

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Festköder Brodifacoum

Product type(s)

PT14: Rodenticides

Authorisation number: 2010-03-04-B01c

R4BP asset number: MT-0008487-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Festköder Brodifacoum
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Detia Freyberg GmbH
	Address	Dr.-Werner-Freyberg-Str.11 69514 Laudenbach Germany
Authorisation number	2010-03-04-B01c	
<i>R4BP asset number</i>	MT-0008487-0000	
Date of the authorisation	22/09/2014	
Expiry date of the authorisation	31/12/2025	

1.3. Manufacturer(s) of the product

Name of manufacturer	Detia Freyberg GmbH
Address of manufacturer	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
Location of manufacturing sites	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany

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 GU34 2QR Alton Hampshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Unit 13, Newman Lane GU34 2QR Alton Hampshire 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	0,005

2.2. Type(s) of formulation

Ready to use bait block

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H360D: May damage the unborn child. H373: May cause damage to organs {0:or state all organs affected, if known:} through prolonged or repeated exposure { 1:state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard: }.
Precautionary statements	P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe dust. P280: Wear protective gloves. P308+P313: IF exposed or concerned: Get medical advice. P405: Store locked up. P501: Dispose of contents to

4. AUTHORISED USE(S)

4.1. Use description

Table 1. House Mouse (Indoor)

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Rodenticide
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Juveniles and adults
Field(s) of use	indoor use Indoor
Application method(s)	Method: Gebrauchsfertiger Köder Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations Covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations
Application rate(s) and frequency	Application rate: 20-50g per bait station Dilution (%): 100 Number and timing of application: ---
Category(ies) of users	trained professional
Pack sizes and packaging material	10g / 20g blocks in plastic bags in folding cartons: 240g and 250g; 10g / 20g/ 25g blocks in plastic coated paper bags in folding cartons: 400g; 10g / 20g/ 25g blocks in plastic buckets: 500g – 10kg; 10g / 20g/ 25g blocks in plastic cans: 500g; 10g / 20g blocks in plastic boxes in folding cartons: 10g and 20g; 10g / 20g/ 25g blocks in carton: 10kg and 12,5kg

4.1.1. Use-specific instructions

1) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

- 1) Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- 2) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
- 3) Bait stations have to be used. Only in areas (e.g. closed cable routes, sub-constructions of e.g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed
- 4) Take the following measures to avoid re-infestation after a successful control:
 - Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
 - Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.

- As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.

5) Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities

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

1) When placing bait points 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

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

4.2. Use description

Table 2. House mouse (outdoor around buildings)

Product type	PT14: Rodenticides
Where relevant, an exact description of the authorised use	Rodenticide
Target organism(s) (including development stage)	Scientific name: <i>Mus musculus</i> Common name: house mouse Development stage: Juveniles and adults
Field(s) of use	outdoor use Outdoor around buildings
Application method(s)	Method: Ready to use bait Detailed description: Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Application rate: 20-50g per bait station Dilution (%): 100 Number and timing of application: ---
Category(ies) of users	trained professional
Pack sizes and packaging material	10g / 20g blocks in plastic bags in folding cartons: 240g and 250g; 10g / 20g/ 25g blocks in plastic coated paper bags in folding cartons: 400g; 10g / 20g/ 25g blocks in plastic buckets: 500g – 10kg; 10g / 20g/ 25g blocks in plastic cans: 500g; 10g / 20g blocks in plastic boxes in folding cartons: 10g and 20g; 10g / 20g/ 25g blocks in carton: 10kg and 12,5kg

4.2.1. Use-specific instructions

- 1) Protect bait from the weathering (e.g. rain, snow, etc.). Place the baiting points in areas not liable to flooding.
- 2) Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

3) Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

- 1) Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- 2) At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.
- 3) Bait stations have to be used. Only in areas which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
- 4) Take the following measures to avoid re-infestation after a successful control:
 - a) Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
 - b) Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
 - c) As far as possible, all existing entries for rodents to buildings (e.g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- 5) Do not apply this product directly in the burrows.
- 6) Do not use the product as permanent baits for the prevention of rodent infestation or monitoring.

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

- 1) 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.

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

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

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- 1) Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- 2) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 3) For the label and / or the leaflet, the authorisation holder has to specify how the equipment (e.g. bait boxes) shall be cleaned and how residues of baits have to be collected. The recommended methods shall lead to minimized exposure.
- 4) 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.
- 5) Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
- 6) The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
- 7) Remove water sources and 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.
- 8) 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.
- 9) 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.).
- 10) Where possible, bait stations must be fixed to the ground or other structures.
- 11) Bait stations have to be mechanically stable and tamper-resistant.
- 12) Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- 13) 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).
- 14) Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures. The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings. The person in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning. The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
 - a) First measures to be taken in case of poisoning,
 - b) Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
 - c) Name of the product and the active substance(s) incl. concentration,
 - d) Contact information of the person in charge of the rodent control,
 - e) Telephone number of a poison information centre and the name of the antidote,
 - f) Date of the beginning of the campaign, i.e. when the baits were deployed first.
- 15) Bait should be secured so that it cannot be dragged away from the bait station.
- 16) Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- 17) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 18) Replace consumed baits at each visit; the uptake of baits has to be documented.
- 19) 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.
- 20) 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.

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

5.2. Risk mitigation measures

- 1) The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").
- 2) Do not use in areas where resistance to the active substance can be suspected.
- 3) Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- 4) 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.
- 5) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 6) Undamaged bait stations and untouched baits may be reused.
- 7) The success of the control measure has to be documented and proven.
- 8) The client has to be informed of possible preventive measures against re-infestation.
- 9) All relevant documents of the control measures have to be provided to the client as well as responsible authorities upon request.

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

- 1) 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.
- 2) Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- 3) 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 [insert country specific information]. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information]
- 4) Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name"; "active substance(s)" and "in case of incident, call a poison centre [insert national phone number]"
- 5) Hazardous to wildlife.

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 in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].

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

- 1) Store in places prevented from the access of children, birds, pets and farm animals.
- 2) Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- 3) Shelf life: 24 months

6. OTHER INFORMATION

- 1) Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- 2) 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.
- 3) The product contains a bittering agent and a dye.

Trained professionals

In Germany :

If required by Annex I no. 3 of the German Ordinance on Hazardous Substances (version 29.03.2017) to be applied only by professional with competence according to Annex I no. 3 of the German Ordinance on Hazardous Substances (version 29.03.2017). Otherwise, the rodenticide can also be applied by the following professional uses:

- a) Professional user with competence according to German Ordinance Governing Specialist Qualifications in Plant Protection (Pflanzenschutz-Sachkundeverordnung)
- b) Professional user with specific experience who can document the participation in a training course providing knowledge on:

- Behaviour, biology and habits of rodents,
- Legal base for the control of rats and mice,
- Rodent control (incl. integrated pest management and resistance management),
- Mode of action of rodenticides (anticoagulants in particular),
- Rodenticides as hazardous substances and risks for human health and the environment during application and appropriate risk mitigation measures (especially to avoid primary and secondary poisoning of non-target animals, risks of PBT-/vPvB-substances),
- Application techniques / Procedure and documentation