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	Ratron Granulat 25 ppm
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-AJ037307-49
Asset No. in R4BP	DE-0019298-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/14.00026 710-05-14-00026-00-00-00-0000
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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, “Ratron Granulat 25 ppm” with the active substance brodifacoum (0.0025 % w/w) is used as a rodenticide (product-type 14) for the control of house mice, Norway/brown rats, house/black rats and bank voles. Mice and voles are to be controlled indoors and outdoors. While rats are to be controlled indoors, outdoors (around buildings as well as open areas and waste dumps) and Norway/brown rats 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. Only the authorisation for the use by non-professional users cannot be granted.

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 Dutch Assessment Report for the approval of the active substance Brodifacoum 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) Brodifacoum (COMMISSION IMPLEMENTING REGULATION (EU) 2017/1381).

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

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[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 brodifacoum in the products shall not exceed 50 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 may be authorised for use in pulse baiting treatments;
(4) Products shall not be authorised for use in permanent baiting treatments;
(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 “Ratron Granulat 25 ppm” contains the active substance brodifacoum.
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 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 professional and non-professional users cannot be granted.

Comparative Assessment

Since the active substance brodifacoum has been identified as a candidate for substitution (see also chapter 2.2.4) a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 17.07.2020.

The German CA concludes that without brodifacoum 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

Ratron Granulat 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	Brodifacoum
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 (%)
Brodifacoum	3-[3-(4'-Brombiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycumarin	Active substance	56073-10-0	259-980-5	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.

2.2.4 Candidate(s) for substitution

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

- Brodifacoum

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

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

- toxic for reproduction category 1A;
- PBT.

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

Brodifacoum does meet the following criteria for substitution:

- Persistent and very persistent, Bio accumulative and Toxic

2.2.5 Type of formulation

Ready-to-use granular bait

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

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

The current harmonised classification of the active substance brodifacoum is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):
The current harmonised classification of the active substance brodifacoum is based on Commission Regulation (EU) No. 2016/1179 (9th ATP):[4]

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.

4 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).
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 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 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[5]

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); House/Black rats, *Rattus rattus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Mouse: 40 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: 40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag) Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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.

5 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.

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 – House 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); House/Black rats, *Rattus rattus* (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: 40 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: 40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag) Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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); House/Black rats, *Rattus rattus* (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	40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag) Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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. 4) Outdoor open areas: • 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)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket;

	25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag) Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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 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

2.4.5 Use 5 appropriate for authorisation – Voles - trained professional - indoor / outdoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Bank vole, *Myodwes glareolus* (Juveniles and adults).
Field(s) of use	Indoor, outdoor
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	40 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	Trained professional
Pack sizes and packaging material	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag (Package with loose granular bait is restricted to separately packed bags with a maximum of 10 kg per packed bag) Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

2.4.5.1 Use-specific instructions for use

1)	Remove and dispose all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
2)	Protect bait from the weathering (e.g. rain, snow, etc.). Place the baiting points in areas not liable to flooding.
3)	Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

2.4.5.2 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.
7) Do not apply this product directly in the burrows.

2.4.5.3 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

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

See chapter 2.5

2.4.5.5 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) 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).

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) Do not open the sachets containing the bait.

23) Place loose bait in the bait station 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.

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

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 months

2.5.6 Other information

1) The product contains a bittering agent and a dye.
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) 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.

2.6 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
Foil bags (sachets)	40 g in 200 - 800 g folding box, 40 g in 4 kg bucket	Paper bag coated with LDPE 50/30 (50 g/m^2 paper and 30 g/m^2 LDPE)	-	Trained professional, Professional, Non-professional	Yes
Folding box	500 g to 1 kg	GD2 350 g/m^2	-	Trained professional, Professional, Non-professional	Yes
Barrel	2.5 kg	PE	-	Trained professional, Professional, Non-professional	Yes
Buckets	5.0 to 10 kg	PP	-	Trained professional, Professional	Yes
Bag	25 kg	Lined paper	-	Trained professional, 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);

	House/Black rats, *Rattus rattus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	Mouse: 40 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: 40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.2 Intended use 2 – House 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); House/Black rats, *Rattus rattus* (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: 40 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: 40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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); House/Black rats, *Rattus rattus* (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	40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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	40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.5 Intended use 5 – House mice - professional - 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	40 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.6 Intended use 6 – Rats - professional - 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); House/Black rats, *Rattus rattus* (Juveniles and adults)
Field(s) of use	Indoor
Application method(s)	In bait boxes
Application rate(s) and frequency	40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.7 Intended use 7 – House mice and rats - professional - 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); House/Black rats, *Rattus rattus* (Juveniles and adults)
Field(s) of use	Outdoor around buildings
Application method(s)	In bait boxes
Application rate(s) and frequency	Mouse: 40 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: 40 - 200g 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag

	Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.8 Intended use 8 – Mice, rats and voles - general public

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); House/Black rats, *Rattus rattus* (Juveniles and adults); Common vole, *Microtus arvalis* (Juveniles and adults); Bank vole, *Myodwes glareolus* (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	Mouse and voles: 40 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: 40 - 200g 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	40 g sachet in 200-800 g folding box; 40 g sachet in 4 kg bucket; 500 g-1 kg folding box; 2.5 kg barrel Sachets: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², barrel: PE

3.1.9 Intended use 9 – Voles - professional - indoor / outdoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Common vole, *Microtus arvalis* (Juveniles and adults); Bank vole, *Myodwes glareolus* (Juveniles and adults).
Field(s) of use	Indoor, outdoor
Application method(s)	In bait boxes; covered and protected baiting

Application rate(s) and frequency	40 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	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

3.1.10 Intended use 10 – Voles - trained professional - indoor / outdoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Common vole, *Microtus arvalis* (Juveniles and adults); Bank vole, *Myodwes glareolus* (Juveniles and adults).
Field(s) of use	Indoor, outdoor
Application method(s)	In bait boxes; covered and protected baiting
Application rate(s) and frequency	40 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	Trained professional
Pack sizes and packaging material	40 g sachets in 200-800 g folding box; 40 g sachets in 4 kg bucket; 500 g - 1 kg folding box; 2.5 kg barrel; 5-10 kg bucket; 25 kg bag Sachet: paper bag coated with LDPE (50 g/m2 paper and 30 g/m2 LDPE), folding box: GD2 350g/m², buckets: PP, barrel: PE; bag (lined paper bag)

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 inspection	Test substance: Ratron Granulat, batch no: 102.316, specification: 0.005 % w/w brodifacoum	Rod-shaped homogeneous granules of 2-3 mm length and about 2 mm in diameter	Anonymous. 2012, Study Report No S11-03651
Colour at 20 °C and 101.3 kPa	Visual inspection	Test substance: Ratron Granulat, batch no: 102.316, specification: 0.005 % w/w brodifacoum	Red	Anonymous. 2012, Study Report No S11-03651
Odour at 20 °C and 101.3 kPa	Olfactory inspection	Test substance: Ratron Granulat, batch no: 102.316, specification: 0.005 % w/w brodifacoum	Weak cereal-like odour immediately after opening	Anonymous. 2012, Study Report No S11-03651
Acidity / alkalinity	CIPAC MT 75.3	Test substance: Ratron Granulat, batch no: 102.316, specification: 0.005 % w/w brodifacoum	pH of a 1% aqueous liquid suspension: 6.40 The acidity/alkalinity was not determined, because the pH was in the range of 4-10.	Anonymous. 2012, Study Report No S11-03651
Relative density / bulk density	CIPAC MT 186	Test substance: Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Pour density: 0.78 g ml^{-1}, tap density (50 taps): 0.80 g ml^{-1}	Anonymous. 2011, Study Report No S11-03649

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 75.3 CIPAC MT 170 CIPAC MT 171 CIPAC MT 178	Test substance: Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Storage stability investigated at 40 °C for 8 weeks Content of active ingredient (brodifacoum) Before storage: 50.1 mg/kg After 8 weeks: 50.6 mg/kg (+ 1.0 %) pH of a 1 % aqueous liquid suspension Before storage: 6.40 After 8 weeks: 6.28 Dustiness Before storage: The test item was found to be nearly dust free. The weight of the dust, determined gravimetrically, was 0.5 mg (≤ 0.002% of the weighed sample). After 8 weeks of storage: The test item was found to be nearly dust free. The weight of the dust, determined gravimetrically, was 0.0 mg. Friability/Attrition before and after 8 weeks of storage:	Anonymous. 2012, Study Report No S11-03652

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			The mean attrition resistance of two tests was determined to be 100 %. Therefore the test item should be considered as stable against attrition. Dry sieve analysis 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 = 2000 µm; Rx ≥ 90% x2 = 3350 µm; Rx ≤ 10%. Before storage: Loss of dust during Sieving was calculated as 0.01 % of the weight. The sum of the dust fractions passing through the 250 µm sieve was determined as 0.03 % of the weight, corresponding to 0.03 g/kg dust. Fine particles of < 100 µm diameter were detected as 0.02 % of the weight, corresponding to 0.02 g/kg dust. Fine particles of < 50 µm diameter were detected as	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			0.02 % of the weight, corresponding to 0.02 g/kg dust. After storage at 40 °C for 8 weeks: Loss of dust during sieving was not calculated. The sum of the dust fractions passing through the 250 µm sieve was determined as 0.02 % of the weight, corresponding to 0.2 g/kg dust) Fine particles of ≤ 100 µm diameter were detected as 0.01 % of the weight, corresponding to 0.10 g/kg dust. Fine particles of ≤ 50 µm diameter were not detected. There was no visible damage or deterioration to the commercial packaging or to the test item after storage. A loss in weight of ≤ 9.0 % was found after 8 weeks of storage. The colour, odour and appearance of the test item were unchanged.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 75.3 CIPAC MT 170 CIPAC MT 171 CIPAC MT 178	Test substance: Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Storage stability investigated at 20 °C for 24 months Content of active ingredient (brodifacoum) Before storage: 50.1 mg/kg After 24 months: 50.2 mg/kg (+ 0.2 %) pH of a 1 % aqueous liquid suspension Before storage: 6.40 After 24 months: 6.36 Dustiness Before storage: The test item was found to be nearly dust free. The weight of the dust, determined gravimetrically, was 0.5 mg (≤ 0.002% of the weighed sample). After 24 months of storage: The test item was found to be nearly dust free. The weight of the dust, determined gravimetrically, was 0.2 mg. Friability/Attrition before and after 24 months of storage:	Anonymous. 2015, Study Report No S11-03653

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			The mean attrition resistance of two tests was determined to be 100 %. Therefore the test item should be considered as stable against attrition. Dry sieve analysis 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 = 2000 µm; Rx ≥ 90% x2 = 3350 µm; Rx ≤ 10%. Before storage: Loss of dust during Sieving was calculated as 0.01 % of the weight. The sum of the dust fractions passing through the 250 µm sieve was determined as 0.03 % of the weight, corresponding to 0.03 g/kg dust. Fine particles of < 100 µm diameter were detected as 0.02 % of the weight, corresponding to 0.02 g/kg dust. Fine particles of < 50 µm diameter were detected as	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			0.02 % of the weight, corresponding to 0.02 g/kg dust. After storage at 20 °C for 24 months: Loss of dust during sieving was found. The sum of the dust fractions passing through the 250 µm sieve was determined as 0.03 % of the weight, corresponding to 0.3 g/kg dust) Fine particles of ≤ 100 µm diameter were detected as 0.01 % of the weight, corresponding to 0.10 g/kg dust. Fine particles of ≤ 50 µm diameter were not detected. There was no visible damage or deterioration to the commercial packaging or to the test item after storage. A loss in weight of ≤ 4.43 % was found after 24 months of storage. The colour, odour and appearance of the test item were unchanged.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **low temperature stability test for liquids**			Data waiver: Not required for ready-to-use granular bait	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Data waiver: Ratron Granulat 25 ppm is stored and transported in light-tight foil bags or plastic buckets and therefore during storage and transport not exposed to UV light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Please see the storage stability tests.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging material is sufficient.	Dangerous Goods Database http://www.dgg.bam.de/en/ BAM-Nr.: 6316-6318
Wettability			Data waiver: Ready-to-use granular bait is not dispersed in water	Waiving[6]

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

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Suspensibility, spontaneity and dispersion stability			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Wet sieve analysis and dry sieve test			For dry sieve analysis please see the storage stability tests. Data waiver: Wet sieve analysis not required for ready-to-use granular bait	 Waiving[6]
Emulsifiability, re-emulsifiability and emulsion stability			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Disintegration time			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Particle size distribution, content of dust/fines, attrition, friability			Please see the storage stability tests.	
Persistent foaming			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Flowability/Pourability/Dustability	CIPAC MT 172	Test substance: Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	For dustability please see the storage stability tests. Flowability: Before storage: No caking was observed. All of the test item passed through the sieve after 3	Anonymous. 2015, Study Report No S11-03648

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			liftings. The unstored test item is considered to be free flowing. After storage at 40°C for 8 weeks under pressure (25 g/cm^2): Caking was observed. After 5 liftings 44.583 g (92.5 %), after 20 liftings 47.261 g (98.0 %) of 48.217 g test item (1.825 g loss in weight by evaporation) passed through the sieve.	
Burning rate — smoke generators			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Burning completeness — smoke generators			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Composition of smoke — smoke generators			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Spraying pattern — aerosols			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Physical compatibility			Data waiver: Not intended to be applied in combination with other products	Waiving[6]
Chemical compatibility			Data waiver: Not intended to be applied in	Waiving[6]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			combination with other products	
Degree of dissolution and dilution stability			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Surface tension			Data waiver: Not required for ready-to-use granular bait	Waiving[6]
Viscosity			Data waiver: Not required for ready-to-use granular bait	Waiving[6]

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 in the confidential annex. The biocidal product consists of red rod-shaped homogeneous granules. The pH of the product is 6.40 and the pour density: 0.78 g mL^{-1}. The requested long-term storage test with “Ratron Granulat 25 ppm” is still ongoing and no test results are available at the moment. However, the long-term stability test with “Ratron Granulat” shows no degradation of the actives substance and no other significant changes of the product and the packaging after 24 months. Therefore, a shelf life of 12 months can be granted for “Ratron Granulat 25 ppm”.

