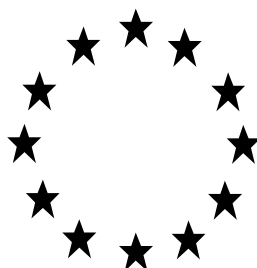


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR NATIONAL AUTHORISATION
APPLICATIONS**



Product identifier in R4BP	frunax DS Rattenfertigmöder 25 ppm
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-UV061044-13
Asset No. in R4BP	DE-0019299-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.00027 710-05-14-00027-00-02
Date	30.07.2020

Tables of content

Overview of applications	3
Current consolidated Summary of the product assessment	4
1 Administrative information	5
2 Product composition and formulation	6
3 Hazard and precautionary statements	6
4 Authorised use(s)	7
5 General directions for use	14
6 Other information	18
Changes after first authorisation	19
7 Change 1 - NA-MIC - BC-FX059531-15	19

Overview of applications

Table 1 - Overview regarding all relevant applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment)	Page
NA-APP	DE	BC-DH037304-56	08.05.2020	First authorisation	-
NA-MIC	DE	BC-FX059531-15	22.07.2020	Minor change (different packaging size)	19
NA-AAT	DE	BC-UV061044-13	30.07.2020	Upload of corrected decision regarding NA-MIC before.	20

Current consolidated Summary of the product assessment

Summary of product characteristics

frunax DS Rattenfertigmöder 25 ppm

Product type(s) 14

Authorisation number DE-0019299-14

R4BP asset number DE-0019299-0000

1 Administrative information

1.1 Trade name(s) of the product

Trade name(s)
frunax DS Rattenfertigmöder 25 ppm

1.2 Authorisation holder

Name and address of the authorisation holder	Name	frunol delicia GmbH
	Address	Hansastraße 74 B 59425 Unna Deutschland
Authorisation number	DE-0019299-14	
R4BP asset number	DE-0019299-0000	
Date of the authorisation	08.05.2020	
Expiry date of the authorisation	08.05.2025	

1.3 Manufacturer(s) of the product

Name of manufacturer	frunol delicia GmbH
Address of manufacturer	Hansastraße 74b 59425 Unna Germany
Location of manufacturing sites	Dübener Str. 145 04509 Delitzsch Germany

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

Active substance	Difenacoum
Name of manufacturer	PelGar International Ltd.
Address of manufacturer	Unit 13, Newman Lane GU34 2QR Alton, Hampshire

	United Kingdom
Location of manufacturing sites	Praszka 54 28002 Kolin Czech Republik

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 (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active substance	56073-07-5	259-978-4	0.0025

2.2 Type of formulation

GB – Grain Bait (ready to use)

3 Hazard and precautionary statements

Hazard statements	H373 - May cause damage to organs (blood) through prolonged or repeated exposure.
Precautionary statements	P260 – Do not breathe dust/fume/gas/mist/vapours/spray. P314 – Get medical advice/ attention if you feel unwell. P501 - Dispose of contents/ container to ...

4 Authorised use(s)

4.1 Authorised use 1 – House mice and rats - trained prof – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	House mice, <i>Mus musculus</i> (Juveniles and adults); Norway/Brown rats, <i>Rattus norvegicus</i> (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations ¹ Covered and protected baiting 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	Mouse: 50 g of bait per baiting point. Rat: 200 g of bait per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 1-206 x 100 g sachet in folding box; 1-123-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 0.5-105-10 kg Bucket (PP); 25 kg bag (lined paper bag). Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m ² paper and 30 g/m ² LDPE).

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.

¹ See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations.

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:
 - 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.
- 6) Do not use the 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 chapter 5

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

See chapter 5

4.2 Authorised use 2 – Mice and rats - trained prof - outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	House mice, <i>Mus musculus</i> (Juveniles and adults); Norway/Brown rats, <i>Rattus norvegicus</i> (Juveniles and adults)
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations. Covered and protected baiting 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	Mouse: 50 g of bait per baiting point. Rat: 200 g of bait per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 1-206 x 100 g sachet in folding box; 1-123-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 0.5-105-10 kg Bucket (PP); 25 kg bag (lined paper bag). Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m ² paper and 30 g/m ² LDPE).

