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 Rattenfertigköder 25 ppm
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-DH037304-56
Asset No. in R4BP	DE-0019299-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.0027 710-05-14-00027-00-00-00-0000
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Tables of content

1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, “frunax DS Rattenfertigköder 25 ppm” with the active substance difenacoum (0.0025 % w/w) is used as a rodenticide (product-type 14) for the control of house mice and norway/brown rats. Mice are to be controlled indoors and outdoors around buildings. While rats are to be controlled indoors, outdoors (around buildings as well as open areas and waste dumps) and in sewers. The applicant applied for authorisation of the use by non-professional, professional and trained professional users.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled. However, the authorisation can only be granted for the use by (trained) professional users.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Finnish Assessment Report for the approval of the active substance difenacoum including the “elements to be taken into account by Member States when authorising products” as requested by the Finnish CA.
2. The specific provisions from the renewal of the approval of the active substance (PT14) difenacoum (COMMISSION IMPLEMENTING REGULATION (EU) 2017/1379).

Approval of the active substance
The active substance difenacoum is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

The authorisations of biocidal products are subject to the following general conditions:

(1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
(2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied.
(3) The nominal concentration of difenacoum in the products shall not exceed 75 mg/kg.
(4) Products shall contain an aversive agent and a dye.
(5) Products shall not be authorised in the form of tracking powder.
(6) Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals.
(7) Only ready-to-use products shall be authorised.
(8) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk-mitigation measures. These include, for example, the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
(9) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions:

(1) Products shall not be authorised for use in sewers, open area or waste dumps.
(2) Products shall not be authorised for use in permanent or pulse baiting treatments.
(3) Products shall only be authorised for use in tamper-resistant bait stations.
(4) Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions:

(1) Products may be authorised for use in sewers, open area or waste dumps.
(2) Products may be authorised for use in 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.
(3) Products shall not be authorised for use in pulse baiting treatments.
(4) Products may only be authorised for use in permanent baiting treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.
(5) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

Composition and formulation

The ready-to-use grain bait “frunax DS Rattenfertigköder 25 ppm” contains the active substance difenacoum.

No substance of concern has been identified.

Please refer to chapter 2.2 (

Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.
Accordingly, the human health risk assessment for this product is based on the active substance

A human health risk assessment has been carried out for non-professional and professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional, professional and trained professional users, bystanders and residents. Regarding non-professional and professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.

A risk assessment for the environment has been carried out for non-professional, professional and trained professional use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the use by professional and trained professional users causes any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed. Only the authorisation for the use by non-professional users cannot be granted.

Comparative Assessment

Since the active substance difenacoum has been identified as a candidate for substitution (see also chapter 2.5) a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 04.12.2019.

The German CA concludes that without difenacoum based products there is not an adequate chemical diversity.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

frunax DS Rattenfertigköder 25 ppm

2.1.2 Manufacturer(s) of the product

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

2.1.3 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

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

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

- The product contains a bittering agent and a dye.
  - ➢ Information on the full composition is provided in the confidential[3] annex (see chapter 5).
- Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☐
  No ☒
- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

2.2.3 Information on the substance(s) of concern

No substance of concern was identified.

[3] Access level: “Restricted” to applicant and authority

2.2.4 Candidate(s) for substitution

The following candidate(s) for substitution was/were identified:

- Difenacoum

Difenacoum does meet the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

- toxic for reproduction category 1B;
- PBT.

And therefore, difenacoum does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

Difenacoum does meet the following criteria for substitution:

- Persistent and very persistent, Bio accumulative and Toxic.

2.2.5 Type of formulation

GB – Grain Bait (ready to use)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance difenacoum the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance difenacoum is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).[5] The current harmonised classification of the active substance difenacoum is based on Commission Regulation (EU) No. 2016/1179 (9th ATP).[6]

4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
5 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/105223
6 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/22870

Table 2

Classification Hazard classes, Hazard categories	Hazard statements
STOT RE 2	H373

Table 3

Labelling	Code	Pictogram / Wording
Pictograms	GHS08	
Signal word	-	Warning
Hazard statements	H373	May cause damage to organs (blood) through prolonged or repeated exposure.
Supplemental hazard information	-	-
Supplemental label elements	-	-
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 …
Note	-	

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[7]

2.4.1 Use 1 appropriate for authorisation – 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, *Mus musculus* (Juveniles and adults); Norway/Brown rats, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations[8] 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; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 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/m2 paper and 30 g/m2 LDPE).

2.4.1.1 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.

7 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

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

2.4.1.2 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.

2.4.1.3 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.

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

See chapter 2.5

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

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation – 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, *Mus musculus* (Juveniles and adults); Norway/Brown rats, *Rattus norvegicus* (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; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 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/m2 paper and 30 g/m2 LDPE).

2.4.2.1 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.

2.4.2.2 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.

2.4.2.3 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.

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

See chapter 2.5

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

See chapter 2.5

2.4.3 Use 3 appropriate for authorisation – 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, *Rattus norvegicus* (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; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 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/m2 paper and 30 g/m2 LDPE).

2.4.3.1 Use-specific instructions for use

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.

2.4.3.2 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.

2.4.3.3 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.

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

See chapter 2.5

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

See chapter 2.5

2.4.4 Use 4 appropriate for authorisation – 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, *Rattus norvegicus* (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; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 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/m2 paper and 30 g/m2 LDPE).

2.4.4.1 Use-specific instructions for use

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.

2.4.4.2 Use-specific risk mitigation measures

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

2.4.4.3 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 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 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 2.5.3 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).

2.5.2 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).

2.5.3 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.

2.5.4 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.

2.5.5 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

2.5.6 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.

2.6 Packaging

Table 4

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Sachet (foil bag) - packaged in folding box/ outer carton	1 x 100 g, 1 x 200 g, 6 x 100 g, 3-12 x 200 g, 100 x 200 g, 200 x 100 g	Finished paper bag coated with LDPE 50/30 (50g/m^2 paper and 30 g/m^2 LDPE)	-	Professional, trained professional	Yes
Bucket	5 kg, 10 kg	PP	Bucket lid PP	Professional, trained professional	Yes
Lined paper bag	25 kg	Lined (HDPE) paper		Professional, trained professional	Yes
Sachet (foil bag) - packaged in folding box	1 x 100 g 1 x 200 g, 6 x 100 g and 3-12 x 200 g	Finished paper bag coated with LDPE 50/30 (50g/m^2 paper and 30 g/m^2 LDPE)		Non-professional	Yes

3 Assessment of the product

3.1 Intended use(s) as applied for by the applicant

3.1.1 Intended 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, *Mus musculus* (Juveniles and adults); Norway/Brown rats, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Mouse: 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters. Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.2 Intended 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, *Mus musculus* (Juveniles and adults); Norway/Brown rats, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Outdoor around buildings

Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Mouse: 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters. Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.3 Intended 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, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Outdoor open areas and waste dumps
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.4 Intended 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, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Sewers
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Trained professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.5 Intended use 5 – House mice - 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, *Mus musculus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes
Application rate(s) and frequency	Mouse: 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters.
Category(ies) of users	Professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag).

	Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.6 Intended use 6 – Rats mice - prof - indoor

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, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes
Application rate(s) and frequency	Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.7 Intended use 7 – House mice and/or rats - 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, *Mus musculus* (Juveniles and adults); Norway/Brown rats, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Outdoor around buildings
Application method(s)	In bait boxes
Application rate(s) and frequency	Mouse: 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters.

	Rat: 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet in folding box; 3-12 x 200 g sachet in folding box; 100 x 200 g sachet in outer carton; 200 x 100 g sachet in outer carton; 5-10 kg Bucket (PP); 25 kg bag (lined paper bag). Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE).

3.1.8 Intended use 8 – Mice - non-prof

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	House mice, *Mus musculus* (Juveniles and adults)
Field(s) of use	Indoor; Outdoor around buildings
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 2-4 meters.
Category(ies) of users	Non-professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet folding box; 3-12 x 200 g sachet in folding box Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE)

3.1.9 Intended use 9 – Rats - non-prof

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, *Rattus norvegicus* (Juveniles and adults)
Field(s) of use	Indoor;

	Outdoor around buildings
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5-10 meters.
Category(ies) of users	Non-professional
Pack sizes and packaging material	1 x 100 g sachet; 1 x 200 g sachet; 6 x 100 g sachet folding box; 3-12 x 200 g sachet in folding box Sachet: Finished paper bag coated with LDPE 50/30 (50 g/m2 paper and 30 g/m2 LDPE)

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual insepection	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	solid	Anonymous (2010a)
Colour at 20 °C and 101.3 kPa	visual insepection	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	Brown-yellowish grain baits covered with a red coating.	Anonymous (2010a)
Odour at 20 °C and 101.3 kPa	olfactory test	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	cereal-like odour was detectable immeadiately after opening the foil bag	Anonymous (2010a)
Acidity / alkalinity	CIPAC (MT 75.3) CIPAC (MT 191)	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	pH of a 1% aqueous liquid suspension at 20°C: before storage: 6.79 after 40°C/8 weeks: 6.75 Not determined because the pH was >4 and <10	Anonymous (2010a)
Relative density / bulk density	CIPAC (MT 186)	frunax ®DS Rattenfertigköder Batch 901.369	Pour density: 0.607 g/mL	Anonymous (2010b)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Difenacoum 0.05%w/w	Tap density after 50 'taps': 0.673 g/mL	
Storage stability test – **accelerated storage**	CIPAC MT 75.3 CIPAC MT 171 CIPAC MT 178 CIPAC MT 58 CIPAC MT 59	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	No significant changes of the determined parameters were found after storage at 40ºC over a period of 8 weeks. Difenacoum content: Start: 50.3 mg/kg 8 weeks/ 40°C: 49.9 mg/kg (-0.8%) pH start: 6.79 8 weeks/ 40°C:6.75 Before and after storage the test item was found to be nearly dust free and the mean attrition resistance of two tests was determined to be 99.8%.	Anonymous (2010a)
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 75.3 CIPAC MT 171 CIPAC MT 178 CIPAC MT 58 CIPAC MT 59	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	Results before and after storage for 2 years at ambient temperature: Appearance: no changes after storage	Anonymous (2012)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Stability of the package (visual): No damage or deterioration. Content of a.s. Before storage 50.3 mg/kg After 24 month storage: 50.0 mg/kg (-0,6%) pH of 1% aqueous liquid suspension: pH = 6.82 (before storage) pH = 6.64 (after 24 month storage) Before and after storage the test item was found to be nearly dust free and the mean attrition resistance of two tests was determined to be 99.8%.	
Storage stability test – **low temperature stability test for liquids**			Not requested. Product is a solid.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			frunax DS Rattenfertigköder 25 ppm is stored and transported in foil bags, or plastic buckets and not exposed to UV light. From the accelerated storage stability (stored in a room) and the shelf life study, there have been no recorded observations of reactivity with packaging.	Waiving[9]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			For the information on effects on content of the active substance and technical characteristics of the biocidal product with regards to temperature and humidity please refer to storage stability study by Anonymous (2012)	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Data about the packaging material is sufficient.	Dangerous Goods Database http://www.dgg.bam.de/en/ BAM-Nr.: 6324-6326

[9] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Wettability			The wettability is not required for this preparation type [GB].	
Suspensibility, spontaneity and dispersion stability			The suspensibility is not required for this preparation type [GB].	
Wet sieve analysis and dry sieve test			The wet sieve analysis is not required for this preparation type [GB].	
	CIPAC MT 58.2	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	The particle size distribution was specified by the range [x1, x2] of two sieves where Rx ≥ 90% and Rx ≤ 10%. The determined particle size range was between: x1 = 1000 µm ; Rx ≥ 90% x2 = 5000 µm ; Rx ≤ 10%. The sum of the dust fractions passing through the 250 µm sieve was determined as 1.01 g (0.84% of the weight) Fine particles of ≤ 100 µm diameter were	Anonymous (2010a)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			detected as 0.26 g (0.22 % of the weight). Fine particles of ≤ 50 µm diameter were detected as 0.27 g (0.22% of the weight; including loss during sieving). Loss of dust during sieving was calculated as 0.21 g (0.17% of the weight).	
Emulsifiability, re-emulsifiability and emulsion stability			The emulsifiability is not required for this preparation type [GB].	
Disintegration time			The disintegration time is not required for this preparation type [GB].	
Particle size distribution, content of dust/fines, attrition, friability			The data on the particle size distribution is provided as dry sieve test. The data on the content of dustiness is provided as dustability.	
Persistent foaming			The persistence of foaming is not required for this preparation type [GB].	
Flowability/Pourability/Dustability	CIPAC MT 172	frunax ®DS Rattenfertigköder Batch 901.369	Before and after storage at 40°C for 8 weeks all of the test item has	Anonymous (2010d)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Difenacoum 0.05%w/w	passed the sieve (5 mm mesh size) after 5 liftings. No caking was observed. Therefore the unstored test item is considered to be free flowing after storage under pressure.	
	CIPAC MT 171	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	The test item was found to be nearly dust-free. The weight of the dust, determined gravimetrically, was before storage: 3.6 mg after 40°C/8 weeks: 3.3 mg (each ≤ 0.01% of the weighed sample).	Anonymous (2010a)
Burning rate — smoke generators			Burning rate is not required for this preparation type [GB].	
Burning completeness — smoke generators			Burning completness is not required for this preparation type [GB].	
Composition of smoke — smoke generators			Composition of smoke is not required for this preparation type [GB].	
Spraying pattern — aerosols			Spraying pattern — aerosols is not required for this preparation type [GB].	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical compatibility			frunax DS Rattenfertigköder 25 ppm is not intended for the application in combination with other products.	
Chemical compatibility				
Degree of dissolution and dilution stability			The Degree of dissolution and dilution stability is not required for this preparation type [GB].	
Surface tension			Not relevant, since the product is a granular bait formulation.	Waiving[9]
Viscosity			The study does not need to be conducted because the Substance is a solid.	Waiving[9]

Table 6

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. For details please consider chapter 5.1.3 (page 123) in the confidential annex. The data provided by the applicant was acceptable. The biocidal product is brown-yellowish grain bait covered with a red coating. The pH of the product is 6.79 and the Pour density: 0.607 g/mL. The requested long-term storage test with “frunax DS Rattenfertigköder 25 ppm” is still ongoing and no test results are available in the moment. However, the longterm stability test with “frunax DS Rattenfertigköder” shows no degradation of the actives substance and no other changes of the product and the packaging. Therefore, a shelf life of 12 months can be granted.