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)	Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Exothermic decomposition energy: 422 J/g (1) 458J/g (2) Decomposition temperature (T_{onset}): 220 °C	Not classified based on GHS/CLP criteria	Anonymous, 2011, Study Report No. 20110389.02
Flammable gases	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving [7]
Flammable aerosols	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
Oxidising gases	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
Gases under pressure	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]

[7] 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
Flammable liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
Flammable solids	Regulation (EC) No 440/2008, EU Method A.10	Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Preliminary test: The test item could not be ignited with a flame.	Not classified based on GHS/CLP criteria	Anonymous, 2011, Study Report No 20110389.01
Self-reactive substances and mixtures	study scientifically not necessary			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.	Waiving[7]
Pyrophoric liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
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.	Waiving[7]
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)

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
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.	Waiving[Fehler! Textmarke nicht definiert.]
Oxidising liquids	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
Oxidising solids	Regulation (EC) No 440/2008, Method A.17	Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Mean burning time: 190 s (mixture of test item and cellulose)) 170 s (reference mixture)	.Not classified based on GHS/CLP criteria	Anonymous, 2011, Study Report No 20110389.04
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.	Waiving[7]
Corrosive to metals	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]
Auto-ignition temperature (liquids and gases)	study scientifically unjustified			The study does not need to be conducted because the product is a solid.	Waiving[7]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Relative self-ignition temperature for solids	Regulation (EC) No 440/2008, Method A.16	Ratron Granulat, batch no: 102.326, specification: 0.005 % w/w brodifacoum	Relative self-ignition temperature: no	No self-ignition observed under the test conditions up to 400 °C	Anonymous, 2011, Study Report No 20110389.03
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.	Waiving[7]

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 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**		
Active substance: Brodifacoum	Solid-liquid extraction & HPLC with UV diode array detection	Specificty was demonstrated.	5.0 – 30.0 mg kg^{-1} = 0.0005 – 0.003 % y = 80.2 L mg^{-1} x + 6.42 R^2 > 0.996	5 measurements RSD = 1.43 % RSD_{max} according to Horwitz: 6.65 % RSD < RSD_{max} Repeatability demonstrated	87.5 – 95.2 at 10 mg kg^{-1} 91.0 – 93.2 at 25 mg kg^{-1}	91.3 91.9	4.22 1.31	In the study the LOQ was defined as the lowest fortified concentration, i. e. 10 mg kg^{-1} = 0.001 %	Longhi, D. 2018, Study Report No BPL-STUDY-18-000070be Longhi, D. 2019, Amendment 1 to the Report No BPL-STUDY-18-000070

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Brodifacoum	0.05 mg/kg	Common limit
Drinking water	Brodifacoum	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Brodifacoum	0.04 µg/L	$PNEC_{aquatic\ organism}$ based on ErC_{50} for algae and LC_{50} for fish (AF 1000), CAR Activa/Pelgar, DocIIA, 4.2.6; 07/2007 $PNEC_{aquatic\ organism}$ based on LC_{50} for fish (AF 1000), CAR Syngenta, DocIIA, 4.2.1; 10/2009
Air	Not required since vapour pressure << 10^{-6} Pa, not sprayed	-	AR Renewal, LoEP, 09/2016
Animal and human body fluids and tissues	Brodifacoum	0.05 mg/L for body fluids 0.1 mg/kg for body tissues	classified as very toxic (T+); AR Renewal, LoEP, 09/2016
Food of plant origin	None since contamination of food and feeding stuff can be excluded.	-	AR Renewal, LoEP, 09/2016
Food of animal origin	None since contamination of food and feeding stuff can be excluded.	-	AR Renewal, LoEP, 09/2016

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**		
brodifacoum	LC-MS/MS, C18 column, ESI-; m/z 521→187	SIM mode and SRM mode: R = 0.99523 and 0.99747, respectively	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	83 - 92	87.8	3.8	0.05 µg/L	Martinez, 2005 CAR, Doc IIIA 4.2 (c)
				0.5 µg/L / 5	77 - 94	82.5	7.2		
				5.0 µg/L / 5	72 - 95	81.7	9.8		
				50 µg/L / 5	83 - 108	97.8	10.6		

Table 12

Analytical methods for soil									
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**		
brodifacoum	LC-MS/MS, C18 column, ESI-; m/z 521→135; 521→142	LC-MS/MS with two transitions	1 – 50 ng/mL that means 0.005 – 0.25 mg/kg in sample; linear, r>0.99	<u>Sandy loam</u> m/z 521→135 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 521→143 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Clay</u> m/z 521→135 0.01 mg/kg / 5 0.1 mg/kg / 5 m/z 521→143 0.01 mg/kg / 5 0.1 mg/kg / 5	 79 - 90 82 - 94 73 – 92 83 - 94 71 - 79 74 - 77 80 – 94 79 - 86	 85 88 81 88 74 75 87 82	 5.1 4.8 9.4 5.2 4.0 1.7 6.7 3.3	0.01 mg/kg	Allen, 2011 AR Renewal, LoEP, 09/2016;

Table 13

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**		
brodifacoum	LC-MS/MS, C18 column, ESI-; m/z 521→187	SIM mode and SRM mode: R = 0.99523 and 0.99747, respectively	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	116 - 124 79 - 88 78 - 99 104 - 112	121 85 87 111	2.9 4.5 7.8 3.6	0.5 µg/L	Martinez, 2005 CAR, Doc IIIA 4.2 (c)

Table 14

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**		
brodifacoum	LC-MS/MS, C18 column, ESI+; m/z 523→187	no interferences	0.5 – 4.0 µg/mL that means 0.05 – 0.4 mg/L in sample; linear, r>0.99	Blood serum 0.06 mg/L / 5 0.3 mg/L / 5	81 -97 86 - 109	92 102	6.5 8.6	0.06 mg/L	Garofani, 2008 CAR, Doc IIIA 4.2 (d)
brodifacoum	LC-MS/MS, C18 column, ESI+; m/z 523→79		0.03 – 1.2 µg/mL linear, R^2: 0.9095 – 0.9963	Meat 0.01 mg/kg / 5 0.1 mg/kg / 5	81 -97 86 - 109	73 61	13 29	0.01 mg/kg	Turnbull, 2005 CAR, Doc IIIA 4.2 (d) (1)

Table 15

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, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
brodifacoum	LC-MS/MS, C18 column, ESI+; m/z 523→79		0.03 – 1.2 µg/mL linear, R^2: 0.9095 – 0.9963	<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>Oilseed rape</u> 0.01 mg/kg / 5 0.1 mg/kg / 5 <u>Lemon</u> 0.01 mg/kg / 5 0.1 mg/kg / 5	 82 -103 86 - 106 88 -126 71 – 90 75 -99 110–134 74 -93 62 - 89	 91 94 107 84 86 119 84 76	 9 9 13 9 10 8 10 13	0.01 mg/kg	Turnbull, 2005 CAR, Doc IIIA 4.3

Table 16

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**		
brodifacoum	LC-MS/MS, C18 column, ESI+; m/z 523→79		0.03 – 1.2 µg/mL linear, R^2: 0.9095 – 0.9963	Meat 0.01 mg/kg / 5 0.1 mg/kg / 5	81 -97 86 - 109	73 61	13 29	0.01 mg/kg	Turnbull, 2005 CAR, Doc IIIA 4.3

Table 17

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

Table 18

Conclusion on the methods for detection and identification
The methods provided regarding the residues of brodifacoum in soil, in drinking and surface water, in body fluids and tissues, and in food and feed of plant and animal origin were acceptable. Methods regarding substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

“Ratron Granulat 25 ppm” is a rodenticide (PT14). It contains 0.0025% Brodifacoum. The product is a ready-to-use granular bait product, which consists of oat flakes, and should be applied in bait boxes.

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

“Ratron Granulat 25 ppm” is intended to be used for the control of commensal rodents: rats (*Rattus norvegicus* and *Rattus rattus*), house mouse (*Mus musculus*) and voles (*Myodes glareolus* and *Microtus arvalis*) in and around buildings by professionals (trained and non-trained) and the general public. Rats should be also controlled in outdoor open areas, waste dumps and sewers by trained professionals.
However, the efficacy of the product “Ratron Granulat 25 ppm” was not demonstrated against common voles (*Microtus arvalis*).

3.5.3 Effects on target organisms, including unacceptable suffering

Brodifacoum inhibits the vitamin K1-epoxide cycle, thereby interrupting the supply of vitamin K1 necessary for producing blood clotting factor precursors.
It is recognised that slow acting anticoagulant rodenticides like Brodifacoum do cause pain for several days in rodents. As rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage, it is considered that these active substances should still be used until better alternatives become available. Alternatives would be e.g. less painful biocidal products with a different mode of action, as well as non-biocidal alternatives.

3.5.4 Mode of action, including time delay

Brodifacoum is a 4-hydroxycoumarin derivate with a second generation anticoagulant action. Brodifacoum inhibits the vitamin K1-epoxide cycle, thereby interrupting the supply of vitamin K1 necessary for producing blood clotting factor precursors. The effect is cumulative in nature. Haemorrhaging and subsequent death is the only effect observed in acute and repeated-dose toxicity tests. Prolongation of prothrombin time is usually observed before clinical signs of toxicity.

3.5.5 Efficacy data

The applicant provided efficacy studies (see Table 19), most of them conducted with a product containing 0.005% of the active substance Brodifacoum instead of 0.0025%. For details please consider chapter **Fehler! Verweisquelle konnte nicht gefunden werden.** in the confidential annex.

As the application for the product “Ratron Granulat 25 ppm“ was submitted in January 2018 the efficacy evaluation is based on the Technical Notes for Guidance on Product Evaluation Appendices to Chapter 7, Product Type 14 Efficacy Evaluation of Rodenticidal Biocidal Products (2009). In accordance with the TNsG (2009; chapter 6.2) only a field or a semi-natural trial is required. However, for the renewal a field trial with the product “Ratron Granulat 25 ppm” is required for house mice, brown rats, black rats and bank voles (TNsG 2016).

House mice (*Mus musculus*):
With house mice two no-choice, and two semi-natural choice and 5 field trials all conducted with the product “Ratron Granulat“ (50 ppm), which contains the double amount of the active substance Brodifacoum, were submitted. Furthermore, two semi-natural trials with the product “Ratron Granulat 25 ppm” showed a mortality of 100% and a palatability of 24 and 25%.
Therefore, the submitted studies are suitable to prove the efficacy of the product “Ratron Granulat 25 ppm” against house mice (in accordance to the TNsG 2009).

