Up to 1000g
	Supplied without outer packaging or in fibreboard carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Up to 20 kg in the outer pack.
	Tamper-evident packs.
	Pouches, PP or laminated PP or PET/PE or PE/paper/aluminium , Up to 15 kg
	Supplied without outer packaging or in fibreboard carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Up to 20 kg in the outer pack.
	Tamper-evident packaging
	Single non-perforated sachets, PE or PP/paper or orientated PP or PE/aluminium or PE/paper/aluminium , 10, 25, 30, 40, 50, 100 or 200 g
	Sachets with or without cardboard outer.
	Tamper-evident packaging
	Bag /Sack, Polypropylene woven or multi-ply paper, Up to 25 kg
	Pail, PP, Up to 20 kg Tub, PP or PE, Up to 2 kg
	Pouch, PET/PE or PP/PE or paper/PE, Up to 10 kg Jerry can with tamper-evident screw top lid, PP or PE, Up to 3 kg
	Box, Fibreboard, Up to 1 kg

Bait in perforated or non-perforated polypropylene/paper or PET/polyethylene or polyethylene/paper or polyethylene/aluminised film sachets (10, 25, 30, 40, 50, 100 or 200g) in the above outer packaging.

Tamper-evident packs

Outer, Cardboard outer, Up to 6.4 kg

Single use or multi-use tamper-proof bait station packed in multiples of 1, 2 or 4, HDPE or PP bait stations in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with cardboard topper, Up to 0.8 kg

Bait in trays (PVC or polystyrene or PP or PET or PET/PE or fibreboard) - 25, 30, 40, 50, 100 or 200 g - with heat-sealed lid (PET/PP or PET/PE or PP) supplied in the above outer packs.

Tamper-evident pack

4.2.1. Use-specific instructions

None

4.2.2. Use-specific risk mitigation measures

None

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

None

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

None

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

None

4.3. Use description

Table 3. In sewers - professionals

Product type	PT14: Rodenticides
Where relevant, an exact description of the	For use in sewers. Professional use only.
authorised use	
	Baits are manually placed in the rodent infested area. The
	bait product can potentially be used under many different

	circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Baits are manually placed in the rodent infested area. The bait product can potentially be used under many different circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Methods of deployment for professional users for this use is in sewers. The product is located in such a way (in sewers) that access by non-target organisms is restricted. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used. The product must never be placed indiscriminately.
Target organism(s) (including development stage)	Scientific name: Rattus norvegicus Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	For use in sewers. Baits are manually placed in the rodent infested area. The bait product can potentially be used under many different circumstances and can be deployed using various means. The method of deployment is dependent on the particular circumstance. A priority is always to exclude non target exposure as much as possible. Methods of deployment for professional users for this use is in sewers. The product is located in such a way (in sewers) that access by non-target organisms is restricted. The vulnerability (of access by non target organisms) of a particular site is assessed in the decision for the deployment method to be used. The product must never be placed indiscriminately.
Application method(s) Application rate(s) and frequency	Method: bait application Detailed description: Method of application: bait application; in bait boxes; Covered/protected bait points Secure up to 200g of bait per station to available structures to ensure the bait 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. Application rate: For rat infestations in sewers use bait points of
Transmission and adquency	up to 200g. Dilution (%): 100 Number and timing of application: The treatment frequency is typically 2-4 applications per year, 3-6 months apart. Baiting programmes are repeated as necessary, due to reinfestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks.
Category(ies) of users	trained professional ; professional

Pack sizes and packaging material

Carton, Double-walled or fibreboard carton lined with polyethylene, Up to 25 kg

Carton, Polyethylene/paper bag in a fibreboard carton, Up to 2 kg

Bag /Sack, Polyethylene-lined polypropylene sack or multi-ply paper sack or polyethylene/polypropylene laminated sack, Up to 25 kg

Tub, pail or jerrican, PP or PE, Up to 20 kg

Loose bait

Tamper-evident packs

Sachets, PE or PP/paper or orientated PP or PE/aluminium or PE/paper/aluminium , Up to $1000\;g$

Supplied without outer packaging or in fibreboard carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Up to 20 kg in the outer pack.

