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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Rodex Whole Wheat Bait

Product type(s)

PT14: Rodenticides

Authorisation number: reg. nr. 736-10

R4BP asset number: DK-0000291-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Tanaco Bromakorn Pro Rodex Whole Wheat Pro
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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	reg. nr. 736-10	
<i>R4BP asset number</i>	DK-0000291-0000	
Date of the authorisation	19/11/2012	
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	PelGar International Limited site 1 Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the) CAMRO A/S Skrænten 11 9610 Nørager Denmark

Name of manufacturer	Doa Rat Production Centre
Address of manufacturer	Mesokeleos Street Palouriotissa Nicosia Cyprus
Location of manufacturing sites	Doa Rat Production Centre site 1 Mesokeleos Street Palouriotissa Nicosia Cyprus

Name of manufacturer	Promedivet SRL
Address of manufacturer	Str. Lunga nr. 46/G 545500 jud. Mures Romania
Location of manufacturing sites	Promedivet SRL site 1 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
Address of manufacturer	Unit 13 Newman Lane GU34 2QR Alton United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	PelGar International Limited site 1 Prazska 54 28002 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-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	active substance	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	H360D: May damage the unborn child. H372: Causes 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:}. EUH208: Contains 1,2-benzisothiazol-3(2H)-on. May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust. P264: Wash skin thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical attention. P405: Store locked up. P102: Keep out of reach of children. P501: Dispose of contents to hazardous waste according to local requirements.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Trained professional (R1) and Professionals (R2) - Indoor and outdoor around buildings

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Adults and juveniles Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: Adults and juveniles
Field(s) of use	indoor use outdoor use In and around Buildings within a maximum distance of 10 meter from the Buildings. The control of rats is however allowed also where an occurrence of rats farther than 10 meters acts as a source of rats in buildings (source control). The product must always be placed in tamper resistant bait stations to prevent poisoning of humans and animals.
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. If more than one bait station is needed, the minimum distance between bait stations should be 5 metres. MICE: 40 g of bait per bait station. If more than one bait station is needed, the minimum distance be... Dilution (%): 0 Number and timing of application: Mice High infestation – 40g bait in bait stations every 2 metres Low infestation – 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	trained professional ; professional

Pack sizes and packaging material	<p>Loose bait:</p> <ul style="list-style-type: none"> - Polyethylene-lined polypropylene sack or polypropylene woven sack or multi-ply paper sack or - polyethylene/polypropylene laminated sack: 3-10 kg - Polyethylene lined double-walled or fibreboard Carton: 3-10 kg - Polyethylene/paper bag in a fibre-board Carton: 3-10 kg - Polypropylene or polyethylene tub, pail or jerrican: 3-10 kg <p>- Polyethylene sachets or polypropylene/paper sachets or orientated polypropylene sachets or polyethylene/aluminium sachets or polyethylene/paper/aluminium sachets (up to 1000g). Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Single sachets: 3-10 kg. Multiple sachets: up to 20 kg.</p> <p>- Polypropylene pouches or laminated polypropylene pouches or PET/polyethylene pouches or polyethylene/paper/aluminium pouches (up to 10 kg). Supplied without outer packaging or in fibre-board carton with or without polyethylene liner or in polyethylene pack or in polypropylene pack or in blister pack. Single pouches: 3-10 kg.</p> <p>Bait in sachets/place packs: Bait in perforated or non-perforated polypropylene/paper film sachets, PET/polyethylene film sachets, polyethylene/paper film sachets or polyethylene/aluminised film sachets (10 g, 25 g, 30 g, 40 g, 50 g, 100 g or 200 g) supplied in the following outer packs:</p> <ul style="list-style-type: none"> - Polypropylene woven sack or multi-ply paper sack: 3-25 kg - Polypropylene or polyethylene pails: 3-20 kg. - Polypropylene or polyethylene tub: 3-10 kg - PET/polyethylene, polypropylene/polyethylene or paper/polyethylene pouch: 3-10 kg - Jerry can, with tamper-evident screw-top lid: 3 kg - Fibreboard box: 3-10 kg <p>Bait in trays ((PVC or polystyrene or polypropylene or PET or PET/polyethylene or fibreboard); 25g, 30g, 40g, 50g, 100g, 150g or 200g)) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) supplied in the following outer packs:</p> <ul style="list-style-type: none"> - Cardboard outer: 3-6.4 kg - Single-use or multi-use tamper-proof HDPE or PP bait station, packed in multiples of 1, 2 or 4 in a cardboard outer or blister pack or cardboard sleeve or heat-sealed bag or poly outer heat-sealed with a cardboard topper. Packed in multipacks of 4, 8, 16, 24, 32, 48, 60, 72, 96, 100, 120, 144: 3-20 kg.
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4.1.1. Use-specific instructions