Conclusion on the physical, chemical and technical properties
For details about bridging please consider chapter 5.1.3 (page 123) in the confidential annex.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Screening procedure: Appendix 6 of the UN-MTC (DSC) Regulation (EC) No 440/2008, EU Method A.14	frunax ®DS Ratten-fertigköder Batch 901.369 Difenacoum 0.05%w/w	Exothermic decomposition energy: 556 J/g (1) 533 J/g (2) Decomposition temperature (T_{onset}): 222 °C (1) 224 °C (2) Sensitiveness to impact (BAM Fallhammer): no explosion Sensitiveness to friction (BAM Friction apparatus): no explosion Thermal stability (Koenen test): no explosion	No explosive properties according to EU test method A.14. Not classified based on GHS/CLP criteria	Anonymous 2010, Study Report No. 20090259.02

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable gases	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Flammable aerosols	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Oxidising gases	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Gases under pressure	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Flammable liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Flammable solids	Regulation (EC) No 440/2008, EU Method A.10	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	Preliminary test: The test item could not be ignited.	Not classified based on GHS/CLP criteria	Anonymous 2010, Study Report No. 20090259.01

[10] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Self-reactive substances and mixtures	study scientifically unjustified			The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID[10]
Pyrophoric liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Pyrophoric solids	study scientifically not necessary			The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.	IUCLID[10]
Self-heating substances and mixtures	study scientifically not necessary			Due to our experience with similar products in the PT 14, the product composition and the results of the EU method A.16, it can be conclude that the product isn't self-heating.	BAM 2.2 (2018)
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			The study does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied.	IUCLID[10]
Oxidising liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Oxidising solids	Regulation (EC) No			Expert statement: No tests were performed because oxidizing properties of the test item can	Anonymous 2010, Study

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	440/2008, EU Method A.17			be excluded by an evaluation of the chemical structures of the components of the test item.	Report No. 20090259.03
Organic peroxides	study scientifically not necessary			The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	
Corrosive to metals	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Auto-ignition temperature (liquids and gases)	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	IUCLID[10]
Relative self-ignition temperature for solids	Regulation (EC) No 440/2008, EU Method A.16	frunax ®DS Rattenfertigköder Batch 901.369 Difenacoum 0.05%w/w	Relative self-ignition temperature: 361 °C		Anonymous 2010, Study Report No. 20090259.01
Dust explosion hazard	study scientifically not necessary			The determination of dust explosion hazard is only applicable to all powders and products containing or able to produce dust that can either ignite or explode when exposed to an ignition source when dispersed in air.	IUCLID[10]

Table 8

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. For details please consider chapter 5.1.3 (page 123) in the confidential annex.

3.4 Methods for detection and identification

Table 9

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	HPLC/DAD at 262 nm	Difenacoum was identified by retention time and confirmed by comparison of the sample with the spectra of a certified reference item.	n= 3 and n= 4 range: 6.4 mg/kg - 32 mg/kg for evaluation of the recovery and 6.28 mg/kg - 44 mg/kg for the evaluation of the precision. R^2 > 0.999 and R^2 > 0.99	10 mg/kg; n=3 and 25 mg/kg; n=3	99.4 % – 101.7 % 103.4 % - 104.1 %	100.6 % 103.7 %	1.12 % 0.4 %	10 mg/kg	Anonymous (2018)
				n=5: 26.0 mg/kg	24.5 – 27.1 mg/kg	25.67 mg/kg	4.83%		

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	difenacoum	0.05 mg/kg	Common limit
Drinking water	difenacoum	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	difenacoum	0.06 µg/L	$PNEC_{water}$ based on LC_{50} for fish (AF 1000), CAR Activa/Pelgar, DocIIA, 4.2.7; 06/2009
Air	Not required since vapor pressure < 10^{-5} Pa, not sprayed	-	AR Renewal, LoEP, 07/2016
Animal and human body fluids and tissues	difenacoum	0.1 mg/kg for body tissues	classified as very toxic (T+); AR Renewal, LoEP, 07/2016
Food of plant origin	difenacoum	0.01 mg/kg	AR Renewal, LoEP, 07/2016
Food of animal origin	difenacoum	0.01 mg/kg	AR Renewal, LoEP, 07/2016

* In body fluids no relevant residues of difenacoum are expected. Based on the study on toxicokinetics (Phillips 2002, Doc IIIA 6.2/01) blood contains never more that 2.2 % of the administered dose.

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→399	no interferences	0.1 – 0.5 µg/mL that means 0.05 – 0.25 µg/L in sample; linear, r>0.99	0.05 µg/L / 5 0.5 µg/L / 5 5.0 µg/L / 5 50 µg/L / 5	88 - 100 76 - 88 81 - 91 92 - 113	94 83 86 100	4.3 5.5 3.9 8.1	0.05 µg/L	Anonymous, 2005 CAR, Doc IIIA 4.2 (c)
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→293, 443→135	two transitions	0.001 –0.05 µg/mL that means 0.005 – 0.25 mg/kg in sample; linear, r^2:0.9999	<u>Sediment</u> m/z 443→135 0.01 mg/kg / 5 0.1 mg/ kg / 5 m/z 443→293 0.01 mg/kg / 5 0.1 mg/ kg / 5	 90 -101 108–109 82 -105 104-107	 98 108 92 105	 4.9 0.5 10.5 1.3	0.01 mg/kg	Anonymous, 2009 Addendum to Annex I Listing, A4.2 (d)

Table 12

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→399	no interferences	0.1 – 0.5 µg/mL that means 0.05 – 0.25 µg/L in sample; linear, r>0.99	0.05 µg/L / 4 0.5 µg/L / 5 5.0 µg/L / 5 50 µg/L / 5	123 - 136 81 - 98 87 - 94 101 - 127	129 88 91 107	4.5 7.5 3.1 4.3	0.5 µg/L	Anonymous, 2005 CAR, Doc IIIA 4.2 (c)

Table 13

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→293, 443→135	two transitions	0.001 –0.05 µg/mL that means 0.005 – 0.25 mg/kg in sample; linear, r^2>0.998	<u>Liver</u> m/z 443→293 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 443→135 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Muscle</u> m/z 443→293 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 443→135 0.01 mg/kg / 5 0.1 mg/kg / 5	 94 -107 73 – 82 95 -108 72 – 84 85 -110 84 – 89 93 -106 80 - 86	 101 76 103 77 101 87 102 93	 4.7 4.7 4.8 6.0 9.7 2.0 5.2 11.3	0.01 mg/kg	Anonymous, 2009 Addendum to Annex I Listing, A4.2 (c)

Table 14

Analytical methods for monitoring of active substances and residues in food and feeding stuff of plant origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→293, 443→135	two transitions	0.002 – 0.075 µg/mL that means 0.005 – 0.19 mg/kg in sample; linear, r²>0.999	<u>Rape seed</u> m/z 443→293 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 443→135 0.01 mg/kg / 5 0.1 mg/kg / 5	 86 - 95 69 – 83 84 - 95 69 – 82	 89 76 89 74	 4.1 7.5 4.5 7.1	0.01 mg/kg	Anonymous, 2009 Addendum to Annex I Listing, A4.2 (c)
Difenacoum	LC-MS/MS, Phenyl-Hexyl column, ESI-		linear, R²: 0.9162 – 0.9969	<u>Cucumber</u> 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Wheat</u> 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Lemon</u> 0.01 mg/kg / 5 0.1 mg/kg / 4	 94 -109 91 - 102 102 - 124 64 – 101 81 -98 60 - 87	 100 98 117 86 87 76	 7 5 8 13 9 15	0.01 mg/kg	Anonymous, 2005 CAR, Doc IIIA 4.3

Table 15

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Difenacoum	LC-MS/MS, C18 column, ESI-; m/z 443→293, 443→135	two transitions	0.001 –0.05 µg/mL that means 0.005 – 0.25 mg/kg in sample; linear, r^2>0.998	<u>Liver</u> m/z 443→293 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 443→135 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Muscle</u> m/z 443→293 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 443→135 0.01 mg/kg / 5 0.1 mg/kg / 5	 94 -107 73 – 82 95 -108 72 – 84 85 -110 84 – 89 93 -106 80 - 86	 101 76 103 77 101 87 102 93	 4.7 4.7 4.8 6.0 9.7 2.0 5.2 11.3	0.01 mg/kg	Anonymous, 2009 Addendum to Annex I Listing, A4.2 (c)

Table 16

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.2.2. Air
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 17

Conclusion on the methods for detection and identification
The methods provided are acceptable. Methods regarding substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

“frunax DS Rattenfertigköder 25 ppm” is a rodenticide containing 0.0025% difenacoum (PT 14). The product is a grain based bait to be used by trained professionals as well as the general public in tamper proof bait boxes. The application is either as loose bait or in 100g sachets.

3.5.2 Organisms to be controlled and products, organisms or objects to be protected

“frunax DS Rattenfertigköder 25 ppm” is intended to be used to control:
Rattus norvegicus (Norway rat, Brown rat)
Mus musculus (House mouse)

An application has been made for the use of “frunax DS Rattenfertigköder 25 ppm” in and around buildings. For professional users, the application extends also to open areas and waste dumps for both rat species, and to sewerage systems for Norway rats.

3.5.3 Effects on target organisms, including unacceptable suffering

Difenacoum is a second generation anticoagulant. Ingestion of a lethal dose leads to internal haemorrhages followed by death of the target rodents usually within 3-8 days.

3.5.4 Mode of action, including time delay

Difenacoum, like other coumarin derivatives, acts as a vitamin K antagonist. Vitamin K in its reduced form, KH2, is essential in the synthesis of intrinsic blood coagulation factors. KH2 is recycled in a two-step process by reductases. Difenacoum blocks these reductases, resulting in the depletion of Vitamin K storage. The synthesis of intrinsic blood coagulation factors is therefore disrupted, which leads to loss of blood clotting ability and subsequently to lethal haemorrhages. After feeding on bait containing the active substance for 2 – 3 days, the animal becomes lethargic and slow moving. Signs of bleeding may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. Death will usually occur within 4-5 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow. Effects are reversible by administration of the antidote vitamin K1, which stimulates the regeneration of the clotting factors.

3.5.5 Efficacy data

The applicant submitted seven studies conducted with the product “frunax DS Rattenfertigköder” containing 0.005% difenacoum. These cannot be considered as proof of efficacy of the product “frunax DS Rattenfertigköder 25 ppm” with 0.0025%. As these studies only serve as additional information, they are briefly summarised in the table below. Please consider chapter 5.1.2 for a comparison of the compositions of “frunax DS Rattenfertigköder” and “frunax DS Rattenfertigköder 25 ppm”.

Two semi-field studies each were conducted with the product containing 0.0025% difenacoum for the target organisms Norway rat and House mouse:

Norway rats:
Semi-field study (Anonymous, 2016a): 2 groups of 8 mixed-sex Norway rats were exposed to the bait and alternative food in a semi-natural environment (group housing). Mortality was 100% and 90%, respectively. Palatability values were 8.1% and 5%, respectively.
House mice:
Semi-field study (Anonymous, 2016a): 2 groups of 16 mixed-sex House mice were exposed to the bait and alternative food in a semi-natural environment (group housing). Mortality was 100%. Palatability values were 68.8% and 83%, respectively.

Two additional studies were conducted with the product containing 0.005% difenacoum weathered under damp conditions, to mimic the conditions in sewerage. Mortality was 100% and 90%, respectively. Palatability values were higher than in the studies conducted on Norway rats with fresh bait: 9.2% and 25.8%. These studies can therefore be used as proof of efficacy also for the bait with reduced active substance content.

The studies conducted with Norway rats and House mice prove the efficacy of the product against these two target species. Provision of field tests was waived, since the semi-field trials provided were conducted with groups of wild strain rodents in a pen to simulate field conditions sufficiently and it can be reasonably assumed that the product is efficacious in the field (i.e. mouse- or rat-infested objects).

Table 18

Experimental data on the efficacy of the biocidal product against target organism(s)								
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**RI**	**Reference**
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder 25 ppm*	*Rattus norvegicus*, wild strain	2 semi-field trials	0.0025% difenacoum	100% Mortality, 8.1% Palatability; 100% Mortality, 5% Palatability	*1*	*Anonymous, 2016a.01*
Rodenticide	*Rodenticide in sewers*	*frunax DS Rattenfertigköder, aged under damp conditions*	*Rattus norvegicus*, wild strain	semi-field trial	0.005% difenacoum	100% Mortality, 9.2% Palatability	*1*	*Anonymous, 2011.04*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder 25 ppm*	*Mus musculus*, wild strain	2 semi-field trials	0.0025% difenacoum	100% Mortality, 68.8% Palatability; 100% Mortality, 83% Palatability	*1*	*Anonymous, 2016b*
Rodenticide	*Rodenticide in sewers*	*frunax DS Rattenfertigköder, aged under damp conditions*	*Rattus norvegicus*, wild strain	semi-field trial	0.005% difenacoum	90% Mortality, 25.8% Palatability	*1*	*Anonymous, 2011.05*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Rattus norvegicus, wild strain*	semi-field trial	0.005% difenacoum	100% Mortality, 20% Palatability		*Anonymous, 2004a.02*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Rattus norvegicus, wild strain*	semi-field trial	0.005% difenacoum	100% Mortality, 38.5% Palatability		*Anonymous, 2004a.03*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Rattus rattus, wild strain*	No-choice trial	0.005% difenacoum	100% Mortality	*2*	*Anonymous, 2004c.29*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Rattus rattus, wild strain*	semi-field trial	0.005% difenacoum	100% Mortality, 14.6% Palatability	*2*	*Anonymous, 2004c.29*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Mus musculus, wild strain*	3 trials: no choice, choice and field (bakery)	0.005% difenacoum	No choice trial: 100% Mortality; semi-field trial: 100% Mortality, 42.7% Palatability; field trial: 100% population reduction	*2*	*Anonymous, 2004; B_5.10.2 17*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Mus musculus, wild strain*	semi-field trial	0.005% difenacoum	100% Mortality, 35% Palatability	*2*	*Anonymous, 2004c.15*
Rodenticide	*Rodenticide*	*frunax DS Rattenfertigköder*	*Mus musculus, wild strain*	field trial (feed lot, zoo)	0.005% difenacoum	97% population reduction	*2*	*Anonymous, 2004; B_5.10.2 18*

3.5.6 Occurrence of resistance and resistance management

The applicant did not provide new data of the biocidal product to evaluate the potential for resistance. Recommendations and details for the development of resistance, and additionally, management strategies for the prevention of development of resistance, are discussed in Document II-A, Section 2.4 and 2.4.1 of the CA-Report (Difenacoum, Hentschke & Sawatzki KG).

