

Summary of product characteristics for a biocidal product

Product name: Formkoeder Difenacoum

Product type(s): PT14 - Rodenticides (Pest control)

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Authorisation number: DE-0001449-14

R4BP 3 asset reference number: DE-0001449-0000

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	2
3. Hazard and precautionary statements	2
4. Authorised use(s)	3
4.1.1 Use-specific instructions for use	3
4.1.2 Use-specific risk mitigation measures	4
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	4
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its	4
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under	4
4.2.1 Use-specific instructions for use	5
4.2.2 Use-specific risk mitigation measures	5
4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid	6
4.2.4 Where specific to the use, the instructions for safe disposal of the product and its	6
4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under	6
5. General directions for use	6
5.1. Instructions for use	6
5.2. Risk mitigation measures	8
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to	8
5.4. Instructions for safe disposal of the product and its packaging	8
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	8
6. Other information	9

Administrative information

1.1. Trade names of the product

Formköder Difenacoum
Mäuse Pelletköder
Getreide-Block Difenacoum
COUMARAT® Formköder
COUMARAT® Getreideriegel

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		DE-0001449-14
R4BP 3 asset reference number		DE-0001449-0000
Date of the authorisation		31/03/2012
Expiry date of the authorisation		26/02/2023

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Detia Freyberg GmbH
Address of the 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	26 - Difenacoum
Name of the manufacturer	PelGar international Limited
Address of the manufacturer	Unit 13, Newman Lane GU34 2QR Alton, Hampshire United Kingdom
Location of manufacturing sites	Praszka 54 280 02 Kolin Czech Republic

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active Substance	56073-07-5	259-978-4	0.005

2.2. Type of formulation

RB - Bait (ready for use)

3. Hazard and precautionary statements

Hazard statements	May damage the unborn child. May cause damage to organs blood through prolonged or repeated exposure .
Precautionary statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Store locked up.

4. Authorised use(s)

4.1 Use description

Use 1 - House mouse (indoor)

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Mus musculus-House mouse-Adults
Field(s) of use	Indoor Indoor
Application method(s)	Bait application - 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. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequencies	Max. 50g - 100 - Max. 50g bait per baiting station Permanent baiting (please see also chapter 5.1)
Category(ies) of users	Trained professional
Pack sizes and packaging material	paper bag / PE coated paper: 100g, 500g, 1000g folding carton / paper bag PE coated paper: 500g plastic bucket (PP): 5kg

4.1.1 Use-specific instructions for use

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

- 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:
 - 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.

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 also chapter 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 also chapter 5.5

4.2 Use description

Use 2 - House mouse (outdoor: around buildings)

Product type	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the authorised use	Not relevant for rodenticides
Target organism(s) (including development stage)	Mus musculus-House mouse-Adults
Field(s) of use	Outdoor Outdoor around buildings
Application method(s)	Bait application - 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. Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species.
Application rate(s) and frequencies	Max. 50g - - g bait per baiting station Permanent baiting
Category(ies) of users	Trained professional
Pack sizes and packaging material	paper bag / PE coated paper: 100g, 500g, 1000g folding carton / paper bag PE coated paper: 500g plastic bucket (PP): 5kg

4.2.1 Use-specific instructions for use

- 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

- 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.

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 also chapter 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 also chapter 5.5

5. General directions for use

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) 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.
- 3) 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.
- 4) The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.
- 5) 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.
- 6) 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.
- 7) 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.).
- 8) Where possible, bait stations must be fixed to the ground or other structures.
- 9) Bait stations have to be mechanically stable and tamper-resistant.
- 10) Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- 11) 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).
- 12) 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.
- 13) Bait should be secured so that it cannot be dragged away from the bait station.
- 14) Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- 15) Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- 16) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- 17) When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- 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.
- 21) 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.
- 22) Place the bait in the baiting point by using a dosage device. Specify the methods to minimise dust (suitable methods shall be moist or wet processes in accordance with the state of the art e.g. wet wiping or suction processes using suitable vacuum cleaners or dust removers).
- 23) Strategic permanent baiting (Strategic permanent baiting independent of infestation is to be distinguished from large scale permanent baiting as defined by the DIN 10523 (permanent- or perimeter baiting).) independent of infestation is permitted for professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, provided that all of the following conditions are met:
 Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewhere protected (e.g. cable lines, sub-construction of electric appliances).
 An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 during an on-site assessment.
 This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e.g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i.e. they need to be necessary in order to protect constitutional rights.
 A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.
 In these cases the use of permanent baits containing the active substances bromadiolone or difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the professional user with

competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 in each individual case. In each case, the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can for instance be made for operations that produce, process, market or store food- or feeding stuff; operations that produce, process or store pharmaceutical or medical products or for waste disposal companies or storage businesses or warehouses.

Permanent baiting with rodenticides containing bromadiolone or difenacoum may only be implemented by or under the supervision of a professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures. It is at the discretion of the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3 to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the professional user with competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3, additional control measures have to be taken due to an actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks. Additional inspections of the permanent bait points in consultation with the pest control company in charge may be carried out also by other trained professional users according to the definition under point 6. (Other information) No. 1 a) and b), if not different required by Annex I No. 3 of the German Ordinance on Hazardous Substances (Version 29.03.2017). The permanent baiting strategy shall be periodically reviewed in the context of integrated pest management (IPM) and the assessment of the risk for re-infestation.

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 [unless authorised for permanent baiting treatments].
- 4) Do not use the product in pulsed baiting treatments.
- 5) 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.
- 6) Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 7) Undamaged bait stations and untouched baits may be reused.
- 8) The success of the control measure has to be documented and proven.
- 9) The client has to be informed of possible preventive measures against re-infestation.
- 10) 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.
In case of:
 - a) Dermal exposure, wash skin with water and then with water and soap.
 - b) Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
 - c) 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]
- 3) 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]"
- 4) 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 a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- 2) Store in places prevented from the access of children, birds, pets and farm animals.
- 3) Shelf life: 24 month

6. Other information

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

Further Precautionary statements:

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P308+313: IF exposed or concerned: Get medical advice/attention.

P501: Dispose of contents/container to ...