- The biocidal product may only be used by trained licensed professionals (R1) and professionals (R2) against the brown rat (*Rattus norvegicus*), and the house mouse (*Mus musculus*) in and around buildings within a

maximum distance of 10 meter from the buildings. The control of rats is however allowed also where an occurrence of rats farther than 10 meters acts as a source of rats in buildings (source control).

- In the case of the use of the biocidal product for source control of rats, the conditions in the Danish Environmental Protection Agency's guidance on the assessment and authorization of biocides against rats and mice must be met ("Miljøstyrelsens vejledning om vurdering og godkendelse af kemiske bekæmpelsesmidler til rotter og mus").

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice. See the Danish Environmental Protection Agency's guidance on the assessment and authorization of biocides against rats and mice ("Miljøstyrelsens vejledning om vurdering og godkendelse af kemiske bekæmpelsesmidler til rotter og mus")

- Protect bait from atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.

4.1.2. Use-specific risk mitigation measures

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals (at least twice a week).
 - Do not use the product in pulsed baiting treatments.

- Do not apply the product directly in the 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

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

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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 locked up and 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.

- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- 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.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective 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.
- Sachets: Do not open the sachets containing the bait (not required if the sachets are designed to be opened).
- Loose grain: Place the bait in the bait station by using a dosage device.

5.2. 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.
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional (R1) and professional users (R2) holding certification demonstrating compliance with the applicable training requirements. See section 6 for the exact information that should be included on the label.
- 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.

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

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- 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 with water between applications.
 - Dispose dead rodents in accordance with local requirements.
 - Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
 - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
 - Wash hands and directly exposed skin after using the product.

 - Not for use against any other pests than indicated on the label and not for use in higher doses than indicated.
 - To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).
 - Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
 - The product information (i.e. label and/or leaflet) shall clearly show that:
 - the product shall not be supplied to the general public (e.g. "for trained professionals (R1) and professionals (R2) only").
 - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").
 - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").
 - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

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 eye-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.

- Hazardous to wildlife.
- 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 incident, call a poison centre [insert national phone number]".

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

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

- The product is not to be disposed of in sewers, including rainwater Canals.

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

- Shelf life: 2 years
- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight .
 - Store the product locked up and out of the reach of children, birds, pets and farm animals and other non-target animals.
- Store the product away from food, drink and animal feeding stuffs.

6. OTHER INFORMATION

The label of the product should contain the following information (in Danish):

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

”Gnavermiddel

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*) og husmus (*Mus musculus*) i og omkring bygninger og kun i en afstand op til 10 meter fra en bygning. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med enten en R1 eller R2 autorisation.”

2) I advarselsfeltet:

”FARE

Kan skade det ufødte barn (H360D)

Forårsager organskader (blod) ved længerevarende eller gentagen eksponering (H372)

Indhent særlige anvisninger før brug.

Anvend ikke produktet, før alle advarsler er læst og forstået.

Indånd ikke pulver.

Vask huden grundigt efter brug.

Der må ikke spises, drikkes eller ryges under brugen af dette produkt.

