

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Brodifacoum 25 Paste; Talon® SoftXT

Product type(s)

PT14: Rodenticides

Authorisation number: 666-16 1-3

R4BP asset number: DK-0024693-0003

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Brodifacoum 25 Paste Talon® SoftXT
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Rentokil Initial Limited
	Address	Hazel House Millennium Park - Naas Ireland
Authorisation number		666-16 1-3
<i>R4BP asset number</i>		DK-0024693-0003
Date of the authorisation		03/04/2019
Expiry date of the authorisation		30/06/2025

1.3. Manufacturer(s) of the product

Name of manufacturer	Rentokil Initial Supplies
Address of manufacturer	Webber Road, Knowsley Industrial Estate L33 7SR Liverpool United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Webber Road, Knowsley Industrial Estate L33 7SR Liverpool United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Brodifacoum
Name of manufacturer	Pelgar International Limited
Address of manufacturer	Unit 13, Newman Lane, Alton, GU34 2QR Hampshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Prazska 54 28002 Kolin Czechia

Active substance	Brodifacoum
Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Schwarzwaldallee 215 CH-4002 Basel Switzerland
Location of manufacturing sites	BASF plc., Lower Road, Halebank WA8 8NS Widnes United Kingdom of Great Britain and Northern Ireland (the)

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 (%)
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	active substance	56073-10-0	259-980-5	0,0025

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H373: May cause damage to organs (blood) through prolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.</p> <p>EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.</p>
Precautionary statements	<p>P314: Get medical attention if you feel unwell.</p> <p>P501: Dispose of contents to to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.</p>

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use #2.1 – Paste - House mice and/or rats – Trained Professional users – indoor

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles
Field(s) of use	indoor use Indoor
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 200g of bait per bait station. Mice: Up to 50g of bait per bait station Dilution (%): 0 Number and timing of application: Rats: Up to 200g of bait per baiting point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per baiting point, every 10 metres, reducing to 5 metres in areas of high infestation.
Category(ies) of users	trained professional

Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>300g white high density polyethylene (HDPE) cartridge – 3kg-10kg</p> <p>400g white high density polyethylene (HDPE) cartridge – 3kg-10kg</p>
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4.1.1. Use-specific instructions

Remove the remaining product at the end of treatment period.

4.1.2. Use-specific risk mitigation measures

4.1.3. 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 (e.g. 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.

4.1.4. 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 stations close to 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

See Section 5.4

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

See Section 5.5

4.2. Use description

Table 2. Use #2.2 – Paste - House mice and/or rats – Trained Professional users – 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)	<p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: adults</p> <p>Scientific name: <i>Rattus norvegicus</i> Common name: brown rat Development stage: juveniles</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: adults</p> <p>Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: juveniles</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: adults</p> <p>Scientific name: <i>Rattus rattus</i> Common name: roof rat Development stage: juveniles</p>
Field(s) of use	<p>outdoor use</p> <p>outdoor around buildings</p>
Application method(s)	<p>Method: bait application</p> <p>Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations</p>
Application rate(s) and frequency	<p>Application rate: Rats: Up to 200g of bait per bait station. Mice: Up to 50g of bait per bait station</p> <p>Dilution (%): 0</p> <p>Number and timing of application:</p> <p>Rats: Up to 200g of bait per baiting point, every 10 metres, reducing to 5 metres in areas of high infestation.</p>

	Mice: Up to 50g of bait per baiting point, every 10 metres, reducing to 5 metres in areas of high infestation.
Category(ies) of users	trained professional
Pack sizes and packaging material	<p>Minimum pack size of 3 kg.</p> <p>300g white high density polyethylene (HDPE) cartridge – 3kg-10kg 400g white high density polyethylene (HDPE) cartridge – 3kg-10kg</p>

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the bait stations in areas non-labile to flooding.
- Replace any bait in bait stations in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- Remove the remaining product at the end of treatment period

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.

- Do not apply this product directly in the burrows.

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 stations 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

See Section 5.4

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

See Section 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Trained professional users

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.

Bait should be secured so that it cannot be dragged away from the bait station.

Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

Wear protective chemical resistant gloves during product handling phase (EN374).

When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. 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 stations 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 paste bait: use a spatula for post-application (cleaning/disposal) of bait.

5.2. Risk mitigation measures

Trained professional users

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.

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 used utensils 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 centre".

Hazardous to wildlife.

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

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

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: 24 months

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.

Bilag 1.2 (Meta SPC 2)

Oplysninger til etiket og brugsanvisning for Brodifacoum Family - PT14, BPR-reg. nr. 666-16-3-x [1] .

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen [2] (Forordning (EU) nr. 528/2012), og CLP-Forordningen [3] .

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk. Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

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*), husrotte (*Rattus rattus*) 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 en R1 autorisation.”

2) I advarselsfeltet:

”ADVARSEL

Kan forårsage organskader (blod) ved længerevarende eller gentagen eksponering (H373).

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

”Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til bekæmpelse af brun rotte (*Rattus norvegicus*), husrotte (*Rattus rattus*) 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 en R1 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 rotter og mus på den pågældende lokalitet, dog må der, mod rotter, højst anvendes 200 g per udlægningssted med minimum fem meters afstand. Ved bekæmpelse af mus må der højst anvendes 50 g per udlægningssted med minimum fem meters afstand 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 uden for 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.

Emballagen må ikke genanvendes"

Farepiktogrammet GHS08.

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

"Søg lægehjælp ved ubehag.

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.

Hvis et dyr uden for målgruppen indtager produktet, ring til en dyrlæge"

3) I deklaraionsfeltet:

a) Teksten "Gnavermiddel BPR-reg. nr. 666-16-3-x [4] . Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "pasta" for dette præparat.

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- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/kg.
 - d) 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.
 - e) Batchnummer eller – betegnelse skal anføres.
 - f) Pakningsstørrelse.
 - g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse:

Der skal mærkes med sikkerhedssætning P501: ”Indholdet/holderen 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.

[1] 'X' skal erstattes af et tal som angivet i godkendelsesbrevets bilag 4.

[2] Europa-Parlamentets og Rådets forordning (EU) Nr. 528/2012 af 22. maj 2012 om tilgængeliggørelse på markedet og anvendelse af biocidholdige produkter.

[3] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008 om klassificering, mærkning og emballering af stoffer og blandinger og om ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring af forordning (EF) nr. 1907/2006

[4] 'X' skal erstattes af et tal, som angivet i godkendelsens bilag 4.