Brown rats resistant to difenacoum have been discovered in south of England, Denmark and northwest Germany. Difenacoum resistance in house mice has been less studied, but there is strong evidence that resistance to difenacoum is also a relevant problem for the control of house mice.
The resistance to difenacoum itself is currently not as widespread as warfarin resistance, but although a gene for warfarin resistance has been identified, not all resistance factors are entirely understood and the likelihood that warfarin resistant rodents will develop difenacoum resistance is high due to the similar mode of action of these anticoagulants. It is well established that difenacoum-resistant rodents are also resistant against warfarin.
It must be concluded that a continuous, uncontrolled use of difenacoum would most probably enhance the development and spread of resistance not only against difenacoum itself but also against e.g. Warfarin.

The following strategy for resistance management has to be followed:

- The habitat management is addressed in the strategy in addition to chemical control: access of rodents should be restricted by physical barriers and no food should be available for rodents.
- Rotation between different anticoagulants is not a reliable means of managing anticoagulant resistance, as all anticoagulants have the same mode of action and the resistance mechanisms are also similar.
- When anticoagulant rodenticides are used, ensure that all baiting points are inspected preferably daily at the beginning of the pest control campaign and weekly thereafter and that old baits are replaced where necessary.
- Continue treatment according to the label until the infestation is completely cleared.
- On completion of the treatment, remove all unused baits.
- Do not use anticoagulant rodenticides as permanent baits. For rodent monitoring, use non-toxic baits, monitoring devices or traps
- Record details of treatment.
- As appropriate during the rodenticide treatment, apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, and prove susceptible areas against rodent access).

3.5.7 Known limitations

Humaneness

The assessment of humaneness of anticoagulant rodenticides including difenacoum concludes that all evaluated anticoagulants can be considered to be markedly inhumane. Unfortunately, there are currently not sufficiently alternatives on the market and anticoagulant rodenticides are considered to be essential for rodent control.

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3.5.8 Evaluation of the label claims

Efficacy of “frunax DS Rattenfertigköder 25 ppm” was proven for the target species Norway rat (*Rattus norvegicus*) and House mouse (*Mus musculus*) for the uses applied for, including use in sewers for *Rattus norvegicus*.

3.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not applicable.

3.5.10 Data waiving and conclusion

Table 19

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 20

Conclusion on the efficacy
Efficacy of “Frunax Rattenfertigköder DS” was proven for the target species Norway rats (*Rattus norvegicus*) and House mice (*Mus musculus*) for the uses applied for, including use in sewers for *Rattus norvegicus*.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 21

Difenacoum	Value	Study	Safety factor
AEL long-term	Not established.	--	--
AEL medium-term	1.1 x 10^{-6} mg/kg bw/d [1,2]	Teratogenicity rabbits; maternal toxicity: LOAEL 0.001 mg/kg bw/d; Druga (2004)	600
AEL acute	Not established (AELmedium-term used for exposure assessment)	--	--

Table 22

Difenacoum	Value	Reference
Inhalative absorption	100 %[1]	Default value
Oral absorption	(74 - 82 %)[1] 68 % bioavailable [1,2]	Philips (2002; 1996) Swan (2006)
Dermal absorption	8 %	Default (4 %) agreed on WG V 2016 and pro rata extrapolation

[1] Based on Assessment-Report

[2] Bioavailability of 68 % has been used to derive the $AEL_{medium\text{-}term}$ (AOEL)

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 23

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	A study on skin corrosion and irritation of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.”

Data waiving was acceptable for the following information requirements	
	For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no information about synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 24

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The content of components classified for skin irritation is below the limits for classification.
Classification of the product according to CLP	Classification for skin irritation/corrosivity is not required.

3.6.2.2 Eye irritation

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	A study on eye irritation of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no information about synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 26

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eyes.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The content of components classified for eye irritation or damage is below the limits for classification.
Classification of the product according to CLP	Classification for eye irritation/damage is not required.

3.6.2.3 Respiratory tract irritation

Table 27

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.

Table 28

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components the biocidal product is not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitization

Table 29

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the

	mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available.

Table 30

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Based on the available data skin sensitisation is not expected.
Justification for the value/conclusion	The biocidal product does not contain known skin-sensitising substances.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitization (ADS)

Table 31

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 32

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Based on the available data respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or their components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 33

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	A study on acute oral toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 34

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on the oral LD_{50} available for the single components the oral LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 35

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	A study on acute inhalation toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.”

Data waiving was acceptable for the following information requirements	
	For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 36

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 37

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	A study on acute dermal toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Dec. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 38

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the dermal LD_{50} available for the single components the dermal LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

Table 39

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	The applicant did not submit any dermal absorption study, a default value of 4 % for grain baits containing 50 ppm active substance was agreed on WG V 2016. Based on this default and pro rata extrapolation according to EFSA Guidance on Dermal Absorption (2012) a value of 8 % has to be used for this biocidal product.

Table 40

Value(s) used in the Risk Assessment – Dermal absorption	
All relevant substance exposure scenarios	All relevant scenarios.
Value	8 %
Justification for the selected value	Default, refer to the table above.

3.6.2.8 Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Not relevant.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Endocrine disrupting properties

According to the assessment report for the renewal of the active substance evaluation difenacoum is not considered to have endocrine disrupting properties.
No co-formulant of the biocidal product was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision.
There are no data indicating that any co-formulant of the biocidal product may have endocrine disrupting properties based on the existing knowledge and the available scientific information. Therefore, the co-formulants are not considered to have endocrine disrupting properties.

3.6.2.11 Other

According to Annex VI of Regulation (EC) No 1272/2008 difenacoum is classified with Repr. 1A, H360D. The specific concentration limit is ≥ 0.003 %. Hence, classification of the biocidal product for reproduction toxicity is not required.
According to Annex VI of Regulation (EC) No 1272/2008 difenacoum is classified with STOT RE 1, H372 (blood). The specific concentration limit for STOT RE 2, H373 is 0.002 % ≤ C < 0.02 %. Hence, classification with STOT RE 2, H373 is required.

3.6.2.12 Summary of effects assessment

Table 41

Endpoint	Brief description
Skin corrosion and irritation	Based on information for single ingredients not classified for skin irritation or corrosion.
Eye irritation	Based on information for single ingredients not classified for eye irritation or damage.
Respiratory tract irritation	Based on information for single ingredients not classified for respiratory tract irritation.
Skin sensitisation	Based on information for single ingredients not classified for skin sensitisation.
Respiratory sensitisation (ADS)	Based on information for single ingredients not ot classified for respiratory sensitisation.
Acute toxicity by oral route	Not classified for acute oral toxicity. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L.
Acute toxicity by dermal route	Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Information on dermal absorption	A default value of 4 % for grain baits containing 50 ppm active substance was agreed on WG V 2016. Based on this default and pro rata extrapolation a value of 8 % has to be used for this biocidal product.
Available toxicological data relating to non-active substance(s)	Not relevant
Available toxicological data relating to a mixture	Not relevant
Other relevant information	The biocidal product is classified with STOT RE 2, H373 (blood).

3.6.3 Exposure assessment[11]

3.6.3.1 Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Table 42[12]

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a.	Yes	n.a.	n.a.	n.a.	n.a.	n.a.
Dermal	n.a.	Yes	Yes	n.a.	n.a.	n.a.	n.a.
Oral	n.a.	n.a.	no	n.a.	n.a.	Yes	no

11 [Please, assess the primary and secondary exposure for each active substance or substances of concern in case of exposure to several active substances or substances of concern within a product]
12 [Please indicate the main paths of human exposure by stating "yes", "no" or "n.a." (not applicable) for each cell.]

List of scenarios

Table 43[13]

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
1	Use 1-7	Application of granular bait in packages less than or equal to 25 kg (≤ 25 kg): - Primary exposure of workers resulting from the application of granules into bait boxes and the disposal/cleaning	Professional/Trained professional user
2	Use 1-7	Application of granular bait in packages up to 10 kg (≤ 10 kg)[1)] - Primary exposure of workers resulting from the application of granules into bait boxes and the disposal/cleaning	Professional/Trained professional user
3	Application and disposal (use 8 and 9)	Biocidal product in sachets (primary exposure) - biocidal product in sachets is placed in bait stations by an adult; max. 5 sachets per bait point, 5 bait points.	Non-professional
4	Mouthing (all uses)	Swallowing/ingestion of baits by toddlers (secondary exposure) a) swallowing of one bait b) transient mouthing of a bait (e.g. with repellent)	General public

13 [Please insert or delete rows for additional scenarios as needed. Include all scenarios in this table and then refer to them by their running number given in column 1. If exposure may take place to one person performing different tasks, please include a separate scenario for each type of (sub)task. If the same people may be exposed in several scenarios, there may be the need to evaluate the combined exposure occurring when performing these tasks.]

3.6.3.1.1 Professional exposure[14]

frunax DS Rattenfertigköder 25 ppm is a ready to use granular bait to control rodenticides. The biocidal product contains difenacoum (CAS-No. 56073-07-5, 0.0025 %) as the active substance (a.s.).
It is applied by placing the bait into bait boxes (mice: 50 g of bait per bait station, rats: 200 g of bait per bait station). The b.p. is intended for the fields of use as followed: indoor, outdoor around buildings, outdoor open areas and waste dumps, sewers.
The biocidal product is marketed in different package sizes: 200 g sachet in folding box; 200 g (openable) sachet in outer carton; 100 g (openable) sachet in outer carton; 5-10 kg loose granules in bucket (PP); 25 kg loose granules in bag (lined paper bag).

The exposure to the a.s. is assessed separately relating to the use of different package sizes and will thus be described in the scenario subsections of the current section (a detailed overview of the exposure calculation for all scenarios can be found in section 4.3.1). It is based on the harmonised document "Biocides Human Health Exposure Methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007. Thus the exposure assessment is based on the study from Chambers et al. (2004).
In Annex 4.3.1, the details of the exposure calculations to the a.s. for the professional user are laid out.

- **Scenario 1**

The exposure assessment for placing the bait from packages (up to 25 kg) is based on model data described in detail in the Biocides Human Health Exposure Methodology Document Version 1 (October 2015). The loose bait will be placed into bait boxes or other baiting points. These are inspected and refilled according to consumption. Dermal exposure and exposure by inhalation are assessed. Oral exposure by the professional user is not expected.
Relevant parameters for the exposure calculation are shown in Table 44.

Dermal exposure is assessed for the decanting of granules into portions (mixing and loading phase), the application of granules and the disposal of residues (post-application phase).
Inhalation exposure is assessed for the decanting of granules into portions (mixing and loading phase). During the application and post-application (cleaning/disposal) phase inhalation exposure is not expected to occur.

14 [Professional users use biocides in the course of their job or business and they have received suitable information, instruction and training in their use. Professional users use end-products outside industry.]

In Tier 2, as a technical risk mitigation measure, it is assumed that the product is divided into inner packages of no more than 10 kg each, so that decanting can be avoided.

Table 44

Relevant parameters of Scenario 1 – Application of granular bait in packages less than or equal to 25 kg (≤ 25 kg)	
Parameters	Value
Concentration of the a.s. difenacoum in the b.p.	0.0025 % (w/w)
Number of decanting	5
Duration of decanting	15 min
Number of bait stations – Application	63
Number of bait stations – Post-Application (cleaning)	16

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 46. Due to the identified risk in Tier 1, a refined exposure assessment is performed. For Tier 2 the technical risk mitigation measure (division of the biocidal product into inner packages less than or equal to 10 kg) and protective gloves are taken into account.
For details of the calculation of dermal and inhalation exposure, please refer to annex 4.3.1, of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on scenario 1

The frequency of bait application is assumed to be up to daily.
No secondary exposure of professionals is expected in view of the anticipated use patterns.

- **Scenario 2**

The exposure assessment for placing loose bait from packages (up to 10 kg) and sachets, which must be opened for the application into bait boxes (information of the applicant), is based on model data described in detail in the Biocides Human Health Exposure Methodology Document Version 1 (October 2015). The assessment of the opened sachets is also covered by the model to assess the application of loose grain bait. The loose bait/opened sachet will be placed into bait boxes or other baiting points. These are inspected and refilled according to consumption. Dermal exposure is assessed. Exposure by inhalation and oral exposure by the professional user are not expected.
Relevant parameters for the exposure assessment are shown in Table 45.

Dermal exposure is assessed for the application of the granules/opened sachets into bait boxes and the disposal of residues (post-application phase).
For a maximum applied size of 10 kg or the opened sachets no previous decanting (mixing and loading phase) is assumed. Exposure by inhalation during the application of the loose granules/opened sachets and the disposal of the residues is not expected (post-application phase) either.

Table 45

Relevant parameters of Scenario 2 – Application of granular bait in packages up to 10 kg (≤ 10 kg) or opened sachets	
Parameters	Value
Concentration of the a.s. difenacoum in the b.p.	0.0025 % (w/w)
Number of bait stations – Application (loading)	63
Number of bait stations – Post-Application (cleaning)	16

Calculations for Scenario 2

The results of the calculation for potential/actual dermal exposure (Tier 1 and Tier 2) are summarised in Table 46. Due to the identified risk in Tier 1, a refined exposure assessment is performed. For Tier 2 protective gloves are taken into account.
For details of the calculation of dermal exposure, please refer to annex 4.3.1, of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on scenario 2

The frequency of bait application is assumed to be up to daily.
No secondary exposure of professionals is expected in view of the anticipated use patterns.

- **Summary of professional exposure**

The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are combined exposure values of all phases.

Table 46

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1	Tier 1:	7.52×10^{-6}	1.13×10^{-2}
	Tier 2: • Protective gloves (EN 374) • Packaging size adjusted to 10 kg	not expected	4.73×10^{-4}
Scenario 2	Tier 1:	not expected	4.73×10^{-3}
	Tier 2: • Protective gloves (EN 374)	not expected	4.73×10^{-4}

The described summary is valid for professional users (e.g. housekeepers) or specialised professional users (e.g. pest control operators). The frequency of bait application is assumed to be up to daily.