Bær beskyttelseshandsker.

Brug kemisk resistente beskyttelseshandsker ved brug af produktet.” (Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet)

”Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*) og husmus (*Mus musculus*) i og omkring bygninger og kun i en afstand op til 10 meter fra en bygning. Bekæmpelse er dog også tilladt, hvor en forekomst af rotter længere væk end 10 meter fungerer som kilde til rotter i bygninger.

Må kun anvendes af personer, der er autoriserede af Miljøstyrelsen til at bekæmpe rotter med enten en R1 eller R2 autorisation.

Ved kildebekæmpelse skal betingelserne i Miljøstyrelsens vejledning om vurdering og godkendelse af kemiske bekæmpelsesmidler til rotter og mus være opfyldt.

Doseringen af det biocidholdige produkt skal afpasses bekæmpelsen af mus og rotter på den pågældende lokalitet, dog må der højst anvendes 40 g pr. udlægningssted for mus og 200 g pr. udlægningssted for rotter af hensyn til faren for forgiftning af mennesker, pattedyr og fugle.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Det biocidholdige produkt skal anbringes i aflåste foderstationer, så mennesker og dyr udenfor målgruppen ikke kan komme i kontakt med giften.

Døde mus og rotter skal eftersøges to gange ugentligt eller efter behov og bortskaffes som dagrenovation af hensyn til faren for sekundær forgiftning af rovfugle og rovdyr.

Produktet må ikke bruges mere end 35 dage uden en evaluering af angrebets status og effekten af behandlingen.

Giftrester og emballage skal afleveres til den kommunale affaldsordning for farligt affald efter endt bekæmpelse.

Foderstationer skal påføres en tekst, hvoraf det fremgår, at der foregår bekæmpelse af mus og rotter i området, og hvorledes man forholder sig i tilfælde af forgiftning. Foderstationer skal være forsynet med kontaktinformation på dem, som udfører bekæmpelsen.

Må ikke benyttes til permanent bekæmpelse af mus og rotter, såsom forebyggende brug i sikringsordninger.

Ved anbringelse af foderstationer tæt på overfladevand eller afløbssystemer skal det sikres, at det biocidholdige produkt ikke kommer i kontakt med vand.

Må ikke tømmes i kloak afløb.

Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.”

Farepiktogrammet GHS08.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

VED eksponering eller mistanke om eksponering: Søg lægehjælp.

”Dette produkt indeholder et antikoagulerende stof.

Ved indtagelse kan der forekomme forsinkede symptomer, såsom næseblod og blødende tandkød.

I svære tilfælde kan der forekomme blå mærker og blod i afføring eller urin.

Modgift: K1-vitamin; må kun administreres af medicinsk/veterinært personale.

Hvis produktet:

- kommer på huden, vaskes huden med vand og sæbe.

- kommer i øjnene, skylles øjnene med øjenrensevæske eller vand; hold øjnene åbne i mindst 10 minutter.

- kommer i munden, skylles munden grundigt med vand.

Giv aldrig en bevidstløs person noget gennem munden.

Fremkald ikke opkastning.

Hvis produktet synkes, søges der straks lægehjælp. Vis produktets beholder eller etiketten til lægen.

Kontakt en dyrlæge, hvis produktet indtages af et kæledyr ”

3) I deklarationsfeltet:

a) Teksten ”Gnavermiddel BPR-reg. nr. 736-10. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.

b) Oplysning om præparattype: ”korn” for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/kg.

d) Sætningen:” Indeholder 1,2-benzisothiazol-3(2H)-on. Kan udløse allergisk reaktion.”

e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

f) Batchnummer eller – betegnelse skal anføres.

g) Pakningsstørrelse i kg.

h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning: ”Indholdet/beholderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”

Derudover skal mærkningen ske efter retningslinjerne:

”Tom emballage og rester skal afleveres til den kommunale affaldsordning for farligt affald.”