Brown Rats (*R. norvegicus*)
For Norway rats one no-choice, three semi-natural choice and three field trials all conducted with the product “„Ratron Granulat“ (50 ppm), which contains the double amount of the active substance Brodifacoum, were submitted. These studies demonstrated a mortality of >90%. Furthermore, in two semi-natural trials each with the product “Ratron Granulat 25 ppm” a mortality of 100% and a palatability of 25 to 30% with the fresh and 15 to 23% with the product stored under damp conditions was proven.
Therefore, the submitted studies are suitable to prove the efficacy of the product “Ratron Granulat 25 ppm” against Norway rats also in sewers (in accordance to the TNsG 2009).

Black Rats (*R. rattus*)
With Black rats one no-choice and three semi-natural choice trials all conducted with the product “„Ratron Granulat“ (50 ppm), which contains the double amount of the active substance Brodifacoum, were submitted. Furthermore, two semi-natural trials with the product “Ratron Granulat 25 ppm” showed a mortality of 100% and a palatability of 27 and 35%.
Therefore, the submitted studies are suitable to prove the efficacy of the product “Ratron Granulat 25 ppm” against Black rats (in accordance to the TNsG 2009).

Bank vole (*M. glareolus*):

With bank voles one no-choice and one choice trial with individually caged individuals all conducted with the product "„Ratron Granulat" (50 ppm), which contains the double amount of the active substance Brodifacoum, were submitted. Furthermore, one choice test with individually caged individuals and one semi-natural trial with the product "Ratron Granulat 25 ppm" showed a mortality of 100% and a palatability of 34.8% for individually caged and of 4 to 10% for grouped voles.

Therefore, the submitted studies are suitable to prove the efficacy of the product "Ratron Granulat 25 ppm" against bank voles (in accordance to the TNsG 2009).

Common vole (*M. arvalis):*

One no-choice and two choice trials with individually caged common voles all conducted with the product "„Ratron Granulat" (50 ppm), which contains the double amount of the active substance Brodifacoum, were submitted.

No laboratory choice-trial with individually caged individuals and no field trial or semi-natural choice trial with the product "Ratron Granulat 25 ppm" was submitted. In accordance with the TNsG (2009, chapter 2) "for each target organism that is claimed on the label, a study should be conducted" and a read across between bank voles and common voles is unacceptable.

Therefore, the efficacy against common voles is not proven for the product "Ratron Granulat 25 ppm".

Table 19

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**	**Reference**
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	No-Choice trial: Semi-natural trial (= pen test)	- test animals: group of 20 (11:9) mice - test room: 6.2 m² - acclimatisation: 7 days - exposure period: 18 days	- mortality: 100% after 15 days	Anonymous 1999 (V 1.8-8460-C 46b/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	No-Choice trial: Semi-natural trial (= pen test)	- test animals: group of 10 (5:5) mice - test room: 1 m² - exposure period: 7 days	- mortality: 100% after 7 days	Anonymous 1999 (V 1.8-8460-C 46b/97)
Rodenticide	Rat, mouse and vole control in and around buildings;	„Ratron Granulat“ (50 ppm)	*M. musculus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 19 (10:9) mice - test room: 6.2 m² - acclimatisation: 7 days	- mortality: 100% after 18 days	Anonymous 1999 (V 1.8-8460-C 46b/97)

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**	**Reference**
	Rats in outdoor open areas, waste dumps and sewers				- exposure period: 18 days - challenge diet: oat flakes		
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 10 (5:5) mice - test room: 0.48 m² - acclimatisation: 7 days - exposure period: 7 days - challenge diet: wheat grains	- mortality: 100% after 7 days	Anonymous 1999 (V 1.8-8460-C 46b/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	Field trial in a zoo in Germany	- pre-baiting period: 1 day - baiting period: 28 days -post-baiting period: 14 days	- population reduction: 98%	Anonymous 1999 (V 1.8-8460-C 46b/97)

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**	**Reference**
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	Field trial in a backery in Germany	- pre-baiting period: 1 day - baiting period: 27 days - post-baiting period: 14 days	- population reduction: 100%	Anonymous 1999 (V 1.8-8460-C 46b/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	Field trial in a cellar in Germany	- pre-baiting period: 1 day - baiting period: 42 days - post-baiting period: 14 days	- population reduction: 100%	Anonymous 1999 (V 1.8-8460-C 46b/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas,	„Ratron Granulat“ (50 ppm)	*M. musculus*	Field trial in a pig farm in Germany	- pre-baiting period: 1 day - baiting period: 28 days	- population reduction: 100%	Anonymous 2003 (OL_030428)

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**	**Reference**
	waste dumps and sewers						
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. musculus*	Field trial in a pig farm in Germany	- pre-baiting period: 1 day - baiting period: 36 days	- population reduction: 90%	Anonymous 2006 (OL/RV 06/13)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	Ratron Granulat 25 ppm	*M. musculus*	Choice trial: Semi-natural trial (= pen test)	- test animals: two groups each of 20 (9:11) and (10:10) mice - test room: 5 m² with 2 hiding boxes - acclimatisation: 3 days - exposure period: 28 days - challenge diet: oak flakes - replicates: 2	- mortality: 100% after 20 days - bait uptake: 23.8 – 24.9%	Anonymous 2017 (203-16-8.2/HM_203-16-8.3/HM)
Rodenticide	Rat, mouse and vole control in and around buildings;	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	No-Choice trial: Semi-natural trial (= pen test)	- test animals: group of 10 (4:6) rats - test room: 1 m² - exposure period: 7 days	- mortality: 100% after 7 days	Anonymous 1999 (V 1.8-8460-C 46a/97)

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**	**Reference**
	Rats in outdoor open areas, waste dumps and sewers						
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 10 (4:6) rats - test room: 1 m² - exposure period: 7 days - challenge diet: wheat grains	- mortality: 100% after 7 days	Anonymous 1999 (BWR 08/03)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Choice trial: Semi-natural trial (= pen test)	- test animals: two groups each of 10 (5:5) and 6 (2:4) rats - test room: 6.2 m² - acclimatisation: 6 days - exposure period: 14 days -post-baiting period: 5 days - challenge diet: wheat grains - replicates: 2	- mortality: 50% after 14 days - mortality: 100% after 6 days	Anonymous 1999 (BWR 08/03)

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**	**Reference**
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Field trial on a small animal husbandry parcel in Germany	- pre-baiting period: 1 day - baiting period: 5 days -post-baiting period: 2 days	- population reduction: 100%	Anonymous 1999 (V 1.8-8460-C 46a/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Field trial in a zoo in Germany	- pre-baiting period: 1 day - baiting period: 14 days -post-baiting period: 14 days	- population reduction: 100%	Anonymous 1999 (V 1.8-8460-C 46a/97)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas,	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Field trial in a cellar in Germany	- pre-baiting period: 1 day - baiting period: 14 days -post-baiting period: 14 days	- population reduction: 100%	Anonymous 1999 (V 1.8-8460-C 46a/97)

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**	**Reference**
	waste dumps and sewers						
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. norvegicus*	Field trial on a small animal husbandry parcel in Germany	- pre-baiting period: 7 days - baiting period: 35 days -post-baiting period: 7 days	- population reduction according to census bait: 97%	Anonymous 2004 (BWR 08/03)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	Ratron Granulat 25 ppm (stored under damp conditions)	*R. norvegicus*	Choice trial: Semi-natural trial (= pen test)	- product and challenge diet: stored for 5 days under warm (29 - 30 °C) and damp (85 - 95%r.h.) conditions prior to testing - test animals: group of 8 (4:4; 6:2) wild strain rats - test room: 6 - 6.3 m² with 4 hiding boxes - acclimatisation: 3 days - exposure period: 14 days - challenge diet: wheat grains - replicates: 2	- mortality: 100% after 11 days - bait uptake: 15.0 – 22.7%	Anonymous 2017a (203-16-8.2/KA; 203-16-8.3/KA)

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**	**Reference**
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	Ratron Granulat 25 ppm	*R. norvegicus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 8 (4:4) wild strain rats - test room: 6 - 6.3 m² with 4 hiding boxes - acclimatisation: 3 days - exposure period: 14 days - challenge diet: wheat grains - replicates: 2	- mortality: 100% after 9 days - bait uptake: 25.0 – 29.6%	Anonymous 2017b (203-16-8.2/WR; 203-16-8.3/WR)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*R. rattus*	No-Choice trial: Semi-natural trial (= pen test)	- test animals: group of 11 (7:4) wild strain rats - test room: 5.0 m² - acclimatisation: 3 days - exposure period: 9 days	- mortality: 100% after 9 days	Anonymous 2004 (HR160904)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas,	„Ratron Granulat“ (50 ppm)	*R. rattus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 12 (6:6), 10 (7:3), 10 (5:5) wild strain rats - test room: 5.0 m² - acclimatisation: 3 days - exposure period: 28 days	- mortality: 66.7% after 42 days - mortality: 60% after 42 days - mortality: 100% after 16 days	Anonymous 2004 (HR160904)

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**	**Reference**
	waste dumps and sewers				-post-baiting period: 14 days - challenge diet: wheat grains - replicates: 3		
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	Ratron Granulat 25 ppm	*R. rattus*	Choice trial: Semi-natural trial (= pen test)	- test animals: group of 9 (5:4) and 8 (4:4) wild strain rats - test room: 6.3 m² with 4 hiding boxes - acclimatisation: 3 days - exposure period: 28 days -post-baiting period: 14 days - challenge diet: wheat grains - replicates: 2	- mortality: 100% after 16 days - palatability: 27.2 – 35%	Anonymous 2017 (203-16-8.2/HR; 203-16-8.3/HR)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. glareolus*	No-Choice trial	- test animals: 10 (5:5) individually caged - test cages: 55 x 34 x 20 cm - acclimatisation: 3 days - exposure period: 14 days -post-baiting period: 10 days	- mortality: 100% after 18 days	Anonymous 2013 (203-13-2.1/RM)

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**	**Reference**
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. glareolus*	Choice trial	- test animals: 10 (5:5) individually caged - test cages: 55 x 34 x 20 cm - acclimatisation: 3 days - exposure period: 21 days -post-baiting period: 10 days - challenge diet: sunflower seeds	- mortality: 100% after 9 days - palatability: 28.9%	Anonymous 2013 (203-13-2.2/RM)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	Ratron Granulat 25 ppm	*M. glareolus*	Choice trial	- test animals: 20 (10:10) individually caged - test cages: 55 x 34 x 20 cm - acclimatisation: 3 days - exposure period: 14 days -post-baiting period: 14 days - challenge diet: sunflower seeds	- mortality: 100% after 24 days - palatability: 34.8%	Anonymous 2017 (203-16-8.3/RM)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas,	Ratron Granulat 25 ppm	*M. glareolus*	Choice trial: Semi-natural trial (= pen test)	- test animals: 20 (10:10) - test room: 6 m² - acclimatisation: 3 days - exposure period: 14 days -post-baiting period: 14 days	- mortality: 100% after 15 days - palatability: 4.1 – 10.4%	Anonymous 2019 (203-19-2.6/RM; 203-19-2.7/RM; 203-19-2.8/RM; 203-19-2.9/RM)

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**	**Reference**
	waste dumps and sewers				- challenge diet: rye, naked oats, sunflower seeds - replicates: 4		
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. arvalis*	No-Choice trial	- test animals: 10 (5:5) individually caged - test cages: 55 x 34 x 20 cm - acclimatisation: 3 days - exposure period: 14 days -post-baiting period: 14 days	- mortality: 100% after 11 days	Anonymous 2013 (203-13-2.1/FM)
Rodenticide	Rat, mouse and vole control in and around buildings; Rats in outdoor open areas, waste dumps and sewers	„Ratron Granulat“ (50 ppm)	*M. arvalis*	Choice trial	- test animals: 10 (5:5) individually caged - test cages: 55 x 34 x 20 cm - acclimatisation: 3 days - exposure period: 21 days -post-baiting period: 10 days - challenge diet: rye, naked oats, sunflower seeds - replicates: 2	- mortality: 90 - 100% after 18 days - palatability: 22.4 – 24%	Anonymous 2013 (203-13-2.2/FM; 203-13-2.3/FM)

3.5.6 Occurrence of resistance and resistance management

Neither clear scientific evidence exists that the target organisms have developed resistance against brodifacoum nor that rats, mice and voles which are resistant against first generation anticoagulants like warfarin show a decreased susceptibility for brodifacoum in a product concentration of 0.0025 %.

3.5.7 Known limitations

Good palatability is crucial for sufficient bait uptake. The product “Ratron Granulat 25 ppm” showed a good palatability in the laboratory choice trials and mortality rates of >90%. Therefore, it can be expected that the bait uptake will be sufficient also when used under field conditions.