3.6.3.1.2 Non-professional exposure

- **Scenario 3**

Table 47

Description of Scenario 3		
The biocidal product is directly applied by the non-professional user, who places the bait sachets at the baiting points. For disposal the non-professional user collects the sachets, which might be partly eaten and damaged. Indicative exposure values were derived from HEEG opinion No. 12. According to the HEEG opinion No. 10 the non-professional user normally places 5 baits at 5 bait points (in total 25 baits) unless the description of the application as provided by the applicant implies a higher number of baits. Based on the physico-chemico properties of the active substance and the specific use inhalation and oral exposure is considered not relevant.		
	Parameters	Value
Tier 1	Indicative exposure value for potential hand exposure, application (recommended by HEEG opinion No 12)	2.04 mg b.p. / manipulation
	Indicative exposure value for potential hand exposure, disposal (recommended by HEEG opinion No 12)	3.79 mg b.p. / manipulation
	No. of manipulations	5
	Concentration a.s. in b.p.	0.0025 g / 100 g
	Dermal absorption (default)	8 %
	Body weight adult (HEEG opinion No 17)	60 kg
Tier 2	Indicative exposure value for potential hand exposure, application (recommended by HEEG opinion No 12) with protection factor 50% (proposed by the HEADhoc working group, BPC-WGV2017)	1.79 mg b.p. / manipulation
	Indicative exposure value for potential hand exposure, disposal (recommended by HEEG opinion No 12)	4.52 mg b.p. / manipulation
	No of manipulations	5
	Concentration a.s. in b.p.	0.0025 g / 100 g
	Dermal absorption (default)	8 %
	Body weight adult (HEEG opinion No 17)	60 kg

Calculations for Scenario 3

Systemic exposure Tier 1

$Exposure_{dermal}$ = (indicative exposure application + indicative exposure disposal) x No of manipulations x concentration a.s. in b.p. x dermal absorption / body weight adult

= (2.04 mg + 3.79 mg) x 5 x 0.0025 % x 8 % / 60 kg

= 9.72×10^{-7} mg / kg bw

Total systemic exposure = 9.72×10^{-7} mg / kg bw

- **Combined scenarios**

Not relevant.

3.6.3.1.3 Secondary exposure of the general public

- **Scenario 4**

Table 48

Description of Scenario 4		
Ingestion and mouthing of rodenticide bait. The ingestion of rodenticide bait is considered as an exceptional scenario, which may occur accidentally. Based on the TNsG on human exposure (2007) it is assumed that a child (toddler) may consume up to 5 g, particularly if no bait boxes are used and no bittering agent is added. For other cases when the risk of oral exposure is minimised by addition of an aversive agent and by an appropriate covering of baits (e.g. by use of a bait station) an ingested amount of 10 mg is expected since the bait is only mouthed but not swallowed as such. Inhalation exposure is considered not relevant due to the physico-chemico properties and the specific use conditions. Potential dermal exposure is covered by the oral exposure assessment.		
	Parameters	Value
Tier 1	a) Ingested amount by swallowing, no aversive agent, no covered application (TNsG on Human Exposure, 2007)	5000 mg
	b) Ingested amount by mouthing, aversive agent, covered application (TNsG on Human Exposure, 2002)	10 mg
	Concentration a.s. in b.p.	0.0025 g / 100 g
	Oral absorption (AR, 2016)	68 %
	Body weight, toddler (HEEG opinion No 17)	10 kg

Calculations for Scenario 4

$Exposure_{oral}$ = Ingested amount x concentration a.s. in b.p. x oral absorption / body weight toddler

a)

$Exposure_{oral}$ = 5000 mg x 0.0025 % x 68 % / 10 kg

= 0.0085 mg/kg bw

b)

$Exposure_{oral}$ = 10 mg x 0.0025 % x 68 % / 10 kg

= 1.7×10^{-5} mg/kg bw

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4a	1	-	-	0.0085 mg/kg bw	0.0085 mg/kg bw
Scenario 4b	1	-	-	1.7×10^{-5} mg/kg bw	1.7×10^{-5} mg/kg bw

- **Combined scenarios**

Not relevant.

3.6.3.2 Dietary exposure

The intended use descriptions of the difenacoum-containing biocidal product for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for control of house mice and rats by professional, trained professional and non-professional bait application that does not come in direct contact with food, feedstuff or livestock animals.

3.6.3.3 Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not relevant.

3.6.3.5 Summary of exposure assessment

Table 50

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1. Application of granular bait in packages less than or equal to 25 kg (≤ 25 kg):	Professional user	Tier 2/ Protective gloves Packaging size adjusted to 10 kg	Acceptable[2)]
2. Application of granular bait in packages up to 10 kg (≤ 10 kg)[1)]	Professional user	Tier 2/ Protective gloves	Acceptable[2)]

1) Scenario includes also the handling of sachets which should be opened according to the applicant
2) For the external exposure values please refer to the section “Professional exposure”

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Section 3.6.1.

3.6.4.2 Maximum residue limits or equivalent

No MRLs are required.

Table 51

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reg (EC) No. 396/2005	all	0.01 mg/kg(default MRL acc. to Reg 396/2005, Art 18(1) b)

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product frunax DS Rattenfertigköder 25 ppm takes into account systemic effects of the active substance difenacoum.

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the

risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

Systemic effects

The primary toxic effect of the active substance difenacoum is the effect on blood coagulation with haemorrhage and prolonged blood clotting time. The quantitative risk characterisation for professional users takes into account dermal exposure to difenacoum resulting from use of the biocidal product.

As reference value the $AEL_{long\text{-}term}$ of $1.1x10^{-6}$ mg/kg bw/day is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to difenacoum from the biocidal product frunax DS Rattenfertigköder 25 ppm, inhalation and dermal exposure to difenacoum is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ $1.1x10^{-6}$ mg/kg bw/d of difencaoum is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of difenacoum, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of difenacoum (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of difenacoum (in mg/kg bw/d) / 8 %-dermal absorption x 100 %.

By this means RV_{inhal} equivalent to $6.6x10^{-6}$ mg/m³ and RV_{derm} equivalent to $1.38x10^{-5}$ mg/kg bw/d are calculated for difenacoum.

Dermal absorption rate

As dermal absorption of the active substance the value of 8 % based on the default value of 4 % (agreed on WG V 2016) and pro rata extrapolation is used.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance difenacoum resulting from use of the biocidal product frunax DS Rattenfertigköder 25 ppm is determined according to the following equation:

RQ_{inhal} = inhalation exposure to difenacoum (in mg/m³) / RV_{inhal} of difenacoum (in mg/m³).

RQ_{derm} = dermal exposure to difenacoum (in mg/kg bw/d) / RV_{derm} of difenacoum (in mg/kg bw/d).

Dermal exposure to difenacoum given in mg/kg bw/d is calculated from dermal exposure to difenacoum given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 52 gives a detailed overview of the risk assessment results referring to the active substance difenacoum for the biocidal product. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 52. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance difenacoum resulting from the use of the biocidal product frunax DS Rattenfertigköder 25 ppm is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 52, the RI of the scenarios application of granular bait in packages less than or equal to 25 kg and application of granular bait in packages up to 10 kg exceeds the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when risk mitigation measures are implemented the risk characterisation result yields a RI of less than 1 in TIER 2.

Table 52: Overview of detailed risk assessment results referring to the active substance difenacoum for the biocidal product frunax DS Rattenfertigköder 25 ppm

Scenario		inhalation external			dermal external				RI	Acceptable
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential / actual exposure		RV_{derm}	RQ_{derm}		
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			yes/no
application of granular bait in packages less than or equal to 25 kg	Tier 1	$7.52x10^{-6}$	$6.60x10^{-6}$	1.14	0.01	$1.88x10^{-4}$	$1.38x10^{-5}$	13.66	14.80	no
	Tier 2	not expected	$6.60x10^{-6}$		$4.73x10^{-4}$	$7.88x10^{-6}$	$1.38x10^{-5}$	0.57	0.57	yes
application of granular bait in packages up to 10 kg	Tier 1	not expected	$6.60x10^{-6}$		$4.73x10^{-3}$	$7.88x10^{-5}$	$1.38x10^{-5}$	5.73	5.73	no
	Tier 2		$6.60x10^{-6}$		$4.73x10^{-4}$	$7.88x10^{-6}$	$1.38x10^{-5}$	0.57	0.57	yes

Tier 1: no PPE; Tier 2: protective gloves (application of granular bait less than or equal to 25 kg, application of granular bait in packages up to 10 kg), packaging size adjusted to 10 kg (application of granular bait less than or equal to 25 kg)

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance difenacoum via the inhalation and dermal route, a risk for professional users resulting from the uses (application of granular bait in packages less than or equal to 25 kg and application of granular bait in packages up to 10 kg) with the biocidal product frunax DS Rattenfertigköder 25 ppm is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 2 consideration. Regarding occupational safety, there are no objections against the use taking into account the provisions described in chapter 2.4 of this PAR.

- **Local effects**

No classification of the biocidal product frunax DS Rattenfertigköder 25 ppm regarding local effects is necessary. Therefore, no risk assessment for professional users regarding local effects is carried out.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product frunax DS Rattenfertigköder 25 ppm is unlikely for the intended uses application of granular bait in packages less than or equal to 25 kg and application of granular bait in packages up to 10 kg. Risk mitigation measures described in chapter 2.4 have to be taken into account in order to ensure safe use of the biocidal product frunax DS Rattenfertigköder 25 ppm.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation

3.6.4.6 Risk for non-professional users

Table 53: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3	1	0.001	0.0000011	9.72×10^{-7}	88	yes

- **Local effects**

Not relevant.

Conclusion

Non-professional use is considered safe if the biocidal product is used as intended and all advices are followed.

3.6.4.7 Risk for the general public

Table 54: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2a	1	0.001	0.0000011	0.00850	772727	no
2b	1	0.001	0.0000011	0.00002	1545	yes, with appropriate RMM

- **Local effects**

Not relevant.

Conclusion

For secondary exposure, a risk has been identified for children ingesting baits accidentally. Hence, specific risk mitigation measures are required to prevent such exposure.
For selection of appropriate risk mitigation measures the Note for Guidance “Harmonised sentences to be used in the different sections of the SPC for anticoagulant rodenticides” and the Summary of product characteristics for a biocidal product containing anticoagulant active substances (on the basis of the harmonised SPC including derogations according to article 37 in Germany) are taken into account.
The smallest sachet-size for application is a 100 g sachet, however for use against mice the smallest application amount per bait point is 50 g. The use is not safe if sachets are opened, therefore it is even more important to inform all users not to open sachets.

3.6.4.8 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

3.6.4.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance difenacoum and no SoC.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product frunax DS Rattenfertigköder 25 ppm is unlikely for the intended uses application of granular bait in packages less than or equal to 25 kg and application of granular bait in packages up to 10 kg. Risk mitigation measures described in chapter 2.4 have to be taken into account in order to ensure safe use of the biocidal product frunax DS Rattenfertigköder 25 ppm (please refer also to Table 52).
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.10.3 Summary of risk characterisation for non-professional user

Table 55

Scenario, Tier	Relevant reference value (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ reference value (%)	Acceptable (yes/no)
3; Tier 1	0.0000011	9.72×10^{-7}	88	yes

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 56

Scenario, Tier	Relevant reference value (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ reference value (%)	Acceptable (yes/no)
4a, Tier 1	0.0000011	0.00850	772727	no
4b, Tier 1	0.0000011	0.00002	1545	yes, with appropriate RMM

3.7 Risk assessment for animal health[15]

Based on the human exposure and risk assessment, a risk for pets and other domestic animals must also be expected by ingestion of this rodenticide. Hence, specific risk mitigation measures are required to prevent such an exposure.

3.8 Risk assessment for the environment

3.8.1 General information

No substance of concern is present in the biocidal product and no new information compared to the data used for the approval and re-approval of the active substance has been provided for the evaluation of the biocidal product. Therefore, the environmental risk assessment for the product is based on the risk assessment of the active substance difenacoum (*cf. Assessment Report Difenacoum PT 14, July 2016 and Annex-I-CAR Difenacoum (Activa/Pelgar Difenacoum and Brodifacoum Task Force; RMS Finland; June 2009)*).

3.8.2 Effects assessment

3.8.2.1 Terrestrial compartment

Within the first approval of the a.s. difenacoum a $PNEC_{soil}$ of 0.877 mg/kg wet weight has been calculated. Within the renewal of the approval of difenacoum an earthworm reproduction study has been

[15] Pets and domestic animals. Regarding wild animals, please refer to chapter 3.8.

provided. The study resulted in a NOEC of 62.5 mg/kg dw. Applying an assessment factor of 100 as has been agreed within the BPC-16 a new, slightly lower $PNEC_{soil}$ was derived:

$PNEC_{soil}$ = 0.625 mg a.s./kg dw.

3.8.2.2 Aquatic compartment (incl. Sediment and STP)

No new information compared to the Annex-I-CAR has been provided. In aquatic studies, acute toxicity data indicate a high toxicity of difenacoum to fish. The most sensitive species in the acute test was the rainbow trout (*Oncorhynchus mykiss*), with a LC_{50} of 0.064 mg/L. Applying an assessment factor of 1000 results in a

$PNEC_{aqua}$ = 0.06 µg/L.

Since no studies with sediment-dwelling organisms are available the $PNEC_{sediment}$ is derived from the $PNEC_{aqua}$ using the equilibrium partitioning method.

$PNEC_{sediment}$ = 2.51 mg/kg ww.

No new information for microorganisms compared to the Annex-I-CAR of the Activa/PelGar Brodifacoum and Difenacoum Task Force has been provided. The outcome of PNEC derivation from an activated sludge respiration inhibition test is a

$PNEC_{STP}$ = 0.48 mg/L (equivalent to the water solubility).

3.8.2.3 Primary and Secondary Poisoning

No new information compared to the Annex-I-CAR has been provided.
For the acute exposure situation, no $PNEC_{oral}$ is determined and no quantitative risk characterisation is performed. Instead a qualitative assessment is done by comparing LD_{50} values to the expected contents of the active substances in birds and mammals.
For the qualitative assessment of acute primary and secondary poisoning the LD_{50} from acute oral studies are used. The lowest LD_{50} value for birds was 56 mg/kg bw, determined for Bobwhite quail *(Colinus virginianus)* females. For mammals the LD_{50} of 1.8 mg/kg bw from the rat study is used.