4.2.1 Use-specific instructions for use

- | |
|--|
| <ol style="list-style-type: none"> 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:
 - 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 this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- 6) Do not use this product in pulsed baiting treatments.
- 7) 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 chapter 5

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

See chapter 5

4.3 Authorised use 3 – Rats - trained prof - Outdoor open areas and waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Norway/Brown rats, <i>Rattus norvegicus</i> (Juveniles and adults)
Field(s) of use	Outdoor open areas and waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations. Covered and protected baiting 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	Rat: 200 g of bait per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 1-206 x 100 g sachet in folding box; 1-123-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 0.5-105-10 kg Bucket (PP); 25 kg bag (lined paper bag). Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m ² paper and 30 g/m ² LDPE).

4.3.1 Use-specific instructions for use

- | |
|---|
| <ol style="list-style-type: none"> 1) Protect bait from the weathering (e.g. rain, snow, etc.). Place the bait stations 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.

4.3.2 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.
Outdoor open areas:
 - 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 this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
 - 6) Do not use this product in pulsed baiting treatments.
 - 7) Do not apply this product directly in the burrows.

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 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.

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

See chapter 5

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

See chapter 5

4.4 Authorised use 4 – Rats - trained prof - sewers

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Norway/Brown rats, <i>Rattus norvegicus</i> (Juveniles and adults)
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Rat: 200 g of bait per baiting point.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 1-206 x 100 g sachet in folding box; 1-123-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 0.5-105-10 kg Bucket (PP); 25 kg bag (lined paper bag). Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m ² paper and 30 g/m ² LDPE).

4.4.1 Use-specific instructions for use

- | |
|--|
| <ol style="list-style-type: none"> 1) Baits must be applied in a way so that they do not come into contact with water and are not washed away. 2) Bait points in sewer systems have to be visited for the first time after 14 days and subsequently every 2 to 3 weeks. 3) Remove and dispose all baits in accordance with local requirements at the end of the treatment period. |
|--|

4.4.2 Use-specific risk mitigation measures

Do not use this product as permanent baits or in pulsed baiting treatments.

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

See chapter 5

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

See chapter 5

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

See chapter 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:
 - First measures to be taken in case of poisoning,
 - Measures to be taken in case of spillage of the bait and the discovery of dead rodents,
 - Name of the product and the active substance(s) incl. concentration,
 - Contact information of the person in charge of the rodent control,
 - Telephone number of a poison information centre and the name of the antidote,
 - 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). [Where relevant, specify any other PPE (e.g. goggles or mask) required when handling the product]

- 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 loose bait in the baiting point 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).

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.
- 10) The following risk mitigation measure shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures):

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

- 1) First aid: Get medical advice/attention if you feel unwell.
- 2) 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.
- 3) Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- 4) 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].
- 5) 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]".
- 6) 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.

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: 12 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) The product contains a bittering agent and a dye.

Changes after first authorisation

7 Change 1 - NA-MIC - BC-FX059531-15

Case No.	BC-FX059531-15
Internal registration/file no:	5.0-710 05/14.00027 710-05-14-00027-00-01
Case type(s)	Minor change (NA-MIC)
CMS	None
Entry into force of change / amendment	22.07.2020

7.1 Changes sought / amendment necessary

The authorisation holder asked for the extension of the pack sizes:

Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 1-206 x 100 g sachet in folding box; 1-123-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 0.5-105-10 kg Bucket (PP); 25 kg bag (lined paper bag). Package is restricted to separately packed bags with a maximum of 10 kg per packed bag. Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m ² paper and 30 g/m ² LDPE).
-----------------------------------	---

7.2 List of new data

No new data.

7.3 Conclusion

Since the change(s) applied for is/are listed in Title 2 of the Annex of Commission Implementing Regulation (EU) No 354/2013 the change(s) of the product is/are not expected to affect the conclusion with regard to the fulfilment of the conditions of Article 19.

8 Amendment 1 - NA-AAT - BC-UV061044-13

Case No.	BC-UV061044-13
Internal registration/file no:	5.0-710 05/14.00027 710-05-14-00027-00-02
Case type(s)	Amendment by CA (NA-AAT)
CMS	None
Entry into force of change / amendment	30.07.2020

8.1 Amendment necessary

The decision taken on 22.07.2020 needed to be corrected and uploaded again because the applicant did not apply for "1-12 x 100 g sachet in folding box" instead of "6 x 100 g sachet in folding box" but for "1-20 x 100 g sachet in folding box".