3.5.8 Evaluation of the label claims

The efficacy of the product “Ratron Granulat 25 ppm” is proven for the control of commensal rodents: rats (*Rattus norvegicus* and *Rattus rattus*), house mouse (*Mus musculus*) and bank voles (*Myodes glareolus*). For Norway rats the efficacy in sewers was also demonstrated.
Shelf life: As the product contains a preservative a shelf life of two years can be claimed, even if no efficacy studies with the aged product were submitted.

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

The biocidal product is not intended to be used with other biocidal products.

3.5.10 Data waiving and conclusion

Table 20

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	---

Table 21

Conclusion on the efficacy
The efficacy of the product “Ratron Granulat 25 ppm” is proven for the control of commensal rodents: rats (*Rattus norvegicus* and *Rattus rattus*), house mouse (*Mus musculus*) and bank voles (*Myodes glareolus*). For Norway rats the efficacy in sewers was also demonstrated. However, the efficacy of the product “Ratron Granulat 25 ppm” was not demonstrated against common voles (*Microtus arvalis*). Shelf life: As the product contains a preservative a shelf life of two years can be claimed, even if no efficacy studies with the aged product were submitted.

3.6 Risk assessment for human health

Table 22

Brodifacoum	Value	Study	Safety factor
AEL long-term	3.3 x 10^{-6} mg/kg bw/d [1]	Two Generation study; Szakonyi IP (2004); NOAEL= 0.001 mg/kg bw/d	300
AEL medium-term	6.67 x 10^{-6} mg/kg bw/d[1]	Rabbit developmental toxicity study (maternal toxicity); Morris K et al., (1995); NOAEL= 0.002 mg/kg bw/d	300
AEL acute	6.67 x 10^{-6} mg/kg bw/d[1,2]	Rabbit developmental toxicity study (maternal toxicity); Morris K et al., (1995); NOAEL= 0.002 mg/kg bw/d	300

Table 23

Brodifacoum	Value	Reference
Inhalative absorption	100 % [1]	Default value
Oral absorption	> 75 % [1] (gerechnet mit 100 %)	Bratt H (1979); Bratt H et al. (1985); Hawkins et al. (1991); Batten P and Bratt H (1987); Thornley, K F (1996).
Dermal absorption	8 %	Default (4 %) agreed on WG V 2016 and pro rata extrapolation

[1] Based on Assessment-Report, Italy (2010) and Assessment-Report (Renewal IT/NL, 2016): AEL long-term: 0.0033 µg/kg bw/d; AEL medium-term: 0.0067 µg/kg bw/d; AEL acute: 0.0033 µg/kg bw

[2] Two different AEL acute values are given in the AR, Italy (2010) for the companies Syngenta and Activa/Pelgar. As the comparisons of the studies used for AEL derivation revealed that the difference is only based on different dose spacing the AEL acute value of Activa/Pelgar was chosen. For the Renewal procedure a combined AR was prepared and one value was given.

3.6.1 Assessment of effects of the product on human health

3.6.1.1 Skin corrosion and irritation

Table 24

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.” 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 25

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.

3.6.1.2 Eye irritation

Table 26

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 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 27

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.

3.6.1.3 Respiratory tract irritation

Table 28

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 29

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.

3.6.1.4 Skin sensitization

Table 30

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 product 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 31

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.

3.6.1.5 Respiratory sensitization (ADS)

Table 32

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 33

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.

3.6.1.6 Acute toxicity

3.6.1.6.1 Acute toxicity by oral route

Table 34

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 35

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.

3.6.1.6.2 Acute toxicity by inhalation

Table 36

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 37

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.

3.6.1.6.3 Acute toxicity by dermal route

Table 38

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 39

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.

3.6.1.7 Information on dermal absorption

Table 40

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Applicant do 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 41

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

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

Not relevant.

3.6.1.9 Available toxicological data relating to a mixture

Not relevant.

3.6.1.10 Endocrine disrupting properties

According to the assessment report for the renewal of the active substance evaluation brodifacoum 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.

3.6.1.11 Other

According to Annex VI of Regulation (EC) No 1272/2008 brodifacoum 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 brodifacoum 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.

3.6.1.12 Summary of effects assessment

Table 42

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 sensitization (ADS)	Based on information for single ingredients not 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).

3.6.2 Exposure assessment

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

Table 43

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

List of scenarios

Table 44

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	Intended use 1-7, 9 and 10	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	professionals
2	Intended use 1-7, 9 and 10	Application of granular bait in packages up to 10 kg (≤ 10 kg) - Primary exposure of workers resulting from the application of granules into bait boxes and the disposal/cleaning	professionals
3	Intended use 1-7, 9 and 10	Application of granular bait in sachets - Primary exposure of workers resulting from the disposal/cleaning	Professionals
4	Intended use 8	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
5	All intended 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

3.6.2.1.1 Professional exposure

Ratron Granulat 25 ppm is a ready to use granular bait to control rodenticides. The biocidal product contains Brodifacoum (CAS-No. 56073-10-0, 0.0025 %) as the active substance (a.s.).
It is applied by placing the bait into bait boxes (mice: 40 g of bait per bait station and rats: 40 - 200 g of bait per bait station).

The biocidal product is marketed for all applied applications in different package sizes:
40 g granules in sachets; or granules in 500 g - 1 kg folding box, 2.5 kg barrel, 5-10 kg bucket or 25 kg bag.

The exposure to the a.s. is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. 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.
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 ready to use 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 45.

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.

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 45

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. Brodifacoum 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 48. 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. For risk characterisation, see chapter 3.6.3.5.

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) 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 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 46.

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

Table 46

Relevant parameters of Scenario 2 – Application of granular bait in packages up to 10 kg (≤ 10 kg)	
Parameters	Value
Concentration of the a.s. Brodifacoum 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 48. 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. For risk characterisation, see chapter 3.6.3.5.

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.

Scenario 3

The exposure assessment for placing bait sachets is based on model data described in detail in the Biocides Human Health Exposure Methodology Document Version 1 (October 2015). The ready to use bait without opening of the 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 47.

Dermal exposure is assessed for the disposal of the biocidal product (post-application phase). Exposure during application is assumed to be negligible, as the sachets will not be opened.
Inhalation exposure during the application and the post-application phase is not expected.

Table 47

Details of Scenario 3 – Application of granular bait in sachets	
Parameters	Value
Concentration of the a.s. brodifacoum in the b.p.	0.0025 % (w/w)
Number of bait stations – Post-Application (cleaning)	16

Calculations for Scenario 3

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in

Table 48. As no risk was identified in Tier 1, it can be considered, that sachets can be handled without risk migration measures.
For details of the calculation of dermal exposure, please refer to annex 4.3.1. For risk characterisation, see chapter 3.6.3.5.

Further information and considerations on scenario 3

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 48

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.**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1	Tier 1:	7.52×10^{-6}	0.01127
	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}
Scenario 3	Tier 1:	not expected	1.52×10^{-3}
	Tier 2: • Protective gloves (EN 374)	not expected	1.52×10^{-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.

3.6.2.1.2 Non-professional exposure

- **Scenario 4**

Table 49

Description of Scenario 4		
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. The indicative exposure values (dermal exposure) 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 specific use inhalation and oral exposure is considered not relevant.		
	Parameters	Value
Tier 1	Indicative exposure value for potential hand exposure, application, > 4 manipulations (recommended by HEEG opinion No 12)	2.04 mg b.p. / manipulation
	Indicative exposure value for potential hand exposure, disposal, > 4 manipulations (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

Calculations for Scenario 4

Systemic exposure

$Exposure_{dermal}$ = (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

= 1.35×10^{-6} mg / kg bw

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

- **Combined scenarios**

Not relevant.

3.6.2.1.3 Secondary exposure of the general public

- **Scenario 5**

Table 50

Description of Scenario 5		
Ingestion and mouthing of rodenticide bait. The ingestion of rodenticide bait is considered as an exceptional scenario, which may occur accidentally. Based on TNsG on human exposure (2007) it is assumed that the 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 minimized by addition of an aversive agent and by an appropriate covering of baits (e.g. by use of 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 adversive agent, no covered application (TNsG on Human Exposure, 2007)	5000 mg
	b) Ingested amount by mouthing, adversive agent, covered application (TNsG on Human Exposure, 2007)	10 mg
	Concentration a.s. in b.p.	0.0025 g / 100g
	Oral absorption (AR)	100 %
	Body weight, toddler (HEEG opinion No 17)	10 kg

Calculations for Scenario 5

Systemic Exposure:

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

a)

$Exposure_{oral}$ = 5000 mg x 0.0025 % x 100 % / 10 kg

= 0.0125 mg / kg bw

b)

$Exposure_{oral}$ = 10 mg x 0.0025 % x 100 % / 10 kg

= 2.5×10^{-5} mg / kg bw

Table 51

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 5a	1	-	-	0.0125 mg / kg bw	0.0125 mg / kg bw
Scenario 5b	1	-	-	2.5×10^{-5} mg / kg bw	2.5×10^{-5} mg / kg bw

- **Combined scenarios**

Not relevant.

3.6.2.2 Dietary exposure

The intended use descriptions of the brodifacoum 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 and trained professional bait application that does not come in direct contact with food, feedstuff or livestock animals.

3.6.2.3 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.

3.6.2.4 Aggregated exposure

Not relevant.

3.6.2.5 Summary of exposure assessment

Table 52

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 (product is divided into inner packages of no more than 10 kg, protective gloves)	Acceptable[1)]
2. Application of granular bait in packages up to 10 kg (≤ 10 kg)	Professional user	Tier 2 (protective gloves)	Acceptable[1)]
3. Application of granular bait in sachets	Professional user	Tier 1 (sachet is not opened)	Acceptable[1)]

1) For the external exposure values please refer to the section “Professional exposure”

3.6.3 Risk characterisation for human health

3.6.3.1 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.

3.6.3.2 Maximum residue limits or equivalent

No MRLs are required.

Table 53

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)

3.6.3.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.3.4 Risk for industrial users

No industrial applications are intended.

3.6.3.5 Risk for professional users

The occupational risk assessment for the biocidal product Ratron Granulat 25 ppm takes into account systemic effects of the active substance brodifacoum.

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

Brodifacoum

The primary toxic effect of the active substance brodifacoum 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 brodifacoum resulting from use of the biocidal product.

As reference value the $AEL_{long\text{-}term}$ of $3.3x10^{-6}$ 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 brodifacoum from the biocidal product Ratron Granulat 25 ppm, inhalation and dermal exposure to brodifacoum is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ $3.3x10^{-6}$ mg/kg bw/d of brodifcaoum is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of brodifacoum, 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/m³) = $AEL_{long\text{-}term}$ of brodifacoum (in mg/kg bw/d) x 60 kg / 10 m³ x 100 % / 100 %-inhalation absorption

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

By this means RV_{inhal} equivalent to $1.98x10^{-5}$ mg/m³ and RV_{derm} equivalent to $4.13x10^{-5}$ mg/kg bw/d are calculated for brodifacoum.

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 brodifacoum resulting from use of the biocidal product Ratron Granulat 25 ppm is determined according to the following equation:

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

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

Dermal exposure to brodifacoum given in mg/kg bw/d is calculated from dermal exposure to brodifacoum 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 54 gives a detailed overview of the risk assessment results referring to the active substance brodifacoum 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 54. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance brodifacoum resulting from the use of the biocidal product Ratron Granulat 25 ppm is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 54, the scenario ‘application of granular bait in sachets’ yields RI of less than 1 already in TIER 1. By contrast, the RI of the scenarios ‘application of granular bait in packages up to 10 kg’ and ‘application of granular bait in packages less than or equal to 25 kg’ exceed 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 results consistently yield RI of less than 1 in TIER 2.