Tamper-evident packs

Pouches, PP or laminated PP or PET/PE or PE/paper/aluminium , Up to $15\ kg$

Supplied without outer packaging or in fibreboard carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Up to 20 kg in the outer pack.

Tamper-evident pack

Single non-perforated sachets, PE or PP/paper or orientated PP or PE/aluminium or PE/paper/aluminium , 10, 25, 30, 40 50, 100 or 200 $\rm g$

Sachets with or without cardboard outer.

Tamper-evident packaging

Bag /Sack, Polypropylene woven or multi-ply paper, Up to 25 kg

Pail, PP , Up to 20~kg Tub, PP or PE , Up to 2~kg Pouches, PET/PE, PP/PE or paper/PE , Up to 10~kg

Jerry can with tamper-evident screw-top lid, PP or PE, Up to 3 kg Box, Fibreboard, Up to 1 kg Bait in perforated or non-perforated polypropylene/paper or PET/ polyethylene or polyethylene/paper or polyethylene/aluminised film sachets (10, 25, 30, 40, 50, 100 or 200g) in the above outer packaging. Tamper-evident pack Outer, Cardboard outer, Up to 6.4 kg Single-use or multi-use tamper-proof bait station, HDPE or PP bait stations in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with cardboard topper, Up to 0.8 kg Bait in trays (PVC or polystyrene or PP or PET or PET/PE or fibreboard) - 25, 30, 40, 50, 100 or 200 g - with heat-sealed lid (PET/PP or PET/PE or PP) supplied in the above outer packs Tamper-evident pack

4.3.1. Use-specific instructions

None

4.3.2. Use-specific risk mitigation measures

None

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

None

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

None

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

None

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Place bait where there are signs of rodent activity, like fresh droppings, inside or near nests and burrows, runways and rodent feeding places.

Place bait points throughout the infested area.

For rat infestations use bait points of up to 200g. Place bait points 10 m apart reducing to 5 m in high infestations.

For mouse infestations use bait points of up to 40g. Place bait points 5 m apart reducing to 2 m in high infestations.

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 no signs of rat activity are seen near a bait point after 7-10 days, move it to an area of higher activity.

Mice are very inquisitive. It may help the control programme to move bait points when they are inspected/topped up.

Protect bait points from non-target animals and from water, preferably using commercially available bait stations. If these are not available, place the bait on bait trays inside pieces of drainage pipe or under sections of slate, board or corrugated iron which are firmly propped against a wall and suitably weighted.

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. Blocks can be wired or nailed in place. 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. It is generally much more efficient to use a larger number of small bait points

not increase the bait point size. It is generally much more efficient to use a larger number of small bait points compared to a smaller number of large bait points. Large bait points increase the risk to wild-life and to other non-target animals.

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.

PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. 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.

5.2. Risk mitigation measures

Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children.

Where possible, secure baits so that they cannot be dragged away.

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. Dispose of dead rodents in accordance with local requirements.

Unless under the supervision of a pest control operator or other competent person, do not use anticoagulant rodenticides as permanent baits. Remove all baits after treatment and dispose of them in accordance with local requirements.

There is a bittering agent (0.01% denatonium benzoate) in all formulations.

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

Particulars of likely direct or indirect effects: Anticoagulant rodenticide

Toxic to most mammalian and avian species, including domesticated animals, wildlife and humans.

First aid instructions: Medical advice: If swallowed, seek medical advice immediately and show this container or label.

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

Antidote: Vitamin K1 (under medical supervision).

Medical professionals should contact the local Poisons Information Service for further advice.

Emergency measures to protect the environment: Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.

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

This material and its container must be disposed of safely.

Dispose of packaging, remains of unused product and dead rodents in accordance with local regulations.

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

Keep in a cool, dry, well ventilated area.

Shelf life of up to 2 years supported.

6. OTHER INFORMATION

There are some errors in the CLP phrases which cannot be corrected using the drop-down menus. Complete list of corrected phrases is:

P262 Do not get on skin.

P270 Do not eat, drink or smoke when using this product.

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