ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Paste Bait

Product type(s)

PT14: Rodenticides

Authorisation number: IE/BPA 70662 1-3

R4BP asset number: IE-0019552-0005

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Brodifacoum 25 Paste
	Talon® SoftXT

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Rentokil Initial Limited
ivalue and address of the authorisation holder	Address	Hazel House Millennium Park - Naas Ireland
Authorisation number		IE/BPA 70662 1-3
R4BP asset number		IE-0019552-0005
Date of the authorisation		02/02/2018
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 Li verpool United Kingdom of Great Britain and Norther n Ireland (the)
Location of manufacturing sites	Rentokil Initial Supplies site 1 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 Hampshir e United Kingdom of Great Britain and Northern Irela nd (the)
Location of manufacturing sites	Pelgar International Limited site 1 Prazska 54 28002 kolin Czechia

Active substance	Brodifacoum
Name of manufacturer	Syngenta Crop Protection AG
Address of manufacturer	Schwarzwaldallee 215 CH-4002 Basel Switzerland
	Syngenta Crop Protection AG site 1 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'-bromobi phenyl- 4-yl)-1,2 ,3,4-tetrahydro -1 -napthyl]-4-hydr oxycoumarin		56073-10-0	259-980-5	0,0025 % (w/w)

2.2. Type(s) of formulation

RB Bait (ready for use)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H373: May cause damage to organs (blood) through p rolonged or repeated exposure {1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard:}.
Precautionary statements	P314: Get medical attention if you feel unwell. P501: Dispose of container 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. P501: Dispose of contents to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 19 – Paste - House mice and/or rats – Professional users with demonstrated competence (equivalent to trained professionals) – 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: Rattus norvegicus Common name: brown rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles Scientific name: Mus musculus Common name: house mouse Development stage: adults Scientific name: Mus musculus Common name: house mouse Development stage: juveniles
Field(s) of use	indoor use Indoor use
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations Covered and protected baiting points
Application rate(s) and frequency	Application rate: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation. Dilution (%): 0 Number and timing of application: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation.
Category(ies) of users	trained professional
Pack sizes and packaging material	300g white high density polyethylene (HDPE) cartridge – 3kg-10kg

	400g white high density polyethylene (HDPE) cartridge – 3kg-10kg
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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

- 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.

4.1.3. 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 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

See 5.4

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

See 5.5

4.2. Use description

 $Table\ 2.\ Use\ \#20\ -\ Paste\ -\ Mice\ and/or\ rats\ -\ Professional\ users\ with\ demonstrated\ competence\ (equivalent\ to\ trained\ professionals)\ -\ outdoor\ around\ buildings$

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development	Scientific name: Rattus norvegicus
stage)	Common name: brown rat
	Development stage: adults
	Scientific name: Rattus norvegicus
	Common name: brown rat
	Development stage: juveniles
	Scientific name: Mus musculus
	Common name: house mouse
	Development stage: adults
	Scientific name: Mus musculus
	Common name: house mouse
	Development stage: juveniles
Field(s) of use	outdoor use
	Outdoor around buildings
Application method(s)	Method: bait application
	Detailed description: Ready-to-use bait to be used in tamper-
	resistant bait stations Covered and protected baiting points
Application rate(s) and frequency	Application rate: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation.
	Dilution (%): 0
	Number and timing of application: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation.
	Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation.
Category(ies) of users	trained professional
Pack sizes and packaging material	300g white high density polyethylene (HDPE) cartridge – 3kg-10kg
	400g white high density polyethylene (HDPE) cartridge – 3kg-10kg

4.2.1. Use-specific instructions

- Protect bait from the atmospheric conditions. Place the baiting points in areas non-liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Follow any additional instructions provided by the relevant code of best practice.
- 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

4.2.2. 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.

4.2.3. 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.

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

See 5.4

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

See 5.5

4.3. Use description

Table 3. Use #21 - Paste - House mice and/or rats - 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: Rattus norvegicus Common name: brown rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles Scientific name: Mus musculus Common name: house mouse Development stage: adults Scientific name: Mus musculus Common name: house mouse
	Development stage: juveniles
Field(s) of use	indoor use Indoor use
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 point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation. Dilution (%): 0
	Number and timing of application: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation.
	Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation.

Category(ies) of users	trained professional
Pack sizes and packaging material	300g white high density polyethylene (HDPE) cartridge – 3kg-10kg
	400g white high density polyethylene (HDPE) cartridge – 3kg-10kg

4.3.1. Use-specific instructions

For mice: The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

For rats: - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

4.3.2. Use-specific risk mitigation measures

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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

- When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

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

See 5.4

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

See 5.5

4.4. Use description

 $\label{eq:conditional} \textbf{Table 4. Use \#22 - Paste - Mice and/or rats - Professional users - outdoor around buildings}$

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Common name: brown rat Development stage: adults Scientific name: Rattus norvegicus Common name: brown rat Development stage: juveniles Scientific name: Mus musculus Common name: house mouse Development stage: adults Scientific name: Mus musculus Common name: house mouse
Field(s) of use	Development stage: juveniles outdoor use Outdoor around buildings
Application method(s)	Method: bait application Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation. Dilution (%): 0 Number and timing of application: Rats: Up to 200g of bait per bait point, every 10 metres, reducing to 5 metres in areas of high infestation. Mice: Up to 50g of bait per bait point every 10 metres, reducing to 5 metres in areas of high infestation.
Category(ies) of users	trained professional
Pack sizes and packaging material	300g white high density polyethylene (HDPE) cartridge – 3kg-10kg

400g white high density polyethylene (HDPE) cartridge – 3kg-10kg

4.4.1. Use-specific instructions

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- The bait stations should be visited [for mice at least every 2 to 3 days at] [for rats only 5 to 7 days after] the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

4.4.2. Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

4.4.3. 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.

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

See 5.4

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

See 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 5.3 for the information to be shown on the label).
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 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.
- 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.
- For paste bait: use a spatula for post-application (cleaning/disposal) of bait

5.2. Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements

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

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.
- Medical professionals should contact the National Poisons Information Service for further advice.
- 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.

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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

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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.