Table 54Overview of detailed risk assessment results referring to the active substance brodifacoum for the biocidal product Ratron Granulat 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	$7.52x10^{-6}$	$1.98x10^{-5}$	0.38	0,01	$1.88x10^{-4}$	$4.13x10^{-5}$	4.55	4.93	no
	Tier 2	not expected	$1.98x10^{-5}$		$4.73x10^{-4}$	$7.88x10^{-6}$	$4.13x10^{-5}$	0.19	0.19	yes
application of granular bait in packages up to 10 kg	Tier 1	not expected	$1.98x10^{-5}$		$4.73x10^{-3}$	$7.88x10^{-5}$	$4.13x10^{-5}$	1.91	1.91	no
	Tier 2		$1.98x10^{-5}$		$4.73x10^{-4}$	$7.88x10^{-6}$	$4.13x10^{-5}$	0.19	0.19	yes
application of granular bait in sachets	Tier 1	not expected	$1.98x10^{-5}$		$1.52x10^{-3}$	$2.53x10^{-5}$	$4.13x10^{-5}$	0.61	0.61	yes

Tier 1: no PPE; Tier 2: protective gloves (application of granular bait in packages 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 in packages 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 brodifacoum via the inhalation and dermal route, a risk for professional users resulting from the uses ('application of granular bait in sachets', 'application of granular bait in packages up to 10 kg' and 'application of granular bait in packages less than or equal to 25 kg') with the biocidal product Ratron Granulat 25 ppm is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the use taking into account the provisions described in chapter 2.5

General directions for use of this PAR.

- **Local effects**

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

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Ratron Granulat 25 ppm is unlikely for the intended uses 'application of granular bait in sachets', 'application of granular bait in packages up to 10 kg' and 'application of granular bait in packages less than or equal to 25 kg'. Risk mitigation measures described in chapter 2.5

General directions for use have to be taken into account in order to ensure safe use of the biocidal product Ratron Granulat 25 ppm.

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

3.6.3.6 Risk for non-professional users

Table 55: 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)
4	1	0.002	0.0000067	9.72×10^{-7}	15	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.

3.6.3.7 Risk for the general public

Table 56: 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)
5a	1	0.002	0.0000067	0.01250	186567	No
5b	1	0.002	0.0000067	0.00003	373	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 measures the Note for Guidance “Harmonised sentences to be used in different sections of SPC for anticoagulant rodenticides” and the Summary of product characteristics for biocidal product containing anticoagulant active substances (on the basis of the harmonized SPC including derogations according to article 37 in Germany) are taken into account.

The applicant proposed maximum packaging-sizes of 4 kg for non-professional users. Based on the risk identified for children the maximum packaging size for non-professional user has to be limited to the amount required for one application. In general a maximum packaging size of 2 kg is considered sufficient in this context.

3.6.3.8 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.

3.6.3.9 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 Brodifacoum and no SoC.

3.6.3.10 Summary of risk characterisation

3.6.3.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.3.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Ratron Granulat 25 ppm is unlikely for the intended uses ‘application of granular bait in sachets’, ‘application of granular bait in packages up to 10 kg’ and ‘application of granular bait in packages less than or equal to 25 kg’. Risk mitigation measures described in chapter 2.5 General directions for use have to be taken into account in order to ensure safe use of the biocidal product Ratron Granulat 25 ppm.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation (please also refer to Table 54).

3.6.3.10.3 Summary of risk characterisation for non-professional user

Table 57

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
4	0.0000067	9.72×10^{-7}	15	yes

3.6.3.10.4 Summary of risk characterisation for indirect exposure

Table 58

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
5a	0.0000067	0.01250	186567	no
5b	0.0000067	0.00003	373	yes, with appropriate RMM

3.7 Risk assessment for animal health

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 Brodifacoum. A combined Assessment Report for Brodifacoum in PT 14 has been established in October 2010. In this combined assessment report the results from both CA Reports (Syngenta and PelGar) have been pooled and a conclusion based on the most conservative values was drawn. For the effects assessment of the product Ratron Granulat 25 ppm the most conservative value from the combined assessment report is considered.

An updated Assessment Report was published within the renewal of the approval of brodifacoum, however at least for the environmental risk assessment no new information has been provided and the conclusions from the original assessment within the first approval of Brodifacoum remain the same (*cf. Assessment Report Brodifacoum, PT 14, September 2016, eCA NL & IT*).

3.8.2 Effects assessment

3.8.2.1 Terrestrial compartment

No new information compared to the original Assessment Report has been provided. Using the available acute earthworm study and an assessment factor of 1000, results in a

$PNEC_{soil}$ of 0.88 mg a.s./kg ww

3.8.2.2 Aquatic compartment

No new information compared to the original Assessment Report has been provided. In aquatic studies, acute toxicity data indicate a high toxicity of brodifacoum to fish and algae. The most sensitive species in the acute test was the green algae *Selenastrum capricornutum* (*Pseudokirchneriella subcapitata)*, with a LC_{50} of 0.04 mg/L. Applying an assessment factor of 1000 the result is

$PNEC_{aqua}$ of 0.04 µg/L.

No studies with sediment organisms are available; therefore, the risk characterisation for the sediment compartment is covered by the risk characterisation for the aquatic compartment increased by a factor of 10.

No new information for microorganisms compared to the Assessment Report been provided. The outcome of PNEC derivation from growth inhibition test with *Pseudomonas putida* is

$PNEC_{STP}$ > 0.0038 mg/l.

3.8.2.3 Primary and Secondary Poisoning

No new information compared to the original Assessment Report 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} for birds was 0.31 mg/kg bw, determined for the mallard duck. For mammals the LD_{50} of 0.4 mg/kg bw from the rat study is used.

The NOEC and NOEL from the avian reproduction study performed for the substance difenacoum are used for derivation of the $PNEC_{oral}$ using an extrapolation factor, as in acute studies brodifacoum is more toxic (by a factor of 26) than difenacoum. The NOEC and NOEL for difenacoum were > 0.1 mg/kg diet and > 0.01 mg/kg bw/d, respectively. With an extrapolation factor of 26, a NOEC of 0.0038 mg/kg diet and a NOEL of 0.00038 mg/kg bw/d was derived for brodifacoum. An assessment factor of 30 is applied according to the TGD. This results in a

$PNEC_{oral,bird}$ of 0.00013 mg/kg food or 1.28E-05 mg/kg bw/d.

The $PNEC_{oral}$ for mammals is based on the NOEC of 0.02 mg/kg food and NOAEL of 0.001 mg/kg bw/d from a two-generation fertility study with rats. An assessment factor of 90 is used resulting in a

$PNEC_{oral,mammal}$ of 2.22E-04 mg/kg food or 1.1E-05 mg/kg bw/d.

3.8.3 Fate and behaviour

The summary of information about the active substance brodifacoum is carried out with the data from the original Combined Assessment Report as no new studies regarding fate and distribution in the environment have been submitted within the renewal of approval of brodifacoum.

For biodegradation in soil new FOCUS kinetic calculations were submitted which are based on the same laboratory studies as evaluated in the first a.s. approval. At BPC WG ENV I/2016 it was agreed a further discussion at EU level is needed before the new FOCUS kinetic calculation can be used. Until then it was decided to use the degradation half-life from the first approval; the half-life in soil was less than 30 days (primary degradation) under aerobic conditions.

3.8.3.1 Terrestrial compartment (including groundwater)

In the combined Assessment Report for brodifacoum an octanol/water partition coefficient log Kow = 5.09 at 283 K under neutral conditions and an organic carbon adsorption coefficient Koc = 50000 $cm^3 \cdot g^{-1}$ (average value from pesticide manual) is indicated. Based on the given K_{oc}, the soil-water partitioning coefficient $K_{soil\text{-}water}$ of $1.5 \cdot 10^3$ $m^3 \cdot m^{-3}$ is calculated and the partition coefficient suspended matter-water $K_{susp\text{-}water}$ equals to $1.251 \cdot 10^3$ $m^3 \cdot m^{-3}$. The elimination rate constant in soil is k_{bio_soil} = $2.326 \cdot 10^{-3}$ d^{-1} according to Guidance BPR IV ENV B+C (2017), chapter 2.3.6.5, table 6.
In addition based on the insolubility of the active substance in water, a log Kow >4 and ionisable groups at environmental pH it is considered that brodifacoum will not have a high mobility in soil and will adsorb to soil particles.

3.8.3.2 Aquatic compartment

Brodifacoum is poor soluble in water ($5.8 \cdot 10^{-5}$ $g \cdot L^{-1}$ at neutral conditions and 293 K corresponding to $5.17 \cdot 10^{-5}$ $g \cdot L^{-1}$ at 285 K). It is hydrolytically stable at environmentally relevant pH 5-9 of natural water, and it undergoes rapid phototransformation in aqueous solution.

3.8.3.3 Air compartment

Brodifacoum is not expected to volatilise to air in significant quantities because of its low vapour pressure ($1.5 \cdot 10^{-22}$ Pa at 285 K). A half-life of 6.61 hours is estimated for brodifacoum 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.

3.8.3.4 Bioconcentration

The log Kow of brodifacoum ranges from 4.91 at pH 9 to 6.27 at pH 5 (at 283 K). According to the combined Assessment Report for brodifacoum a BCF value of 35645 L/kg has been estimated using a log Kow of 6.1. A high potential for bioaccumulation via bioconcentration thus can be assumed. For further information on bioaccumulation of brodifacoum please refer to the PBT-assessment.

3.8.4 Exposure assessment

3.8.4.1 General information

The environmental exposure to brodifacoum was assessed for the use of the active substance formulated as “Ratron Granulat 25 ppm” as a rodenticide granular bait (product type 14) for use in and around buildings (including animal housings), in open areas, on waste dumps and in sewer systems. Target organisms are the Brown rat (*Rattus norvegicus*), Norway rat *(Rattus rattus)*, the house mouse *(Mus musculus)*, the common vole (*Microtus arvalis*) and the bank vole (*Myodes glarelous*).
The local environmental concentrations of brodifacoum were estimated based on the respective Emission Scenario Document for biocides used as rodenticides (ESD PT14, EUBEES 2003), the Guidance BPR IV ENV B+C (2017) and the combined Assessment Report for brodifacoum.
The formulation of the granulated bait Ratron Granulat 25 ppm is considered not to alter any of the physicochemical properties of the active substance brodifacoum. The product is marketed as ready-to-use bait (40 g sachets) containing the active substance brodifacoum at a concentration of 25 mg/kg (0.0025 % w/w). Ratron Granulat 25 ppm is available in folding boxes with 200-800 g and 4 kg plastic buckets (packaged in 40-g portion bags), in folding boxes with 500 g to 1 kg, 2.5 kg barrel, 5-10 kg bucket and 25 kg bag.

Table 59: Intended uses

Assessed PT	*PT 14 Rodenticides*
Assessed scenarios	*Scenario 1: in and around buildings, rat and voles control* *Scenario 2: outdoor - open areas, bait application in burrows, rat and voles control* *Scenario 3: outdoor - waste dumps, rat control* *Scenario 4: sewer, rat control*
ESD(s) used	*Emission Scenario Document for biocides used as rodenticides (ESD PT 14, 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	Refinement for PECgroundwater assessment was made by using FOCUS PEARL 4.4.4 for the scenarios 2
Confidential Annexes	
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 60: 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 buidlings	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 61: **Input parameters (only set values) for calculating the fate and distribution in the environment**

Input	Value	Unit	Remarks
Molecular weight	523.4	g mol^{-1}	
Melting point	235.8	°C	
Boiling point	Not applicable	°C	
Vapour pressure (at 12°C)	$1.46 \cdot 10^{-22}$	Pa	
Water solubility (at 12°C)	$5.17 \cdot 10^{-2}$	mg/L	
Log Octanol/water partition coefficient	5.09	Log 10 (at 10°C/pH 7)	
Organic carbon/water partition coefficient (Koc)	50000	L/kg	

Input	Value	Unit	Remarks
Henry's Law Constant (at 12°C)	$1.48 \cdot 10^{-18}$	Pa/m³/mol	
Biodegradability	*No*		
Rate constant for STP	0	h^{-1}	
DT_{50} for biodegradation in surface water	28	d (at 22±2°C)	3.5% biodegradation
DT_{50} for hydrolysis in surface water	stable to hydrolysis	(at 25ºC /pH 7)	
DT_{50} for photolysis in surface water	12	hr	
DT_{50} for degradation in soil	298	d (at 12ºC)	
DT_{50} for degradation in air	0.276	d	

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 Ratron Granulat 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**

Ratron Granulat 25 ppm is applied as ready-to-use bait typically placed secured to sewer walls and platforms where rats run. In the cesspools, the bait can be fixed with a wire to avoid removal by the rodents or carrying off by water or used in bait stations in order to avoid contact with wastewater. The default emission scenario from ESD PT14 (described in chapter 2.3.3) should be adapted in that way that Ratron Granulat 25 ppm as granulated 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 62.