The $PNEC_{oral}$ for birds is derived from the 5-day dietary test with Japanese quail *(Coturnix coturnix japonica).* An LC_{50} of 1.4 mg/kg food (equivalent to 0.3 mg/kg bw/d) was derived in this study. An assessment factor of 3000 is applied according to the Guidance on the BPR, Vol IV, Part B+C.

$PNEC_{oral,bird}$ = 0.0005 mg/kg food or 0.0001 mg/kg bw/d.

The $PNEC_{oral}$ for mammals is based on the NOEC of 0.6 mg/kg food and NOAEL of 0.03 mg/kg bw/d from the 90-day rat repeated-dose toxicity test. An assessment factor of 90 is applied.

$PNEC_{oral,mammal}$ = 0.007 mg/kg food or 0.0003 mg/kg bw/d.

3.8.3 Fate and behaviour

The active substance in the biocidal product “frunax DS Rattenfertigköder 25 ppm” is difenacoum manufactured by PelGar International Limited, member of the Activa/PelGar Brodifacoum and Difenacoum Task Force. The assessment of the environmental exposure to difenacoum is carried out with the data from the Assessment Report (AR) for the renewal of difenacoum prepared by Finland (see AR difenacoum PT 14, July 2016) and from the Competent Authority Report (CAR) for the first approval of difenacoum (June 2009). The endpoints from the Taskforce in the LoEP are used for the exposure estimations.

No new studies were provided on biodegradation or abiotic degradation and conclusions of the original assessment remain valid.

Difenacoum is not expected to volatilise to air in significant quantities (vapour pressure $<5 \cdot 10^{-5}$ Pa at 318 K corresponding to $5.6 \cdot 10^{-6}$ Pa at 285 K). A half-life of 6.24 hours is estimated for difenacoum due to phototransformation in air (OH radical concentration of $5 \cdot 10^5$ radicals$\cdot$cm^{-3} over 24 hours) assuming no accumulation potential of the a.s. in the atmosphere.

Difenacoum is slightly soluble in water ($4.3 \cdot 10^{-1}$ mg$\cdot$L^{-1} at neutral conditions and 293 K corresponding to $3.83 \cdot 10^{-1}$ mg$\cdot$L^{-1} at 285 K). It is hydrolytically stable in the pH range of natural water.

Difenacoum undergoes rapid phototransformation. Two breakdown products above 10% were detected, but not chemically identified. Possible structures of degradation products are presented in Doc IIIA.7.1.1.1.2. Because aqueous photo-degradation is regarded as a minor removal process for difenacoum and the exposure to water is low, no further characterization of metabolites was deemed necessary.

Difenacoum is not readily or inherently biodegradable. Degradation in soil has not been studied, but it can be assumed the half-life is over 300 days.

The assessment report for the renewal of difenacoum (July 2016) indicates an octanol/water partition coefficient log Kow = 4.78 under neutral conditions and an organic carbon-water partitioning coefficient Koc of $1.8 \cdot 10^6$ L kg^{-1} (see LoEP). This Koc value was used in the risk assessment.

The formulation of the biocidal product “frunax DS Rattenfertigköder 25 ppm” is considered not to alter any of the physico-chemical properties of the active substance difenacoum.

3.8.3.1 Bioaccumulation

No new information has been submitted for the evaluation of the bioaccumulation potential of the product. However, new studies on bioaccumulation in fish and earthworms were submitted after original evaluation of the active substance difenacoum. In addition, an experimentally derived log Kow was provided. In the original assessment no bioaccumulation studies were included and BCFs were calculated from the QSAR log Kow of 7.6. At the environmentally relevant pH of 7 the experimentally derived log Kow is 4.78.

The bioaccumulation factors (BAF) derived from the earthworm bioaccumulation test were 1.32 kg soil/kg worm (kinetic) and 0.81 kg soil/kg worm (steady state). Higher bioaccumulation potential was observed in the fish bioaccumulation study. BPC-2016-I-ENV decided that the growth corrected kinetic BCF of 1100 L/kg shall be used for the risk assessment. The experimentally derived BCFs for fish and earthworms were significantly lower compared to calculated QSAR values of 9010 L/kg and 477 729 L/kg used in the original risk assessment for the first approval of difenacoum. The study however revealed some deficiencies and it was concluded at the BPC-WG-2016-I-ENV that the derived BCF values may be too low. Moreover, it was agreed that the aquatic BCF from the study should not be the only aspect considered when discussing the bioaccumulation potential of difenacoum; the available information on residues of difenacoum in biota in a great variety of non-target species, including both terrestrial and aquatic species, across Europe also needs to be acknowledged (see Assessment Report difenacoum, July 2016).

3.8.4 Exposure assessment

3.8.4.1 General information

The environmental exposure to difenacoum was assessed for the use of the active substance formulated as “frunax DS Rattenfertigköder 25 ppm” as a rodenticide granular bait (product type 14). The concentration of the a.s. substance in the product is 0.0025 %, i.e. 25 ppm. The b.p. is foreseen for indoor and outdoor use against house mouse (*Mus musculus*) and brown rat (*Rattus norvegicus*). The bait is provided in 100 g and 200 g ready-to-use sachets and as loose bait. The application amount of

bait per baiting point is 50 g and 200 g against house mouse and rats, respectively. The local environmental concentrations of difenacoum were estimated based on the respective Emission Scenario Document for biocides used as rodenticides (ESD PT14, EUBEES 2, 2003), the Guidance BPR IV ENV B+C (2017) and the Assessment Report for the renewal of difenacoum (July 2016). The following scenarios described in the ESD PT14 were assessed: In and around buildings, open areas, waste dumps/landfills and sewer system.

Table 57

Assessed PT	PT 14
Assessed scenarios	Scenario 1: in- and outdoor - in and around buildings Scenario 2: outdoor - open areas, bait application in burrows Scenario 3: outdoor - waste dumps Scenario 4: outdoor - sewer
ESD(s) used	Emission Scenario Document for biocides used as rodenticides (ESD PT14, EUBEES 2), May 2003
Approach	in and around buildings: direct and indirect emission to soil open areas: direct emission to soil waste dumps: direct emission to soil sewer: indirect emission to water and soil The exposure estimations are based on the scenarios where the highest release to the environment is expected to take place.
Distribution in the environment	Calculation based on „Guidance on the Biocidal Products Regulation Vol. IV Environment – Assessment and Evaluation (Parts B + C) Version 2.0, October 2017” (Guidance BPR IV ENV B+C (2017))
Groundwater simulation	No A groundwater simulation by using FOCUS PEARL was not necessary for the assessed scenarios because the reference value of 0.01 µg/L was not exceeded.
Confidential Annexes	No
Life cycle steps assessed	All Scenarios: Production: No Formulation: No Use: Yes Service life: No
Remarks	

3.8.4.2 Fate and distribution in exposed environmental compartments

Table 58 summarises the environmental compartments which are exposed by application of “frunax DS Rattenfertigköder 25 ppm”.

Table 58

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Other**
In and around buildings	No	No	No	No	No	Yes	Yes	No	Neither
Open areas	No	No	No	No	No	Yes	Yes	No	Neither
Waste dumps	No	No	No	No	No	Yes	Yes	No	Neither
sewer	Yes	Yes	No	No	Yes	Yes	Yes	No	Neither

Table 59 summarises relevant PC-data, which characterise fate and distribution of difenacoum in the environment.

Table 59

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	444.5	g/Mol	
Melting point	221.15	°C	Average value between 216.3°C and 226°C
Boiling point		°C	No data
Vapour pressure (at 12°C)	5.597×10^{-6}	Pa	LoEP: < 5×10^{-5} Pa (45°C) converted to 12°C
Water solubility (at 12°C)	0.383	mg/L	LoEP: 0.43 mg/L (20°C, pH 6.5) converted to 12°C
Log Octanol/water partition coefficient	4.78	Log 10	Value taken from the AR
Organic carbon/water partition coefficient (Koc)	1,803,018	L/kg	log Koc = 6.256
Henry's Law Constant	6.496×10^{-3}	$Pa/m^3/Mol$	calculated from vapour pressure and water solubility at 12°C
Biodegradability	0		
Rate constant for STP	0	h^{-1}	
DT_{50} for biodegradation in surface water	0	d (at 12ºC)	
DT_{50} for degradation in soil	30,000	d	CAR 2009, Doc IIA, ch. 4.1.1.2, agreement TMII/04 use TGD default value
DT_{50} for degradation in air	6.24	hr	OH radicals ($5 \cdot 10^5$ radicals·cm^{-3} over 24 hours)

3.8.4.3 Aquatic compartment (including sediment and STP)

- **Emission estimation**

- **Scenario 1-3: in and around buildings, open areas, waste dumps/landfills**

According to the ESD PT14 (EUBEES 2003) release to the sewer system and further to the STP and surface water are “not relevant” for the application scenarios in and around buildings, open areas and waste dumps/landfills. Thus, exposure of microorganisms in the STP, of surface water and sediment can be regarded as negligible for these use patterns of “frunax DS Rattenfertigköder 25 ppm”. Also direct emissions to surface water are assumed as negligible because the baits are applied in bait stations or introduced directly deep into the rat holes.

- **Scenario 4: sewer**

According to the applicant “frunax DS Rattenfertigköder 25 ppm” is applied as ready-to-use bait in bait stations typically placed on the benching of the infested sewer. The bait is manually placed on the tray from the manhole above or added using a dispenser with maximum amount of 20 kg product in a control operation in one week. The default emission scenario from ESD PT14 (described in chapter 2.3.3) should be adapted in that way that “frunax DS Rattenfertigköder 25 ppm” as granular bait is used during a control operation and the amount of product used in suitable places is 200 g instead of 300 g. Thus, the amount of product used in the first week of control operation is 20.0 kg. The input parameters to calculate the local emission to waste water are summarised in Table 60.

Table 60: Input parameters for calculating the local emission

Input according to chapter 2.4.3.2, ESD PT14 (2003)	Value	Unit	Remarks
Scenario*: sewer system*			
Amount of product used in the control operation after one week - *Qprod*	20.0	*kg*	S
Fraction of a.s. in product - *Fcprod*	0.000025	-	S
Number of emission days (realistic worst case during the control operation) - Temission	7	d	D
Fraction of active ingredient metabolised - *Fmetab*	0.21	-	S
Fraction of active ingredient released - Freleased	0.69	-	S
Output			
Mean local emission of active substance to waste water during episode - $Elocal_{water}$	$4.93 \cdot 10^{-5}$	kg/d	O

The distribution of difenacoum in the STP was calculated with the Simple Treat model 4.0. The following values have been calculated, see Table 61.

Table 61: Calculated fate and distribution in the STP

Compartment	Percentage [%]	Remarks
Air	0.0	
Water	7.63	
Sludge	92.37	
Degraded in STP	0.0	Not biodegradable, k = 0 d^{-1}

The predicted environmental concentrations for the subsequently affected compartments are estimated according Guidance BPR IV ENV B+C (2017) as follows:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 42, chapter 2.3.6.7.
- PECsurface_water according to equation 51, chapter 2.3.7.3.1.
- PECsediment according to equation 53, chapter 2.3.7.3.2.

The calculated PEC values of difenacoum in STP and the aquatic compartment after application of "frunax DS Rattenfertigköder 25 ppm" in sewer systems are summarised in Table 62**Table 62**.

Table 62: Summary of the outputs of STP (Clocaleff, Csludge), and of the PECs in surface water and sediment resulting from application of "frunax DS Rattenfertigköder 25 ppm" in sewer systems

Output parameters	Symbol	Value
Concentration of a.s. in treated wastewater = PEC for microorganisms in the STP	Clocalinf = PEC_{STP}	$2.5 \cdot 10^{-2}$ µg·L^{-1}
Concentration in dry sewage sludge	Csludge	$5.76 \cdot 10^{-2}$ mg·kg^{-1}
Predicted environmental concentration in surface water	PECsurface water	$5.08 \cdot 10^{-5}$ µg·L^{-1}
Predicted environmental concentration in sediment	PECsediment	$1.99 \cdot 10^{-3}$ mg·kg^{-1}

3.8.4.4 Terrestrial compartment (including groundwater)

- **<u>Emission estimation</u>**

According to the ESD PT14 (EUBEES 2003), emission of the active substance to soil is the most relevant contribution to local environmental exposure resulting from rodenticide application in the environment.

The estimation of the local PEC for the terrestrial compartment includes also the groundwater. The PECgroundwater is calculated as a first worst-case estimation according to equation 71, chapter 2.3.7.6, Guidance BPR IV ENV B+C (2017).

- **Scenario 1 - In and around buildings**

Direct and indirect releases of difenacoum to soil following application of "frunax DS Rattenfertigköder 25 ppm" are estimated according to chapter 2.4 in ESD PT14. The direct releases from the bait date from spills at refilling or cleaning operations of bait stations, whereas the indirect releases are expected from rodents' urine, faeces and carcasses.

The resulting concentrations due to the direct and indirect releases from "frunax DS Rattenfertigköder 25 ppm" applied in protected bait points in and around buildings and the predicted environmental concentration in soil (PECsoil) are estimated using equations (2) to (5) from ESD PT14. The input parameters and the output results are summarised in Table 63.

Table 63: Input parameters for calculating the local emission and output results

Input parameters for calculating the local emission and output results			
Input according to chapter 2.4.3.2, ESD PT 14 (2003)	**Value**	**Unit**	**Remarks**
Scenario: *in and around buildings*			
Amount of product used at each refilling in the control operation for each bait - *Qprod* box	200	*g*	S
Fraction of active substance in the product - *Fcprod*	0.000025	-	S
Number of application sites - *Nsites*	10	-	D
Number of refilling times - *Nrefil*	5	-	D
Fraction of a.s. released directly to soil - *Frelease-D,soil*	0.01	-	D
Fraction of a.s. that is metabolised - *Fmetab*	0.21	-	S
Fraction of a.s. released indirectly to soil - *Frelease-ID,soil*	0.69	-	S
Area directly exposed to rodenticide (around the box) - *AREAexposed-D*	0.09	m^2	D
Area indirectly exposed to rodenticide - *AREAexposed-ID*	550	m^2	D
Depth of exposed soil - *DEPTHsoil*	0.1	m	D
Density of exposed soil – *RHOsoil*	1700	kg/m^3	D
Output			
Local direct emission rate of active substance to soil from a campaign - *Elocal,soil-D-campaign*	2.5	mg	
Local indirect emission rate of active substance to soil from a campaign - *Elocal,soil-ID-campaign*	170.78	mg	

Input parameters for calculating the local emission and output results			
Input according to chapter 2.4.3.2, ESD PT 14 (2003)	**Value**	**Unit**	**Remarks**
Concentration in soil due to direct release after a campaign - *Clocal soil-D*	$1.63 \cdot 10^{-2}$	mg/kg	
Concentration in soil due to indirect (disperse) release after a campaign - *Clocal soil-ID*	$1.83 \cdot 10^{-3}$	mg/kg	
Predicted environmental concentration in soil taking into account both direct and indirect releases - ***PECsoil***	$1.82 \cdot 10^{-2}$	mg/kg	

The **PECsoil** of difenacoum resulting from application of "frunax DS Rattenfertigköder 25 ppm" as 200 g-baits in bait stations in and around buildings is equal to **$1.82 \cdot 10^{-2}$ mg·kg^{-1}**.
The **PEC in groundwater** according to the first tier assessment results in **$5.71 \cdot 10^{-4}$ µg·L^{-1}**. This value is below the reference value for groundwater of 0.01 µg·L^{-1} which was derived from the toxicological values during the approval for renewal of difenacoum (ref. to Difenacoum AR, July 2016). Therefore refinement of the groundwater assessment for the scenario in and around buildings is not necessary.

- **Scenario 2 – Outdoor: Open Areas**

For the estimation of direct emissions to soil and calculation of the local predicted environmental concentration in soil (PECsoil) the emission scenario from ESD PT14 "open areas" was applied. The release of difenacoum to soil are estimated according to chapter 2.5, equations (9) and (10) from ESDPT14, the input parameters and the output results are summarised in Table 64.
The emission estimation according to scenario in and around buildings has to be used in case the application takes place in bait stations, see results above.

Table 64: Input parameters for calculating the local emission and output results

Input according to chapter 2.5.3.2, ESD PT14 (2003)	Value	Unit	Remarks
Scenario: *open areas (application direct in vole corridors)*			
Amount of product used at each refilling in the control campaign per hole - *Qprod*	200	*g*	S
Fraction of a.s. in product - *Fcprod*	0.000025	-	S
Number of application sites - *Nsites*	1	-	D
Number of refilling times - *Nrefil*	2	-	D
Fraction of a.s. released to soil during application - *Frelease, soil, appl*	0.05	-	D
Fraction of a.s. released to soil during use - *Frelease, soil, use*	0.2	-	D

Density of exposed soil - *RHOsoil*	1700	kg/m^3	D
Soil volume exposed to a.s. - *Vsoilexposed*	$8.48 \cdot 10^{-3}$	m^3	D/O
Output			
Local emission rate of active substance to soil during control campaign - *Elocal,soil-campaign*	2.5	mg	O
Predicted environmental concentration in soil at each hole per control campaign - ***PECsoil***	0.17	mg/kg	O

The **PECsoil** of difenacoum resulting from application of frunax DS Rattenfertigköder 25 ppm as 200g-bait directly into rat corridors and holes is equal to **0.17 mg·kg^{-1}**.
The **PEC in groundwater** according to the first tier assessment results in **$5.45 \cdot 10^{-3}$ µg·L^{-1}**. This value is below the reference value for groundwater of 0.01 µg·L^{-1} (ref. to Difenacoum AR, July 2016). Therefore a refinement of the groundwater assessment for the scenario open areas is not necessary.

- **<u>Scenario 3 – Outdoor: Waste Dumps</u>**

Rodent control operations of waste dumps and landfills potentially lead to exposure of soil. It is assumed that available coverings are used. According to the ESD PT14 most of the bait is metabolised by the rodents and released to the soil. The release of difenacoum to soil and the predicted environmental concentration in soil (PECsoil) are estimated according to chapter 2.6, equations (17) and (18) from ESD PT14, the input parameters are summarised in Table 65.

Table 65: Input parameters for calculating the local emission and output results

Input according to chapter 2.6.3.2, ESD PT14 (2003)	Value	Unit	Remarks
Scenario: *waste dumps/landfills*			
Amount of product used in the control operation per application- *Qprod*	24.2	kg	S
Fraction of a.s. in product - *Fcprod*	0.000025	-	S
Number of applications - *Napp*	7	-	D
Fraction of a.s. released indirectly to soil during application - *Frelease, soil*	0.69	-	S
Area exposed to rodenticide - *AREAexposed*	10,000	m^2	D
Depth of exposed soil - *DEPTHsoil*	0.1	m	D
Density of exposed soil - *RHOsoil*	1700	kg/m^3	D
Output			
Local emission of active substance to soil during control campaign - *Elocal,soil-campaign*	$2.92 \cdot 10^3$	mg	O
Predicted environmental concentration in soil after a campaign - ***PECsoil***	$1.72 \cdot 10^{-3}$	mg/kg	O

The **PECsoil** of difenacoum resulting from application of frunax DS Rattenfertigköder 25 ppm as 200g-bait on waste dumps and landfills is equal to **$1.72 \cdot 10^{-3}$ mg·kg^{-1}**.
The **PEC in groundwater** according to the first tier assessment results in **$5.41 \cdot 10^{-5}$ µg·L^{-1}**. This value is below the reference value for groundwater of 0.01 µg·L^{-1} (ref. to Difenacoum AR, July 2016). Therefore a refinement of the groundwater assessment for the scenario waste dump/landfills is not necessary.

- **Scenario 4: sewer**

For application of frunax DS Rattenfertigköder 25 ppm in the sewer system direct emission to soil can be excluded, the soil is indirectly contaminated by fertilisation with sludge.
The estimation of releases to the soil compartment premises calculation of predicted concentrations of the a.s. in dry sewage sludge as part of a.s. load leaving a STP. The **PEC in soil** due to 10 years of continuous sludge deposition from STP on agricultural land is **$8.16 \cdot 10^{-4}$ mg·kg^{-1}**.
The **PEC in groundwater** according to the first tier assessment results in **$2.56 \cdot 10^{-5}$ µg·L^{-1}**. This value is clearly below the reference value for groundwater of 0.01 µg·L^{-1} (ref. to Difenacoum AR, July 2016). Therefore a refinement of the groundwater assessment for the sewer scenario is not necessary.

3.8.4.5 Atmosphere

In view of the limited volatility of difenacoum and the anticipated use patterns, emissions to the air are regarded to be not significant in relation to all intended use patterns and are assumed to be negligible for all scenarios.

3.8.4.6 Non-compartment specific effects

- **Primary poisoning**

Rodenticide bait formulations entail the possibility of bait consumption by non-target animals. Particularly birds and mammals of the same size as the target rodents are vulnerable to primary poisoning as these are able to enter bait stations. Moreover, target animals can carry baits away from bait stations/points and thus, non-target animals may be exposed. According to ESD PT14 and to the 23rd CA meeting a qualitative and quantitative risk assessment is conducted for the acute and long-term poisoning situation, respectively.
The qualitative first tier assessment (short term situation) assumes that non-target animals are directly exposed to the bait, without considering bait avoidance and assuming that the non-target animal obtains the diet exclusively in the treated area. The estimation of daily uptake (ETE) of difenacoum by non-target animals is calculated according to equation 19 of ESD PT14. In the second tier assessment, the

avoidance factor and the fraction of diet obtained in the treated area are set to 0.9 and 0.8, respectively. An elimination factor of 0.4 (according to CAR, DocIIB, ch. 3.3.5.1) is used to calculate the expected concentration (EC1) in the non-target animal after one day of exposure (ref. to eq. 20 in ESD PT14).

The highest values for ETE as well as EC1 are received by the tree sparrow as representative for birds and the dog as representative for mammals and were shown in Table 66 (AV=0.9, PT=0.8).

Table 66

Summary table on estimated theoretical exposition (ETE) and EC1		
	ETE	**EC1**
	[mg/kg*d^{-1}]	**[mg/kg*d^{-1}]**
tree sparrow	6.22	3.73
dog	1.08	0.65

To carry out an estimation for a long-term exposure, the expected concentration in non-target animals after 5 days of exposure taking elimination into account should be calculated according to ESD PT14 (ref. to eq. 21). For a worst case situation the values for AV, PD, and PT are set to 1.
These EC5 values are used for quantitative risk assessment of primary poisoning in long-term situation (as agreed upon at 23rd CA-Meeting). The maximum values of expected difenacoum concentration for long-term (poisoning) situation due to primary poisoning are calculated again for tree sparrow with **EC5 = 8.6 mg·kg^{-1}** and for dogs with **EC5 = 1.49 mg·kg^{-1}** (AV=0.9, PT=0.8).

- **Secondary poisoning**

Predatory birds and mammals are especially susceptible for indirect poisoning effects caused by the intake of already accumulated substances with their prey. Two different accumulation pathways have to be distinguished: first the bioaccumulation of rodenticide via the aquatic food chain in fish and consequently in fish-eating birds or mammals and second the bioaccumulation of rodenticide via the terrestrial food chain in earthworms and consequently in worm eating birds or mammals.
Aquatic food chain:
The concentration of difenacoum in food (fish) of fish eating predators (PECoral,predator) is calculated according to eq. 95 in chapter 3.8.3.4 of Guidance BPR IV ENV B+C (2017) from the PEC for surface water, the measured bioconcentration factor BCF for fish (1100 L·kg^{-1}) and the biomagnification factor (BMF = 2, ref. to table 23 of Guidance BPR IV ENV B+C (2017)). The PEC in surface water ($5.08 \cdot 10^{-5}$ µg·L^{-1}) was taken from the sewer scenario, where rodent control is performed by use of "frunax DS Rattenfertigköder 25 ppm".

PECoral for fish eating predators = 5.58×10^{-05} mg·kg^{-1}.

Terrestrial food chain:

The bioaccumulation of difenacoum via the terrestrial food chain in earthworms and consequently in worm eating birds or mammals is calculated according to chapter 3.8.3.7 of the Guidance BPR IV ENV B+C (2017). The $PEC_{oral,predator}$ is a function of PEC_{soil}, $PEC_{porewater}$ as well as bioaccumulation for earthworms (BCF = 1.32 kg soil/kg worm). The predicted environmental concentration of a.s. and its residues in food via this pathway are estimated for the scenarios in and around buildings, open areas and waste dumps/landfills, the values are shown in Table 67.

Table 67: Summary of $PEC_{oral, predator}$ via terrestrial food chain

Scenario/Application	$PEC_{oral, predator}$ [$mg \cdot kg^{-1}$]
Scenario 1: In and around buildings (bait boxes)	$1.85 \cdot 10^{-3}$
Scenario 2: Open areas (rat holes)	**$1.77 \cdot 10^{-2}$**
Scenario 3: Waste dumps/landfills (bait boxes)	$1.75 \cdot 10^{-4}$
Scenario 4: Sewer (sewage sludge application)	$8.31 \cdot 10^{-5}$

The secondary poisoning assessment of non-target animals via food chain according to the Guidance BPR IV ENV B+C (2017) considers the oral intake of difenacoum via fish and worms. However, rodenticide active substances may enter the food chain of terrestrial predators also via rodenticide bait → rodent → rodent-eating mammal or rodent-eating bird. For estimation of secondary poisoning risk through poisoned rats or voles, the amount of difenacoum in the target animals is estimated in the same way as the non-target body concentrations for primary poisoning (eq. 19 and 21 in ESD PT14).

In the calculation for **short-term** (poisoning) situation of non-target animals (qualitative estimation), PEC_{oral} is defined as the concentration in the rodent immediately after a last meal on day 5. The fraction of the food type in the diet (PD) is set to 1 and F_{rodent} = 1 (non-target animals consume 100 % of their daily intake on poisoned rats).

PEC_{oral} (EC5) is equal to 5.76 $mg \cdot kg^{-1}$.

For the **long-term** (poisoning) situation a tired quantitative assessment is carried out for secondary poisoning. Following the first tier, the PEC_{oral} is the concentration in rodent after a last meal on day 5, PD = 1 and F_{rodent} = 0.5.

PEC_{oral} (EC5) is equal to 2.88 $mg \cdot kg^{-1}$.

The PEC_{oral} in tier 2 evaluation is the concentration in non-target animals after a single day of exposure (ref. to ESD PT14 and 23rd CA-Meeting). The values for PEC_{oral} resulting from tier 2 evaluation are summarised in Table 68.

Table 68: Expected concentration PEC_{oral} of difenacoum in non-target animals due to secondary poisoning after a single day of exposure, rodents caught by predators on day 5.

Species	$PEC_{oral, predator}$ [$mg \cdot kg^{-1}$]
Barn owl	0.71
Kestrel	**1.08**
Little owl	0.82
Tawny owl	0.66
Fox	0.26
Polecat	0.55
Stoat	0.78
Weasel	**1.13**

The maximum values of expected difenacoum concentration for long-term (poisoning) situation due to secondary poisoning are calculated for weasel (mammals) and kestrel (birds), cf. bold values in Table 68.

. Bold values are used as PEC_{oral} for the second tier quantitative risk characterisation of secondary poisoning for birds and mammals, respectively.

3.8.4.7 Calculated PEC values

The calculated PEC values for all scenarios and all compartments are summarised in Table 69.

Table 69

Summary table on calculated PEC values								
	PEC_{STP}	PEC_{water}	PEC_{sed}	$PEC_{seawater}$	PEC_{seased}	PEC_{soil}	PEC_{GW}	PEC_{air}
	[mg/m^3]	[µg/L]	[mg/kg_{wwt}]	[mg/L]	[mg/kg_{wwt}]	[mg/kg]	[µg/L]	[mg/m^3]
Scenario 1	n.r.	n.r.	n.r.	n.r.	n.r.	$1.82 \cdot 10^{-2}$	$5.71 \cdot 10^{-4}$	n.r.
Scenario 2	n.r.	n.r.	n.r.	n.r.	n.r.	$1.73 \cdot 10^{-1}$	$5.45 \cdot 10^{-3}$	n.r.
Scenario 3	n.r.	n.r.	n.r.	n.r.	n.r.	$1.72 \cdot 10^{-3}$	$5.41 \cdot 10^{-5}$	n.r.
Scenario 4	$2.50 \cdot 10^{-2}$	$5.08 \cdot 10^{-5}$	$1.99 \cdot 10^{-3}$	n.r.	n.r.	$8.16 \cdot 10^{-4}$	$2.56 \cdot 10^{-5}$	n.r.