Table 62: 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 - Q_{prod}	**20.0**	***kg***	**S**
Fraction of a.s. in product - Fc_{prod}	**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**	**-**	**D**
Fraction of active ingredient released - $F_{released}$	0.9	-	D
Output			
Mean local emission of active substance to waste water during episode - $Elocal_{water}$	$6.43 \cdot 10^{-5}$	$kg \cdot d^{-1}$	O

As brodifacoum is not readily biodegradable the degradation rate constant in sewage treatment plant is k_{STP} = 0 h^{-1} (Guidance BPR IV ENV B+C (2017), chapter 2.3.6.4, table 4). The distribution and degradation of the a.s. in the STP is simulated using the model SimpleTreat (version 4.0). The fraction of emissions directed to wastewater (F_{stp}) amounts to 13.6% and the fraction of emissions directed to sludge (F_{sludge}) amounts to 86.5%. For the distribution in the STP the values are listed in the following Table 63.

Table 63: Calculated fate and distribution in the STP

Compartment	Percentage [%]	Remarks
Air	0.0	
Water	13.6	
Sludge	86.5	
Degraded in STP	0.0	Not biodegradable, k = 0 d^{-1}

The predicted environmental concentrations for the subsequently affected compartments are estimated as follows:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 42, chapter 2.3.6.7, by Guidance BPR IV ENV B+C (2017).
- $PEC_{surface\_water}$ according to equation 51, chapter 2.3.7.3.1, by Guidance BPR IV ENV B+C (2017).
- PECsediment according to equation 53, chapter 2.3.7.3.2, by Guidance BPR IV ENV B+C (2017).

The calculated PEC values of brodifacoum in STP and the aquatic compartment after application of Ratron Granulat 25 ppm in sewer systems are summarised in Table 64.

Table 64: Summary of the outputs of STP ($Clocal_{eff}$, C_{sludge}), and of the PECs in surface water and sediment resulting from application of Ratron Granulat 25 ppm in sewer systems

Output parameters	Symbol	Value
Concentration of a.s. in treated wastewater (influent)	$Clocal_{inf} = PEC_{STP}$	$3.21 \cdot 10^{-2}$ µg·L^{-1}
Concentration in dry sewage sludge	C_{sludge}	$7.03 \cdot 10^{-2}$ mg·kg^{-1}
Predicted environmental concentration in surface water	$PEC_{surface\ water}$	$4.07 \cdot 10^{-4}$ µg·L^{-1}
Predicted environmental concentration in sediment	$PEC_{sediment}$	$4.42 \cdot 10^{-1}$ µg·kg^{-1}

3.8.4.4 Terrestrial compartment (including groundwater)

- **Emission estimation**

According to the ESD PT14 (EUBEES 2003), emission of the active substance (a.s.) 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 $PEC_{groundwater}$ 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 brodifacoum to soil following application of Ratron Granulat 25 ppm are estimated according to chapter 2.4 in ESD PT14. The direct releases from the sachets date from spills at refilling or cleaning operations of bait stations, whereas the indirect releases are expected from rodents' urine, faeces and carcasses. According to the decision on TM 1/2006 the rate of a.s. released directly to soil could be reduced from 1% to 0.1% for paste baits in sachets.

The resulting concentrations due to the direct and indirect releases from Ratron Granulat 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 are summarised in Table 65.

Table 65: Input parameters for calculating the local emission

Input according to chapter 2.4.3.2, ESD PT14 (2003)	Value	Unit	Remarks
Scenario*: in and around building*			
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	-	S
Fraction of a.s. released indirectly to soil - *Frelease-ID,soil*	0.9	-	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	$kg \cdot m^{-3}$	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*	222.75	mg	
Concentration in soil due to direct release after a campaign - *Clocal soil-D*	$1.64 \cdot 10^{-2}$	$mg \cdot kg^{-1}$	
Concentration in soil due to indirect (disperse) release after a campaign - *Clocal soil-ID*	$2.38 \cdot 10^{-3}$	$mg \cdot kg^{-1}$	
Predicted environmental concentration in soil taking into account both direct and indirect releases - ***PECsoil***	$1.87 \cdot 10^{-2}$	$mg \cdot kg^{-1}$	

The PECsoil of brodifacoum resulting from application of Ratron Granulat 25 ppm as 200g-baits in bait stations in and around buildings is equal to **$1.87 \cdot 10^{-2}$ $mg \cdot kg^{-1}$**.

The PEC in groundwater according to the first tier assessment results in **0.0212 $\mu g \cdot L^{-1}$**. This value fall below the trigger value of 0.1 $\mu g \cdot L^{-1}$ of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC (ref. to LoEP in AR (September 2016)). Therefore, a refinement of the groundwater assessment is not necessary. Indirect release of the a.s. depends on the fraction that is metabolised by the rodents. According to the Assessment Report for brodifacoum in PT 14 (2016) of the active substance 50–80% of the administered dose was excreted via the faeces. Nevertheless, 0% was assumed as the fraction of brodifacoum that is metabolised (Fmetab) to calculate the case with highest input of emission into environment.

- **<u>Scenario 2 – Outdoor: Open Areas</u>**

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. This scenario enclose in opinion of the eCA also the application of direct bait introduction into the holes in the close neighbourhood of buildings which is also foreseen by the applicant as use in and around buildings for rat and voles control. The release of brodifacoum to soil and the predicted environmental concentration in soil (PECsoil) are estimated according to chapter 2.5, equations (9) and (10) from ESD PT14, the input parameters are summarised in Table 66.

Table 66: Input parameters for calculating the local emission

Input according to chapter 2.5.3.2, ESD PT14 (2003)	**Value**	**Unit**	**Remarks**
Scenario: *open area (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	$kg \cdot m^{-3}$	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*	$2.5 \cdot 10^{-3}$	g	O
Predicted environmental concentration in soil at each hole per control campaign - ***PECsoil***	0.173	$mg \cdot kg^{-1}$	O

The PECsoil of brodifacoum resulting from application of Ratron Granulat 25 ppm as 20 g-bait in rat or vole corridors in the vicinity of individual bait points is equal to **0.173 $mg \cdot kg^{-1}$**.
The PEC in groundwater according to the first tier assessment results in **0.197 $\mu g \cdot L^{-1}$**. This value exceeds the trigger value of 0.1 $\mu g \cdot L^{-1}$ of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC. Therefore a refinement of the groundwater assessment is necessary.
The refinement of the PECs in groundwater were calculated using the FOCUS groundwater scenarios (PEARL 4.4.4 model) according to Revised ESD for PT14 (2018). For use in open areas 100 bait points are assumed per hectare. It is assumed that baits are dispersed 3 times per season on 15th March, 17th

March, 22nd March in spring and 15th September, 17th September, 22nd September in autumn. The crops grass/alfalfa are be used as typical crops. The application rate for brodifacoum is calculated to 0.013 g·ha^{-1}. The input-parameters for the FOCUS PEARL model are summarized in Table 67.

Table 67: Summary of parameters of brodifacoum used for FOCUS PEARL 4.4.4 simulations

	brodifacoum	
Parameter	**Value**	**Remarks**
Physico-Chemical parameters		
Molecular weight [g/mol]	523.4	AR for brodifacoum in PT 14 (2016)
Water solubility [mg/L] (20°C)	5.8 x 10^{-2} (pH 7)	AR for brodifacoum in PT 14 (2016)
Vapour pressure [Pa] (20°C)	2.6 x 10^{-22}	AR for brodifacoum in PT 14 (2016)
Degradation in soil		
DT_{50} soil [d]	298 at 12°C	AR for brodifacoum in PT 14 (2016)
Sorption to soil		
K_{oc} [mL/g]	50000	AR for brodifacoum in PT 14 (2016)
K_{om} [mL/g]	2900.2	Derivation from Koc
Freundlich exponent 1/n [-]	0.9	FOCUS recommendation
Crop/ Management related parameters		
a) Gras / alfalfa		
Plant uptake factor [-]	0	FOCUS recommendation for non-systemic a.s.
Application Schemes		
Application type	to the soil surface	Indirect release via urine, faeces and carcasses
Gras / alfalfa: Dosage [kg/ha]	6 x 5 ·10^{-5}	6 times (ref. to text here above)

From the FOCUS PEARL calculation it can be seen that the average concentrations of brodifacoum closest to the 80th percentile are <0.000001 µg·L^{-1}. This applies to all 9 EU-Scenarios at 1 m soil depth for the grass/alfalfa scenario.

- **<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 brodifacoum 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 68.

Table 68: Input parameters for calculating the local emission

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*	0.9	-	D
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	$kg \cdot m^{-3}$	D
Output			
Local emission of active substance to soil during control campaign – *Elocal,soil-campaign*	3.81	g	O
Predicted environmental concentration in soil after a campaign - ***PECsoil***	$2.24 \cdot 10^{-3}$	$mg \cdot kg^{-1}$	O

The PECsoil of brodifacoum resulting from application of Ratron Granulat 25 ppm as 200g-bait on waste dumps and landfills is equal to **$2.24 \cdot 10^{-3}$ $mg \cdot kg^{-1}$.**
The PEC in groundwater according to the first tier assessment results in **$2.54 \cdot 10^{-3}$ $\mu g \cdot L^{-1}$**. This value fall below the trigger value of 0.1 $\mu g \cdot L^{-1}$ of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC. Therefore a refinement of the groundwater assessment is not necessary.

- **Scenario 4 – sewer**

For application of Ratron Granulat 25 ppm in the sewer system direct emission to soil can be excluded, the soil is indirectly contaminated by fertilization 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 **$1.75 \cdot 10^{-4}$ $mg \cdot kg^{-1}$**.
The PEC in groundwater according to the first tier assessment results in **$1.98 \cdot 10^{-4}$ $\mu g \cdot L^{-1}$**. This value is clearly below the trigger value of 0.1 $\mu g \cdot L^{-1}$ of the Drinking Water Directive 98/83/EC and of the Ground Water Directive 2006/118/EC. 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 brodifacoum and the anticipated use pattern, emissions to the air are regarded to be not significant in relation to the intended use pattern 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 brodifacoum 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 0.3 (default-value) 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 and EC1 are received by the tree sparrow as representative for birds and the dog as representative for mammals and were shown in Table 69 (AV=0.9, PT=0.8).

Table 69: Summary table on estimated theoretical exposition (ETE) and EC1

Non-target animal	ETE	EC1
	[mg/kg*d^{-1}]	[mg/kg $_{bw}$]
tree sparrow	6.22	4.35
dog	1.08	0.76

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 brodifacoum concentration for

long-term (poisoning) situation due to primary poisoning are calculated again for tree sparrow with **EC5 = 16.77 mg·kg^{-1}** and for dogs with **EC5 = 2.91 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.
The bioaccumulation of brodifacoum via the aquatic food chain in fish and consequently in fish-eating birds or mammals: The concentration of brodifacoum 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 estimated bioconcentration factor BCF (4.232·10^3 L·kg^{-1}) for fish and the biomagnification factor (BMF = 10, ref. to table 23 of Guidance BPR IV ENV B+C (2017)). The PEC in surface water (4.0664·10^{-4} µg·L^{-1} was taken from the sewer scenario, where rodent control is performed by use of Ratron Granulat 25 ppm.

PECoral for fish eating predators = 8.60 x 10^{-03} mg·kg^{-1}.

The bioaccumulation of brodifacoum 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 bioconcentration for earthworms. The bioconcentration factor for earthworms on wet weight basis is calculated according to eq. 104d in chapter 3.8.3.7 of Guidance BPR IV ENV B+C (2017) as $BCF_{earthworm}$= 1.477·10^{3}L·kg^{-1}. 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 70. The calculation is done without scenario 4: sewer justified by the fact that the input of a.s. over the pathway sewage plant (sewage sludge → digested sludge) to the soil is less compared to scenario 1-3.

Table 70: Summary of $PEC_{oral,\ predator}$ via terrestrial food chain

Scenario/Application	$PEC_{oral,\ predator}$ [mg·kg^{-1}]
Scenario 1: In and around buildings (bait boxes)	1.50·10^{-2}
Scenario 2: Open areas (bait boxes)	**1.39·10^{-1}**
Scenario 3: Waste dumps/landfills (bait boxes)	1.80·10^{-3}
Scenario 4: Sewer system	1.31·10^{-4}

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 brodifacoum 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 brodifacoum 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 6.93 mg·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} is equal to 3.47 mg·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 71.