3.8.5 Risk characterisation

The risk characterisation is performed for the biocidal product frunax DS Rattenfertigköder 25 ppm for use in and around buildings (including animal housings) in bait boxes, open areas (rat holes/burrows), on waste dumps/landfills and in sewer systems. Bait points contain up to 200 g and 50 g bait for rat control and mice control, respectively. The active substance difenacoum is present in the product "frunax DS Rattenfertigköder 25 ppm" products at a concentration of 0.0025 % w/w. The biocidal product contains no substance of concern. Therefore, the risk characterisation is based on the risk characterisation of the active substance with respect to the environmental exposure and the different intended uses in particular.

3.8.5.1 Terrestrial compartment

3.8.5.1.1 Soil

According the ESD PT14 direct emissions to soil may occur from the use in and around buildings (in bait boxes), at open areas (rat holes) and at waste dumps/landfills. For application in and around buildings also an indirect exposure via rodent urine, faeces and carcasses are considered for the calculation of the PEC. From the application in the sewer systems release to soil may occur indirectly via spreading of sewage sludge from sewage treatment plants that have been exposed to frunax DS Rattenfertigköder 25 ppm.

Table 3.8-70: PEC/PNEC ratios for soil resulting from application of frunax DS Rattenfertigköder 25 ppm in different scenarios

Exposure scenario / Application	**PEC** [mg/kg ww]	**PNEC** [mg/kg dw]	**PEC / PNEC**
In and around buildings (bait boxes)	$1.82 \cdot 10^{-02}$	0.625	0.03
Open areas (rat holes)	$1.73 \cdot 10^{-01}$	0.625	0.28
Waste dumps and landfills	$1.72 \cdot 10^{-03}$	0.625	0.003
Sewer systems	$8.16 \cdot 10^{-04}$	0.625	0.0013

Conclusion to the risk assessment

The PEC/PNEC ratios for soil are below 1 for all exposure scenarios. Therefore, no unacceptable risk for the terrestrial compartment is indicated for all exposure scenarios.

3.8.5.1.2 Groundwater

Leaching of the substance from the soil to the groundwater was calculated for the different scenarios according to the Guidance on the BPR, Vol IV, Part B+C.

Table 3.8-71: PEC/PNEC ratios for groundwater resulting from application of frunax DS Rattenfertigköder 25 ppm in different scenarios

Exposure scenario / Application	**PEC** [µg/L]	**Trigger** [µg/L]*	**PEC / Trigger value**
In and around buildings (bait boxes)	$5.71 \cdot 10^{-04}$	0.01	0.06
Open areas (rat holes)	$5.45 \cdot 10^{-03}$	0.01	0.55
Waste dumps and landfills	$5.41 \cdot 10^{-05}$	0.01	0.006
Sewer systems	$2.56 \cdot 10^{-5}$	0.01	0.0026

* The maximum permissible concentration of the active substance in groundwater must not exceed the reference value of 0.01 $\mu g \cdot l^{-1}$ which was derived from the toxicological values during the renewal for approval of difenacoum (ref. to Difenacoum AR, July 2016).

Conclusion to the risk assessment

The calculated PECs of the active substance in ground water do not exceed the reference value of 0.01 µg/L (ref. to Difenacoum AR, July 2016). Therefore, no unacceptable risk for groundwater is indicated in all emission scenarios.

3.8.5.2 Aquatic compartment (incl. sediment)

According to ESD PT14, releases of frunax DS Rattenfertigköder 25 ppm to surface water results only from the use of the product for rodent control in sewer systems. The PEC/PNEC ratios for this application are described in

Table 3.8-72. From the intended uses in and around buildings, in open areas and on waste dumps/landfills the ESD PT14 regards releases to the surface water as not relevant and negligible for these use patterns.

Table 3.8-72: PEC/PNEC ratios for surface water, sediment and STP after application of frunax DS Rattenfertigköder 25 ppm in sewer systems

Exposure scenario	PEC	PNEC	PEC / PNEC
Surface water	$5.08 \cdot 10^{-05}$ µg·L^{-1}	0.06 µg·L^{-1}	0.00085
Sediment*	$1.99 \cdot 10^{-03}$ mg·kg^{-1}ww	2.51 mg·kg^{-1} ww	0.00079
STP	$2.5 \cdot 10^{-02}$ µg·L^{-1}	480 µg·L^{-1}	$5.2 \cdot 10^{-5}$

Conclusion to the risk assessment

The PEC/PNEC ratios for surface water, sediment and STP micro-organisms after the application in sewer systems are all below 1. Therefore, an unacceptable risk for the aquatic environment resulting from the use of frunax DS Rattenfertigköder 25 ppm in sewer systems is not indicated.

3.8.5.3 Atmosphere

The active substance difenacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Difenacoum has a potential for rapid photo-oxidative degradation in the air (half-life about 6.24 hours). Difenacoum is not expected to have a potential for long-range atmospheric transport or contribute to global warming, ozone depletion or acidification on the basis of its physical and chemical properties.
Due to low vapour pressure of the active substance difenacoum, no adverse effects of the product frunax DS Rattenfertigköder 25 ppm are expected via atmospheric exposure. In conclusion there is no risk in relation to all intended use pattern.

3.8.5.4 Primary and secondary poisoning

The exposure of primary and secondary poisoning has been assessed according to the scenarios developed for rodenticides (hereafter called ESD). Pursuant to ESD PT14 and to the Addendum

relevant to Biocides to the TGD, CA-Nov06Doc.4.3, a qualitative and quantitative risk assessment is conducted for the acute and long-term poisoning situation, respectively.

Table 3.8-73: PNECs to be used in the risk characterisation of primary and secondary poisoning

Species	**PNECoral** [mg/kg food]	**PNECoral** [mg/kg bw/d]
Birds	0.0005	0.0001
Mammals	0.007	0.0003

3.8.5.4.1 Primary Poisoning

3.8.5.4.1.1 Tier 1 Assessment

The Tier 1 assessment of primary poisoning is based on the comparison of the concentration of a.s. in the bait and the $PNEC_{oral}$ related to the concentration in food.

Table 3.8-74: PEC/PNEC ratios for acute situation of primary poisoning

Species	**PEC** [mg/kg] Concentration in bait	**PNEC** [mg/kg] Concentration in food	**PEC/PNEC**
Birds	25	0.0005	**50 000**
Mammals	25	0.007	**3571**

It is quite obvious that frunax DS Rattenfertigköder 25 ppm produces risk for both birds and mammals in the Tier 1 scenario as the purpose of the rodenticide baits is to kill the target rodents and the mode of action is similar in both target and non-target vertebrates.

3.8.5.4.1.2 Tier 2 Assessment

According to the ESD the comparison of concentration in the non-target animals and the $PNEC_{oral}$ describes the long-term risk for primary poisoning. The expected concentration in the non-target animals are calculated after five days intake and elimination.

Table 3.8-75: Tier 2 risk characterisation for long-term situation

Species		PEC EC5 [mg/kg bw]	PNEC [mg/kg bw/d]	PEC/PNEC
Tree sparrow	*Passer montanus*	8.602	0.0001	**86020**
Dog	*Canis familiaris*	1.494	0.0003	**4980**

The results of the risk characterisation show that in a long-term situation frunax DS Rattenfertigköder 25 ppm, if ingested by mammals or birds, poses a high risk for primary poisoning and will cause long-term effects of difenacoum in these species. Due to high food intake in relation to the body weight the birds are at considerably higher risk than mammals.

3.8.5.4.1.3 Qualitative risk assessment for the short-term situation

The maximum values of expected difenacoum concentration (PECs) for short-term (poisoning) situation due to primary poisoning are calculated for dogs (mammals) and tree sparrow (birds) (cf.
Table 3.8-76). For the acute exposure situation, no PNECoral is determined and no quantitative risk characterisation is performed. Instead a qualitative assessment is done by comparing LD50 values to the expected contents of the active substances in birds and mammals.

Table 3.8-76: Qualitative comparison of EC1 and LD50 values for bird and mammals

Species	EC1 [mg/kg bw]	LD_{50} [mg/kg bw]
Birds	3.73	56
Mammals	0.65	1.8

Regarding the values given in Table 3.8-76, it can be followed that one day consumption of difenacoum containing baits is not assumed to kill birds and mammals. However, the species specific sensitivity differences are not taken into account in this assumption (i.e. no assessment factor is applied on the LD_{50} values), and hence this description must not be considered as a risk characterisation.

3.8.5.4.1.4 Conclusion from primary poisoning

Non-target mammals and birds are at risk for primary poisoning if they get access to the frunax DS Rattenfertigköder 25 ppm. Lethal and sub-lethal effects are very likely in both animal groups. Primary poisoning incidents can be minimized by preventing the access of non-target animals to the baits. It is assumed in the ESD that if the rodenticide baits are used according to the label instructions, the risk for primary poisoning is negligible. However, it may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals and birds of equal or smaller size than the target rodents.

3.8.5.4.2 Secondary Poisoning

3.8.5.4.2.1 Aquatic and terrestrial food chains

Birds and mammals may be at risk for secondary poisoning if they feed on contaminated soil organisms (i.e. earthworms) or contaminated aquatic species (i.e. fish). The risk characterisation is done for both birds and mammals to be consequent with the calculations done according to the ESD.

Table 3.8-77: Secondary poisoning via aquatic and terrestrial food chain

Species	**Aquatic** $PEC_{oral, Predator}$ [mg/kg]	**Terrestrial** $PEC_{oral, Predator}$ [mg/kg]	$PNEC_{oral}$ [mg/kg food]	**Aquatic PEC/PNEC**	**Terrestrial PEC/PNEC**
Birds	0.000056	0.0177	0.0005	**0.1**	**35**
Mammals	0.000056	0.0177	0.007	**0.008**	**2.5**

It can be followed from the results that both animal groups are at risk when get exposed to frunax DS Rattenfertigköder 25 ppm via the terrestrial food chain, albeit the indicated risk for birds again is higher than for mammals. In contrast, no unacceptable risks are indicated for birds and mammals which prey on contaminated fish. However, it should be noted that the $PEC_{oral,predator}$ used for the risk assessment of the aquatic food chain is based on measured BCF values from a bioconcentration study in fish which exhibit some uncertainties and thus the presented results should be interpreted carefully and critically.

3.8.5.4.2.2 Qualitative assessment for the short-term situation

A qualitative assessment of the acute secondary poisoning is made by comparing the concentration in the rodents to LD_{50} values from acute oral studies. Rodents are assumed to eat entirely on bait containing difenacoum and the non-target animals are assumed to consume entirely poisoned rodents.

Table 3.8-78: Qualitative assessment of acute secondary poisoning. Expected concentration (EC) in rat on day 5

Species	**EC5** [mg · kg_{bw}^{-1}]	**LD_{50}** [mg · kg_{bw}^{-1}]
Birds	5.76	56
Mammals	5.76	1.8

The qualitative assessment indicates that birds are likely to survive and mammals are likely to die if they eat poisoned rats. The species specific sensitivity differences or other aspects normally covered by the assessment factors are not taken into account in the qualitative assessment.

3.8.5.4.2.3 Tier 1 assessment

The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food, i.e. poisoned rodents. In the long-term exposure, the rodents are assumed to consume entirely the bait (PD = 1), while the predator's or scavenger's daily food intake consists of poisoned rodents only (F_{rodent} = 1). The rodents are assumed to eat the baits in five successive days, whereas the predator or the scavenger is assumed to eat the poisoned rodents during one day.

Table 3.8-79: PEC/PNEC ratios for long-term situation of secondary poisoning

Species	**PEC** [mg/kg] Concentration in rodent	**PNEC** [mg/kg] Concentration in food	**PEC/PNEC**
Birds	2.88	0.0005	**5764**
Mammals	2.88	0.007	**411**

The Tier 1 risk characterisation shows that birds and mammals are at risk for secondary poisoning when eating rats, which are poisoned by frunax DS Rattenfertigköder 25 ppm.

3.8.5.4.2.4 Tier 2 assessment

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators is compared to $PNEC_{oral}$ related to the daily dose. The predator is assumed to catch the rodent after last meal on day 5.

Table 3.8-80: Tier 2 risk characterisation. The expected concentrations (EC) in non-target animals are compared to $PNEC_{oral}$.

Species	**PEC** EC [mg/kg bw]	**PNEC** [mg/kg bw/d]	**PEC/PNEC**
Birds (Kestrel)	1.08	0.0001	**10840**
Mammals (Weasel)	1.13	0.0003	**3763**

The Tier 2 risk characterisation shows high risks for secondary poisoning, too. No data are available on the sensitivity of the example species to difenacoum. Only one day exposure of predators is assumed in the ESD, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators because daily elimination of difenacoum from the predators is assumed to be less than the daily intake.

3.8.5.4.2.5 Conclusion from secondary poisoning

The theoretical calculations clearly show that difenacoum poses a risk for secondary poisoning. In the terrestrial food chain (worm eating and rodent eating birds and mammals) secondary poisoning is

possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely source for difenacoum residues in raptorial birds and mammalian predators.

The CA report of difenacoum (Assessment Report Difenacoum PT 14, 17 September 2009 and CAR Difenacoum (Activa/Pelgar Difenacoum and Brodifacoum Task Force; RMS Finland; June 2009)) contains several literature references which examined the secondary poisoning in barn owls that were fed with difenacoum poisoned rodents. These studies indicate that PEC/PNEC ratios based on measured concentrations in rats and mice were lower than the respective figures calculated according to the ESD, but are still considerably higher than 1, indicating a risk for secondary poisoning of barn owls (ref. DOC IIC, section 2.4.3.5, CAR).

In addition, several monitoring studies which demonstrate residues of difenacoum in wildlife animals are mentioned in the CAR (ref. DOC IIC, section 2.4.3.6, CAR).

The conclusion is that difenacoum poses a high risk for secondary poisoning. Therefore, it is very important to follow the use instructions of the rodenticide baits in order to reduce the risk for secondary poisoning.

3.8.5.5 PBT assessment

According to the Assessment Report for the renewal of the approval of difenacoum (Assessment Report, PT 14, July 2016) the active substance difenacoum fulfils the criteria for PBT substances:

> **P-criterion**: Difenacoum is not readily biodegradable and hydrolytically stable, but photolytic degradation in water is rapid. The photolytic degradation is not regarded as a major transformation pathway in nature. The half-life of 439 d at 20 °C (833 d, 12 °C) was determined in the aerobic soil degradation test. The half-life in soil exceeds the criteria for P (120 days) and vP (180 days). Difenacoum thus fulfils the P and vP criteria.
>
> **B-criterion**: The original assessment of the B criterion was based on the calculated log Kow (7.6) and BCF (35 645 L/kg, Guidance on the BPR, Vol IV, Part B+C and 9010 L/kg, EPIWIN). After original assessment log Kow has been experimentally determined for difenacoum (4.78 at pH 7). The log Kow still exceed the screening criteria of ≥4.5 (Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT/vPvB assessment. Version 2.0. November 2014).

An aquatic and a terrestrial bioaccumulation study were submitted for the renewal evaluation of difenacoum. The bioaccumulation potential detected in the earthworm *Eisenia fetida* was low, probably due to adsorption of difenacoum to soil. The steady state and kinetic bioaccumulation factors (BAF) for earthworm were 0.81 and 1.32 kg soil/kg worm, respectively.

From the aquatic bioaccumulation study in rainbow trout *Oncorhynchus mykiss* the growth corrected kinetic BCF of 1100 L/kg has been derived. The BCF 1100 L/kg was below the B criterion of 2000 L/Kg. On the basis of this study difenacoum does not fulfil the bioaccumulation criterion. However, there are some deficiencies to this study and the result is conflicting to the fact that residues of difenacoum are commonly found in non-target species that prey on rodents or feed on carcasses of rodents. The conclusion from the ad hoc follow up after BPC-WG-2016-I-ENV was therefore that difenacoum should be considered as bioaccumulative in terms of the B-assessment (please refer to the Assessment Report Difenacoum July 2016).

T-criterion: Difenacoum is acutely very toxic to fish, algae and daphnia with the lowest LC_{50} value being 0.0064 mg/l established in a short-term test with rainbow trout. In the avian reproduction study the NOEC is 0.31 mg/kg food. Difenacoum is also classified as toxic for reproduction, category 1B and STOT RE 1 H372. Therefore, difenacoum has to be classified as toxic in terms of the T-assessment.

Nevertheless, difenacoum is not a candidate for a persistent organic pollutant (POP) as it does not have a potential for long-range atmospheric transport.

According to the TNsG in Annex I conclusion, with these properties difenacoum was only allowed to be included in Annex I if an environmental exposure can be effectively prevented. To prevent this exposure the risk mitigation measures (see chapter 2.5.2) have to be followed strictly.

3.8.5.6 Endocrine disrupting properties

No new information on endocrine disruptor properties has been provided since the original approval and hence the conclusion that difenacoum does not fulfil the ED-criteria remain valid.
The full composition of the product is listed in the confidential annex to the PAR (see chapter 5.1).
There are no indications that a non-active substance of the product may have endocrine disrupting properties based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is

contained in the candidate list for substances of very high concern (SVHC) for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

3.10.1 Background

The active substance difenacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.4).
Therefore, in line with Article 23 (1) BPR a comparative assessment for the product frunax DS Rattenfertigköder 25 ppm has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:
(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532[16]. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the German CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

3.10.2 Conclusion

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the German CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical

[16] COMMISSION IMPLEMENTING DECISION (EU) 2017/1532 of 7th September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The German CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, the available Technical Guidance Note (TGN) on comparative assessment[17] does not contain criteria for the evaluation of non-chemical control methods. We therefore were not able to evaluate the available information in order to prove that those non-chemical alternatives are sufficiently effective according to the TGN with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of the product frunax DS Rattenfertigköder 25 ppm will granted for 5 years.

Another conclusion is that criteria and clearly defined requirements for the assessment of non-chemical control methods in the framework of comparative assessment according to Article 23 of the BPR are not available and thus should be elaborated prior to the next renewal of anticoagulant rodenticides. Otherwise, the result of comparative assessment of anticoagulant rodenticides with non-chemical methods in the future will always be that no adequate non-chemical alternatives are available and anticoagulant rodenticides will remain approved although they practically fail to fulfil the conditions for approval according to Article 4 of the BPR.

[17] Technical guidance note on Comparative assessment of biocidal products, available at https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e

4 Annexes

4.1 List of studies for the biocidal product

Table 81

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
1	3.1.1. 3.1.2. 3.1.3. 3.2.	Physico-chemical Properties of the Granular Bait "frunax DS Rattenfertigköder" before and after Accelerated Storage at 40ºC for 8 Weeks	Anonymous[18]	2010
2	3.3.	Pour and Tap density of the granular bait "frunax DS Rattenfertigköder"	Anonymous[18]	2010
3	3.4.1.1. 3.5.3. 3.5.6.	Physico-chemical Properties of the Granular Bait "frunax DS Rattenfertigköder" before and after Accelerated Storage at 40 ºC for 8 weeks	Anonymous[18]	2010
4	3.4.1.2.	Physico-chemical Properties of the Granular Bait “frunax®DS Rattenfertigköder” when stored in commercial packaging material over a period of 2 Years at 20 °C	Anonymous[18]	2012
5	3.5.8.	1) Flowability of the Granular Bait " frunax DS Rattenfertigköder before and after accelerated storage at 40 ºC ±2 ºC for 8 weeks; 2) Physico-chemical Properties of the Granular Bait "frunax DS Rattenfertigköder" before and after Accelerated Storage at 40ºC for 8 Weeks	Anonymous[18]	2010
6	4.1.	frunax DS Rattenfertigköder (granular bait) Batch No.: 901.369 Explosive Properties A.14 (OPPTS 830.63.16	Anonymous[18]	2010

[18] Please, refer to IUCLID file for the name of the author(s).

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
7	4.7. 4.17.2.	frunax DS Rattenfertigköder (granular bait) Batch No.: 901.369 Flammability (Solids) A.10 Auto-Flammability (Solids-Determination of Relative Self-ignition temperature) A.16	Anonymous[18]	2010
8	4.14.	frunax® DS Rattenfertigköderl (granular bait) Batch No.: 901.369 Oxidising properties of solids A.17. (Statement)	Anonymous[18]	2010
9	5.1.	Development and Validation of an Analytical Method for the Determination of the Content of active ingredient Difenacoum in the Granular Bait "frunax DS Rattenfertigköder"	Anonymous[18]	2010
10	5.1.	Analytical Method for the determination of the Content of active ingredient Difenacoum in the granular bait "frunax DS Rattenfertigköder 25 ppm"	Anonymous[18]	2018
11	6.7.	Prüfung von frunax D Rattenfertigköder (B-285-00-00) auf Wirksamkeit und Attraktivität gegen Wanderratten in Raum, Tierstall und Freiland gemäß § 18 Infektionsschutzgesetz Trial: 203-15-4.2/WR	Anonymous[18]	2016
12	6.7.	Prüfung von frunax D Rattenfertigköder (B-285-00-00) auf Wirksamkeit und Attraktivität gegen Wanderratten in Raum, Tierstall und Freiland gemäß § 18 Infektionsschutzgesetz Trial: /WR_203-15-4.3/WR	Anonymous[18]	2016
13	6.7.	Prüfung der Wirksamkeit von Frunax D mit 0,005% Difenacoum in einem Wahlversuch mit Wanderratten (Rattus norvegicus)	Anonymous[18]	2004
14	6.7.	Ergebnisbericht über die nach §18 Infektionsschutzgesetz durchgeführten Laboruntersuchungen zur rodentiziden Wirksamkeit des von der frunol delicia GmbH Dübener Str. 137, 04509 Delitzsch, eingereichten handels- und auslegefertigen Fertigköders "frunax DS contra Ratten" (B-0172-00-00)	Anonymous[18]	2004
15	6.7.	Prüfung von "Frunax DS-Rattenfertigköder" (B-0172-00-01) auf Wirksamkeit und Attraktivität gegen Wanderratten in der Kanalisation gemäß §18 Infektionsschutzgesetz Trial 1 of 2	Anonymous[18]	2011
16	6.7.	Prüfung von "Frunax DS-Rattenfertigköder" (B-0172-00-01) auf Wirksamkeit und Attraktivität gegen Wanderratten in der Kanalisation gemäß §18 Infektionsschutzgesetz Trial 2 of 2	Anonymous[18]	2011
17	6.7.	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 1 of 8	Anonymous[18]	1999
18	6.7.	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 5 of 8	Anonymous[18]	1999

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
19	6.7.	Prüfung der Wirksamkeit von Delicia Ratron - Granulat an Wanderrattenrudeln und Mäusegruppen in Wahlversuchen Trial 2 of 4	Anonymous[18]	1999
20	6.7.	Prüfung von Ratron Granulat (B-143-00-01) mit 25 ppm Brodifacoum auf Wirksamkeit und Attrakitivität gegen Wanderratten unter Kanalisationsbedingungen gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.2/KA	Anonymous[18]	2017
22	6.7.	Prüfung von Ratron Granulat (B-143-00-01) mit 25 ppm Brodifacoum auf Wirksamkeit und Attrakitivität gegen Wanderratten unter Kanalisationsbedingungen gemäß Par. 18 Infektionsschutzgesetz Trial: _203-16-8.3/KA	Anonymous[18]	2017
23	6.7.	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Wanderratten in Raum, Tierstall und Freiland gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.3/WR	Anonymous[18]	2017
24	6.7.	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 6 of 8	Anonymous[18]	1999
25	6.7.	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 7 of 8	Anonymous[18]	1999
26	6.7.	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 8 of 8	Anonymous[18]	1999
27	6.7.	Prüfung der Wirksamkeit von Ratron Granulat (0,005% Brodifacoum) an Wanderratten (Rattus norvegicus) im Biotopversuch auf einem Bungalowgrundstück in Magdeburg	Anonymous[18]	2004
28	6.7.	Prüfung der Attraktivität und Wirksamkeit von Frunax D mit 0,005 % Difenacoum in einem Wahlversuch mit Hausmäusen (Mus musculus domesticus RUTTY, 1772)	Anonymous[18]	2004
29	6.7.	Ergebnisbericht über die nach §18 Infektionsschutzgesetz durchgeführten Laboruntersuchungen zur rodentiziden Wirksamkeit des von der frunol delicia GmbH, Dübener Str. 137, 04509 Delitzsch eingereichten, handels- und auslegefertigen Fertigköders "frunax DS contra Ratten" (B-0172-00-00) Trial 1 of 3	Anonymous[18]	2004
30	6.7.	Prüfung von frunax D Rattenfertigköder (B-0285-00-00) auf Wirksamkeit und Attraktivität gegen Hausmäuse in Raum und Tierstall gemäß § 18 Infektionsschutzgesetz Trial: 203-15-4.2/HM	Anonymous[18]	2016
31	6.7.	Prüfung von frunax D Rattenfertigköder (B-0285-00-00) auf Wirksamkeit und Attraktivität gegen Hausmäuse in Raum und Tierstall gemäß § 18 Infektionsschutzgesetz Trial: 203-15-4.3/HM	Anonymous[18]	2016

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
32	6.7.	Prüfung der Wirksamkeit von Frunax-D (0,005% Difenacoum) an Hausmäusen im Biotopversuch auf dem Futterboden vom Zoo Magdeburg	Anonymous[18]	2004
33	6.7.	Ergebnisbericht über die nach §18 Infektionsschutzgesetz durchgeführten Laboruntersuchungen zur rodentiziden Wirksamkeit des von der frunol delicia GmbH, Dübener Str. 137, 04509 Delitzsch eingereichten, handels- und auslegefertigen Fertigköders "frunax DS contra Ratten" (B-0172-00-00) Trial 3 of 3	Anonymous[18]	2004
34	6.7.	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Hausmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.2/HM	Anonymous[18]	2017
35	6.7.	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Hausmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.3/HM	Anonymous[18]	2017
36	6.7.	Gutachterliche Äußerung über "Ratron-Granulat" Trial 3 of 7	Anonymous[18]	1999
37	6.7.	Gutachterliche Äußerung über "Ratron-Granulat" Trial 4 of 7	Anonymous[18]	1999
38	6.7.	Prüfung der Wirksamkeit von Delicia Ratron - Granulat an Wanderrattenrudeln und Mäusegruppen in Wahlversuchen Trial 3 of 4	Anonymous[18]	1999
39	6.7.	Gutachterliche Äußerung über "Ratron-Granulat" Trial 5 of 7	Anonymous[18]	1999
40	6.7.	Gutachterliche Äußerung über "Ratron-Granulat" Trial 6 of 7	Anonymous[18]	1999
41	6.7.	Gutachterliche Äußerung über "Ratron-Granulat" Trial 7 of 7	Anonymous[18]	1999
42	6.7.	Bericht zur Amtlichen Prüfung von Pflanzenschutzmitteln (MUSXMU; Ratron-Granulat)	Anonymous[18]	2006
43	6.7.	Bericht zur Amtlichen Prüfung von Pflanzenschutzmitteln (Musxmu; Ratron-Granulat)	Anonymous[18]	2003
44	6.7.	Ergebnisbericht über die nach §18 Infektionsschutzgesetz durchgeführten Laboruntersuchungen zur rodentiziden Wirksamkeit des von der frunol delicia GmbH, Dübener Str. 137, 04509 Delitzsch eingereichten, handels- und auslegefertigen Fertigköders "frunax DS contra Ratten" (B-0172-00-00) Trial 2 of 2	Anonymous[18]	2004

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year
45	6.7.	Ergebnisbericht - Ratron Granulat(B-0143-00-00) Trial 3 of 4	Anonymous[18]	2004
46	6.7.	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen HAusratten in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.2/HR	Anonymous[18]	2017
47	6.7.	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen HAusratten in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial 203-16-8.3/HR	Anonymous[18]	2017

4.2 List of studies for the active substance(s)

4.2.1 Difenacoum

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[19]) of the active substance Difenacoum for use in rodenticides (product-type 14). Please, refer to the corresponding Assessment Report for a reference list.

19 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

Exposure assessment