Table 71 Expected concentration PEC_{oral} of brodifacoum 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·kg^{-1}]
barn owl	0.86
kestrel	**1.31**
little owl	0.98
tawny owl	0.79
fox	0.32
Polecat	0.66
stoat	0.94
weasel	**1.36**

3.8.4.7 Calculated PEC values

Table 72: Summary table on calculated PEC values

	PEC_{STP} [mg/L]	PEC_{water} [mg/L]	PEC_{sed} [mg/kg_{wwt}]	$PEC_{seawater}$ [mg/L]	PEC_{seased} [mg/kg_{wwt}]	PEC_{soil} [mg/kg]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
Scenario 1	-	-	-	-	-	$1.87 \cdot 10^{-2}$	$2.12 \cdot 10^{-2}$	n.r.
Scenario 2	-	-	-	-	-	$1.73 \cdot 10^{-1}$	$1.97 \cdot 10^{-1}$	n.r.
Scenario 3	-	-	-	-	-	$2.75 \cdot 10^{-3}$	$2.54 \cdot 10^{-3}$	n.r.
Scenario 4	$3.21 \cdot 10^{-5}$	$4.07 \cdot 10^{-7}$	$4.42 \cdot 10^{-4}$	-	-	$1.75 \cdot 10^{-4}$	$1.98 \cdot 10^{-4}$	n.r.

3.8.5 Risk characterisation

The risk characterisation is performed for the biocidal product Ratron Granulat 25 ppm for its 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 40 g bait for rat control and mice control, respectively. The active substance brodifacoum is present in the product Ratron Granulat 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 to the ESD PT14 direct emissions to soil during application, refilling, and disposal operations may occur from the use of Ratron Granulat 25 ppm in and around buildings (in bait boxes), at open areas (rat holes/burrows), waste dumps/landfills and sewer systems. Moreover, an indirect exposure via rodent urine, faeces and carcasses is considered for the calculation of the PEC_{soil}. From the application in the sewer systems release to soil may occur indirectly via spreading of sewage sludge from sewage treatment plants if the sewage has been exposed to Ratron Granulat 25 ppm.

Table 3.8-73: PEC/PNEC ratios for soil resulting from application of Ratron Granulat 25 ppm in different scenarios

Exposure scenario / Application	**PEC** [mg/kg ww]	**PNEC** [mg/kg ww]	**PEC / PNEC**
In and around buildings (bait boxes)	$1.87 \cdot 10^{-2}$	0.88	0.021

Exposure scenario / Application	PEC [mg/kg ww]	PNEC [mg/kg ww]	PEC / PNEC
Open areas (rat holes)	$1.73 \cdot 10^{-1}$	0.88	0.197
Control on waste dumps/landfills	$2.24 \cdot 10^{-3}$	0.88	0.0025
Sewer systems	$1.75 \cdot 10^{-4}$	0.88	$1.98 \cdot 10^{-4}$

Conclusion to the risk assessment

The PEC/PNEC ratios for all exposure scenarios presented in Table 3.8-73 are below 1. Therefore, no risk for the terrestrial compartment is indicated for the intended uses.

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 TGD (2003).

Table 3.8-74: PEC/PNEC ratios for groundwater resulting from application of Ratron Granulat 25 ppm in different scenarios

Exposure scenario / Application	PEC [µg/L]	Trigger [µg/L]*	PEC / Trigger value
In and around buildings (bait boxes)	$2.12 \cdot 10^{-2}$	0.1*	0.212
Open areas (rat holes)	$1.97 \cdot 10^{-1}$	0.1*	1.97
Control on waste dumps/landfills	$2.54 \cdot 10^{-3}$	0.1*	0.025
Sewer systems	$1.98 \cdot 10^{-7}$	0.1*	$1.98 \cdot 10^{-6}$

* The maximum permissible concentration of the active substance or of any other substance of concern in groundwater must not exceed the limit value of 0.1 µg l^{-1} as laid down by directive 2006/118/EC and directive 98/83/EC.

Conclusion to the risk assessment

The calculated PECs of the active substance in groundwater do not exceed the limit value of 0.1 µg/L as laid down by Directives 2006/118/EC and 98/83/EC except for the application of the product in rat burrows in the open area.

For this reason, the simulation model FOCUS PEARL 4.4.4 is used for the refinement of $PEC_{groundwater}$. Calculations have been performed for all FOCUS scenarios with brodifacoum. As a result of these calculations it has been shown that the predicted groundwater concentrations of brodifacoum are below the threshold criteria of 0.1 µg/L for all scenarios (cf. chapter 3.8.4.4).

3.8.5.2 Aquatic compartment (incl. sediment)

According to ESD PT14, releases of Ratron Granulat 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 3.8-75. From the other intended uses the ESD PT14 regards releases to the surface water as not relevant and negligible for these use patterns.

Table 3.8-75: PEC/PNEC ratios for surface water, sediment and STP after application of Ratron Granulat 25 ppm in sewer systems

Exposure scenario	PEC	PNEC	PEC / PNEC
Surface water	$4.07 \cdot 10^{-4}$ µg·L^{-1}	0.04 µg·L^{-1}	0.01
Sediment*	$4.42 \cdot 10^{-4}$ mg·kg^{-1}		0.1
STP	$3.21 \cdot 10^{-5}$ mg·L^{-1}	0.0038 mg·L^{-1}	0.0085

* According to the TGD the PEC/PNEC ratio for the aquatic compartment - increased by an additional factor of 10 due to log K_{ow} > 5 - was used for the risk characterisation of the sediment.

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, a risk for the aquatic environment resulting from the use of Ratron Granulat 25 ppm in sewer systems is not indicated.

3.8.5.3 Atmosphere

The active substance brodifacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure ($1.5 \cdot 10^{-22}$ Pa at 12°C) and Henry's Law ($1.48 \cdot 10^{-18}$ Pa m^3 mol^{-1}) constant. Brodifacoum 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 brodifacoum, no adverse effects of the product Ratron Granulat 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 (cf. also Appendix 5 of the Guidance BPR IV ENV B+C (2017)), a qualitative and quantitative risk assessment is conducted for the acute and long-term poisoning situation, respectively.

Table 3.8-76: PNECs to be used in the risk characterisation of primary and secondary poisoning

Species	**PNECoral** [mg/kg food]	**PNECoral** [mg/kg bw/d]
Birds	1.30E-04	1.28E-05
Mammals	2.22E-04	1.10E-05

3.8.5.4.1 Primary Poisoning

3.8.5.4.1.1 Qualitative risk assessment for the short-term situation

The maximum values of expected brodifacoum concentration (PECs) for short-term (poisoning) situation due to primary poisoning are calculated for dogs (mammals) and tree sparrow (birds) (cf. Table 2.8-8). 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 after 1 day exposure (EC1) and under consideration of excretion.

Table 3.8-77: Qualitative comparison of EC1 and LD_{50} values for birds and mammals

Species	**PEC EC1** [mg/kg bw]	**LD_{50}** [mg/kg bw]
Birds	4.35	0.31
Mammals	0.76	0.4

Regarding the values given in Table 3.8-77, it can be concluded that a one day consumption of baits containing brodifacoum is assumed to be lethal to birds and mammals. The expected concentration of the active substance in the non-target animals after a single meal (EC1) is higher than the dose required to kill half of a test population (LD_{50}) of either mammals or birds. It is therefore assumed that Ratron Granulat 25 ppm is acutely toxic to birds and mammals.

3.8.5.4.1.2 Quantitative risk assessment for the long-term situation

Tier 1 Assessment

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

Table 3.8-78: PEC/PNEC ratios for primary poisoning of non-target animals. PECoral is the concentration of the a.s. in the bait.

Species	**PECoral** [mg/kg] Concentration of a.s. in bait	**PNEC** [mg/kg] Concentration of a.s. in food	**PEC/PNEC**
Birds	25	1.30E-04	**192308**
Mammals	25	2.22E-04	**112613**

The uptake of Ratron Granulat 25 ppm by non-target animals poses a high risk of primary poisoning to both birds and mammals in the Tier 1 scenario. This is quite obvious as the purpose of rodenticide baits is to kill target rodents and the mode of action of anticoagulant rodenticides is similar in all warm-blooded organisms.

Tier 2 Assessment

According to the ESD the comparison of the concentration in a non-target animal with the $PNEC_{oral}$ describes the long-term risk for primary poisoning. The expected concentration in the non-target animals are calculated after five days exposure (EC5) under consideration of excretion.

Table 3.8-79: Tier 2 risk characterisation for long-term situation. PECoral is the expected concentration of the a.s. in a non-target animal after five days exposure.

Species		**PECoral (EC5)** [mg/kg bw]	**PNEC** [mg/kg bw/d]	**PEC/PNEC**
Tree sparrow	*Passer montanus*	16.77	1.28E-05	**1310156**
Dog	*Canis familiaris*	2.91	1.10E-05	**264545**

The results of the risk characterisation show that in a long-term situation Ratron Granulat 25 ppm, if ingested by mammals or birds on five consecutive days, poses a very high risk for primary poisoning even if taking excretion into account. Due to high food intake in relation to the body weight birds are at considerably higher risk than mammals.

3.8.5.4.1.3 Conclusion from primary poisoning

Non-target mammals and birds are at high risk for primary poisoning if they get access to the Ratron Granulat 25 ppm. Lethal and sub-lethal effects are very likely in both animal groups in a short-term as well as long-term situation. 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 i.e. in bait boxes, the risk for primary poisoning can be mitigated significantly. 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 will be accessible to non-target mammals and birds of equal or smaller size than the target rodents as well.

3.8.5.4.2 Secondary Poisoning

3.8.5.4.2.1 Aquatic and terrestrial food chains

Avian and mammalian predators of the aquatic and terrestrial food chains may be at risk for secondary poisoning if they feed on contaminated water or soil organisms such as fish or earthworms. The risk characterisation is done for both birds and mammals to be consequent with the calculations done according to the ESD.

Table 3.8-80: 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
Mammals	0.0086	0.139	0.00022	**66**	**1071**
Birds	0.0086	0.139	0.00013	**39**	**627**

It can be followed from the results that both animal groups are at high risk when get exposed to Ratron Granulat 25 ppm via the aquatic as well as the terrestrial food chain.

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 expected concentration of the a.s. in rodents to LD_{50} values from acute oral toxicity studies with birds and mammals. Rodents are assumed to eat entirely on bait containing brodifacoum and the non-target animals are assumed to consume 100 % of their daily intake on poisoned rodents.

Table 3.8-81: Qualitative assessment of acute secondary poisoning. Expected concentration (EC) in rodent after five days exposure

Species	PEC_{oral} (EC5) [mg · kg_{bw}^{-1}]	LD_{50} [mg · kg_{bw}^{-1}]
Birds	6.93	0.31
Mammals	6.93	0.4

Even though the species specific sensitivity differences or other aspects normally covered by the assessment factors are not taken into account in the qualitative assessment the comparison of the given values indicates that both mammals and birds are very likely to die if they eat poisoned rats. The expected concentration of the active substance in the rodent immediately after a last meal on day five (EC5) is more than one order of magnitude higher than the dose required to kill half of a test population (LD_{50}) of either mammals or birds.

3.8.5.4.2.3 Quantitative risk assessment for the long-term situation

Tier 1 assessment

The Tier 1 assessment of secondary poisoning is based on the concentration in the predators' or scavengers' food i.e. poisoned rodents. In the first tier of the long-term assessment of secondary poisoning, it is assumed that rodents are consuming only the bait (PD = 1) on five consecutive days (EC5), while the daily dietary of predators or scavengers consists to 50 % of poisoned rodents (F_{rodent} = 0.5). The predators or the scavengers are assumed to eat the poisoned rodents during one day.

Table 3.8-82: PEC/PNEC ratios for long-term situation of secondary poisoning in the first tier. PECoral is the expected concentration (EC) in the rodent after a five days exposure

Species	PEC_{oral} (EC5) [mg/kg] Concentration in rodent	PNEC [mg/kg] Concentration in food	PEC/PNEC
Birds	3.465	$1.30 \cdot 10^{-4}$	**26654**
Mammals	3.465	$2.22 \cdot 10^{-4}$	**15608**

The Tier 1 risk characterisation shows that birds and mammals are at very high risk when feeding on rodents which have taken up Ratron Granulat 25 ppm over five days.

Tier 2 assessment

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators after a single day of exposure (PEC_{oral}) is compared to $PNEC_{oral}$ related to the daily dose. The predator is assumed to catch the rodent after its last meal on day 5. Furthermore, it is assumed that the non-target animal consume 50 % of its daily intake on poisoned rats.

Table 3.8-83: PEC/PNEC ratios for long-term situation of secondary poisoning in the second tier. PEC oral is the expected concentration (EC) of a non-target animals after one day exposure.

Species	PEC_{oral} EC1 [mg/kg bw]	PNEC [mg/kg bw/d]	PEC/PNEC
Birds (Kestrel)	1.31	$1.28 \cdot 10^{-5}$	**101953**
Mammals (Weasel)	1.36	$1.10 \cdot 10^{-5}$	**123545**

The second tier risk characterisation shows that non-target organisms are at very high risk of secondary poisoning, too. No data are available on the sensitivity of the example species to brodifacoum. 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 brodifacoum in predators is assumed to be less than the daily intake.

3.8.5.4.2.4 Conclusion from secondary poisoning

The calculations clearly demonstrate that Ratron Granulat 25 ppm poses a very high risk of secondary poisoning to non-target birds and mammals. In the aquatic food chain (fish-eating birds and mammals) the secondary poisoning is possible via contaminated fish. In the terrestrial food chain (worm eating and rodent eating birds and mammals) secondary poisoning is possible via contaminated soil invertebrates and rodents, whereby the latter animals are the most likely source for brodifacoum residues in raptorial birds and mammalian predators. For both the aquatic and the terrestrial food chain a risk is identified.

3.8.5.5 PBT assessment

As no new information has been provided within the authorisation of the biocidal product Ratron Granulat 25 ppm, the PBT assessment relies on information considered within the approval and renewal of the approval of the active substance brodifacoum (cf. Assessment Report Brodifacoum, eCA NL & IT, September 2016). Within the renewal of the approval of brodifacoum the PBT status of brodifacoum was reconsidered. As a result, brodifacoum has been confirmed to fulfil the PBT criteria.

3.8.5.5.1 Persistence

Experimental data indicate that brodifacoum is not readily, inherently or anaerobically biodegradable. The DT50 in soil is 157 days at 20 °C, the DT50 considering the temperature correction to 12°C is 298 days. Brodifacoum is also hydrolytically stable, but photolytic degradation in water is rapid. The photolytic degradation is not regarded as a major transformation pathway in nature. In the combined CA report it has therefore been concluded that brodifacoum is potentially persistent in the environment. The assessment of the P-criterion in accordance with the currently applicable criteria given in the REACH

Guidance, however, results in a classification of brodifacoum as persistent (P) and very persistent (vP) because DT50 values in soil are higher than the trigger values of 120 and 180 days respectively.

3.8.5.5.2 Bioaccumulation

The estimated BCF for brodifacoum, using a log Kow value of 6.12, is 35645 according to TGD equation 75. Since no experimental data is available, brodifacoum is considered to fulfill the B-criterion (BCF > 2000). In addition, brodifacoum has also to be classified as very bioaccumulative (vB), the estimated BCF based on log Kow is above the trigger value of 5000.

Second-generation anticoagulant substances, which are predominantly released to the terrestrial environment, accumulate in the liver of target rodents and it can be assumed that they also accumulate in the livers of non-target mammals and birds. This is confirmed by the fact that the second-generation anticoagulant substances are found in livers of non-target species worldwide.

3.8.5.5.3 Toxicity

Brodifacoum is acutely very toxic to fish, algae and Daphnia with the lowest value being E_rC_{50} = 0.04 mg/l established in a 72-h test with the green algae *Selenastrum capricornutum*. Since long-term ecotoxicological data is not available, brodifacoum has to be classified as toxic (T) in terms of the PBT assessment.
No long-term data for aquatic organisms are available. Due to the lack of reliable long-term study with birds, a NOEC= 0.012 mg brodifacoum/kg diet was estimated by extrapolation from the reference anticoagulant difenacoum.
Regarding mammalian toxicity a substance fulfils T criterion when it is classified as the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Regulation EC No 1272/2008; or there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.
Regarding toxic for reproduction, RAC decided that brodifacoum is to be classified with H360D, because it contains the same chemical moiety responsible for teratogenicity of warfarin and it has the same mode of action that is a known mechanism of teratogenicity in humans.
Based on the RAC opinion, brodifacoum is classified as H300/310/330, H372 (blood) and H360D.
Overall conclusion is that brodifacoum fulfils the T criterion.

3.8.5.6 Endocrine disrupting properties

No new information is available. According to the Assessment Report (September 2016) brodifacoum is not considered to have endocrine disrupting properties.
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.

3.8.5.7 Summary of risk characterisation

The biocidal product Ratron Granulat 25 ppm contains no substance of concern. Therefore, the environmental risk assessment for the product is based on the active substance brodifacoum (see Combined Assessment Report Brodifacoum PT 14; RMS Italy, 17 September 2009, revised 16 December 2010 and Assessment Report for the renewal of brodifacoum, September 2016).

The risk assessment based on the biocidal product Ratron Granulat 25 ppm demonstrates that the intended uses of the product do not cause an unacceptable risk in the aquatic and terrestrial environment and in the atmosphere.

Apart from that, a considerable risk for primary and secondary poisoning of birds and non-target mammals can be anticipated. However, this risk is considered to be mitigated adequately when the rodenticide baits are used according to the label instructions and in compliance with the applied risk mitigating measures (cf. instructions for use and risk mitigation meausres in the SPC). For instance, the risk for primary poisoning can be reduced by deploying baits so that they can hardly be reached by non-target animals. The risk for secondary poisoning is more difficult to control as poisoned rodents may be available for predators for several days after intake of Ratron Granulat 25 ppm. The use of the product inside of buildings may reduce the risk for secondary poisoning, but does not exclude it as the exposed rodents may move out of the building. Since this assumption cannot be ruled out, specific measures have to be taken in order to minimise the risk for secondary poisoning. These measures include the collection of unconsumed baits and dead rodents during and after the control campaign (cf. SPC).
In addition, the active substance brodifacoum is considered as a PBT/vPvB substance. Therefore, releases to the environment have to be minimised effectively. This can only be achieved by appropriate

risk mitigation measures which have to be applied in the form of specific provisions. Their compliance is assumed to be only possible for trained professionals, i.e. pest control operators. This is why the use of Ratron Granulat 25 ppm is restricted to this user category.

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 brodifacoum meets the criteria for exculsion 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 Ratron Granulat 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[8] 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 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[9] 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 Ratron Granulat 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.

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8 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

9 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 84

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. 3.5.3. 3.5.8.	Physico-chemical Properties of the Granular Bait" Ratron®Granulat"	Anonymous[10]	2012
2	3.3.	Pour and Tap Density of Ratron®Granulat	Anonymous[10]	2011
3	3.4.1.1.	Physico-chemical Properties of the Granular Bait "Ratron®Granulat" before and after Accelerated Storage at 40 °C for 8 Weeks	Anonymous[10]	2012
4	3.4.1.2.	Physico-chemical Properties of the Granular Bait "Ratron®Granulat" when stored in Commercial Packaging Material over a Period of 2 Years at 20 °C	Anonymous[10]	2014
5	3.5.8.	Flowability of the Granular Bait "Ratron®Granulat" before and after accelerated storage at 40 °C ± 2 for 8 weeks	Anonymous[10]	2012
6	4.1.	E X P L O S I V E P R O P E R T I E S A.14. (OPPTS 830.6316)	Anonymous[10]	2011
7	4.14.	O X I D I S I N G P R O P E R T I E S A.17.	Anonymous[10]	2011
8	4.17.2.	AUTO_F L A M M A B I L I T Y (solids - determination of relative self-ignition temperature) A.16.	Anonymous[10]	2011
9	4.7.	F L A M M A B I L I T Y (S O L I D S) A.10.	Anonymous[10]	2011
10	5.1.	Analytical method for the determination of the content of active ingredient Difenacoum in the granular bait "Ratron Granulat 25 ppm"	Anonymous[10]	2018

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

11	6.7	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 1 of 8	Anonymous[10]	1999
12	6.7	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 5 of 8	Anonymous[10]	1999
13	6.7	Prüfung der Wirksamkeit von Delicia Ratron - Granulat an Wanderrattenrudeln und Mäusegruppen in Wahlversuchen Trial 2 of 4	Anonymous[10]	1999
14	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[10]	2017
15	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[10]	2017
16	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 203-16-8.2/WR	Anonymous[10]	2017
17	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[10]	2017
18	6.7	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 6 of 8	Anonymous[10]	1999
19	6.7	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 7 of 8	Anonymous[10]	1999
20	6.7	Gutachterliche Äußerung - Ratron-Granulat (B-0143-00-00) Trial 8 of 8	Anonymous[10]	1999
21	6.7	Prüfung der Wirksamkeit von Ratron Granulat (0,005% Brodifacoum) an Wanderratten (Rattus norvegicus) im Biotopversuch auf einem Bungalowgrundstück in Magdeburg	Anonymous[10]	2004
22	6.7	Ergebnisbericht - Ratron Granulat(B-0143-00-00) Trial 3 of 4	Anonymous[10]	2004

23	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[10]	2017
24	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[10]	2017
25	6.7	Gutachterliche Äußerung über "Ratron-Granulat" Trial 3 of 7	Anonymous[10]	1999
26	6.7	Gutachterliche Äußerung über "Ratron-Granulat" Trial 4 of 7	Anonymous[10]	1999
27	6.7	Prüfung der Wirksamkeit von Delicia Ratron - Granulat an Wanderrattenrudeln und Mäusegruppen in Wahlversuchen Trial 3 of 4	Anonymous[10]	1999
28	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[10]	2017
29	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[10]	2017
30	6.7	Gutachterliche Äußerung über "Ratron-Granulat" Trial 5 of 7	Anonymous[10]	1999
31	6.7	Gutachterliche Äußerung über "Ratron-Granulat" Trial 6 of 7	Anonymous[10]	1999
32	6.7	Gutachterliche Äußerung über "Ratron-Granulat" Trial 7 of 7	Anonymous[10]	1999
33	6.7	Bericht zur Amtlichen Prüfung von Pflanzenschutzmitteln (MUSXMU; Ratron-Granulat)	Anonymous[10]	2006
34	6.7	Bericht zur Amtlichen Prüfung von Pflanzenschutzmitteln (Musxmu; Ratron-Granulat)	Anonymous[10]	2003

35	6.7	Prüfung von Ratron Granulat (B-143-00-00), mit 25 ppm Brodifacoum auf Wirksamkeit und Attrakitivät gegen Rätelmäuse in RAum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-16-8.3/RM	Anonymous[10]	2017
36	6.7	Prüfung von Ratron Granulat (B-0143-00-00) auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-13-2.1/RM	Anonymous[10]	2013
37	6.7	Prüfung von Ratron Granulat (B-0143-00-00) auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-13-2.2/RM	Anonymous[10]	2013
38	6.7	Prüfung von Ratron Granulat (B-0143-00-00) auf Wirksamkeit und Attraktivität gegen Feldmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-13-2.1/FM	Anonymous[10]	2013
39	6.7	Prüfung von Ratron Granulat (B-0143-00-00) auf Wirksamkeit und Attraktivität gegen Feldmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-13-2.2/FM	Anonymous[10]	2013
40	6.7	Prüfung von Ratron Granulat (B-0143-00-00) auf Wirksamkeit und Attraktivität gegen Feldmäuse in Raum und Tierstall gemäß Par. 18 Infektionsschutzgesetz Trial: 203-13-2.2/FM	Anonymous[10]	2013
41	6.7	Prüfung von "Ratron Granulat" (B-0143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß §18 Infektionsschutzgesetz Trial 203-19-2.6/RM	Anonymous[10]	2019
42	6.7	Prüfung von "Ratron Granulat" (B-0143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß §18 Infektionsschutzgesetz Trial 203-19-2.7/RM	Anonymous[10]	2019

43	6.7	Prüfung von "Ratron Granulat" (B-0143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß §18 Infektionsschutzgesetz Trial 203-19-2.8/RM	Anonymous[10]	2019
44	6.7	Prüfung von "Ratron Granulat" (B-0143-00-00), mit 25 ppm Brodifacoum, auf Wirksamkeit und Attraktivität gegen Rötelmäuse in Raum und Tierstall gemäß §18 Infektionsschutzgesetz Trial 203-19-2.9/RM	Anonymous[10]	2019

4.2 List of studies for the active substance(s)

4.2.1 Brodifacoum

- 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[11]) of the active substance Brodifacoum for use in rodenticides (product-type 14). Please, refer to the corresponding Assessment Report for a reference list.

11 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

calculation_of_derma
l_and_inhalative_exp