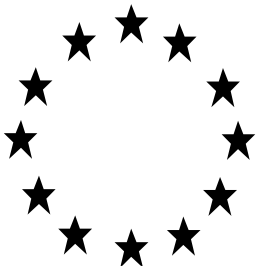
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION

(submitted by the eCA)



Klerat® Pellets XT

Product type 14

# Brodifacoum

## Evaluating Competent Authority: The Netherlands

## May 2022

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# 1. CONCLUSION

Klerat® Pellets XT is a ready for use pellet bait. The identity of the product is adequately described. The physical and chemical properties were addressed. A shelf life of 2 years is supported. No classification based on phys-chem properties is required.

| Use(s) appropriate for authorisation | |
|---|---|
| 1 | House mice and Brown Rats (indoor, general public) |
| 2 | House mice and Brown Rats (outdoor around buildings, general public) |
| 3 | House mice and Brown Rats (indoor, professionals) |
| 4 | House mice and Brown Rats (outdoor around buildings, professionals) |
| 5 | House mice and Brown rats (indoor, trained professionals) |
| 6 | House mice and Brown rats (outdoor around buildings, trained professionals) |

**National specific regulations in the Netherlands:**

Due to Dutch national specific regulations in the Netherlands only trained professionals and non-professionals are allowed to apply rodenticides (no professional use). Only trained professionals with additional IPM training are allowed to apply rodenticides outdoors. In addition, the use against house mice is restricted to use in buildings and for both house mice and rats use in covered and protected bait points or burrows is not allowed (derogations based on art 37 BPR).

Therefore, in the Netherlands the authorised use of this product will consist of the following uses (see table). The only application method of the product in the Netherlands will be in tamper-resistant bait boxes.

| Use(s) appropriate for authorisation in the Netherlands | |
|---|---|
| 1 | House mice (indoor, general public) |
| 2 | House mice and Brown rats (indoor, trained professionals) |
| 3 | Brown rats (outdoor around buildings, trained professionals with IPM training) |

Human health

For professional (trained professional – professional) use on the control of rats and mice, when decanting, loading and cleaning tasks are combined, no adverse effects are expected with the use of proper PPE (gloves).

Non-professional users are expected to use the product less frequently than trained professional or professional users. Therefore, the estimated uptakes have been assessed against the $AEL_{short\text{-}term}$ of $3.3 \times 10^{-6}$ mg/kg bw/day. Therefore, no adverse effects are expected for non- professional users without the use of PPE (gloves).

Exposure for infants indicates no safe use. However, in order to prevent accidental ingestion of bait by toddlers, the following risk mitigation measures are applied as stated in the instructions for use:

- The product is to be applied in tamper resistant bait stations by non-professional and professional users.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- This product contains a bittering agent.
- Store in places prevented from the access of children, birds, pets and farm animals.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- If the product was ingested accidentially, the following instructions are provided on the label/instructions for use:
    - Note to Physician: Antidote: Vitamin K1 administered by medical personnel only.
    - General: Have the product container, label or Safety Data Sheet with you when calling the emergency number, a poison control centre or physician, or going for treatment.
- Bait stations must be labelled with the following information:
    - Do not move or open
    - Contains a rodenticide
    - Product name or authorisation number
    - Active substance
    - In case of incident, call a poison centre [insert national phone number and name of the organisation].

Food, drinking water or livestock exposure is not foreseen as the product should not be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets, therefore the following risk mitigation measures apply which are stated on the label/instructions for use:

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

No livestock exposure is foreseen as the product is not intended to be applied to areas where livestock are present or may become exposed. To mitigate the risk of secondary animal exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

- Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry);
  Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

Risk assessment for the environment

No new data was provided. According to the risk assessment, the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 23 ppm in the ecotoxicology risk assessment.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR.

# 2. ASSESSMENT REPORT

## 2.1. Summary of the product assessment

### 2.1.1. Administrative information

#### 2.1.1.1. Identifier of the product

| Identifier | Country (if relevant) |
|---|---|
| Klerat® Pellets XT | EU/EEA/CH |

For confidential identifiers, see confidential Annex 3.6

#### 2.1.1.2. Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | Syngenta Crop Protection AG |
| | **Address** | Rosentalstrasse 67<br>4058 Basel<br>Switzerland |

#### 2.1.1.3. Manufacturer(s) of the product

| | |
|---|---|
| **Name of manufacturer** | Syngenta Hellas SA |
| **Address of manufacturer** | 2nd km Kinotiki odos<br>32011 Enofyta Viotias<br>Greece |
| **Location of manufacturing sites** | 2nd km Kinotiki odos<br>32011 Enofyta Viotias<br>Greece |

#### 2.1.1.4. Manufacturer(s) of the active substance(s)

| | |
|---|---|
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | Syngenta Crop Protection AG |

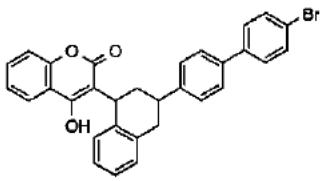
| | |
|---|---|
| **Address of manufacturer** | Rosentalstrasse 67<br>4058 Basel<br>Switzerland |
| **Location of manufacturing sites** | Vertellus Specialities UK Ltd<br>Hale Bank<br>Widnes, WA8 8NS<br>United Kingdom |

### 2.1.2. Product composition and formulation

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 ☒

#### 2.1.2.1. Identity of the active substance

| **Main constituent(s)** | | |
|---|---|---|
| **ISO name** | Brodifacoum (ISO) | |
| **IUPAC or EC name** | 3-[(1*RS*,3*RS*;1*RS*,3*SR*)-3-(4′-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-coumarin | |
| **EC number** | 259-980-5 | |
| **CAS number** | 56073-10-0 | |
| **Index number in Annex VI of CLP** | 607-172-00-1 | |
| **Minimum purity / content** | ≥950 g/kg (95% w/w) | |
| **Structural formula** |  | |
| **Index number in Annex VI of CLP** | 607-172-00-1 | |
| **Classification according to CLP, 9th ATP Commission Regulation EU/2016/1179** | *Hazard Class and Category Code* | *Hazard statement Code(s* |
| | Repr. 1A<br>Acute Tox. 1<br>Acute Tox. 1<br>Acute Tox. 1 | H360D<br>H330<br>H310<br>H300 |

| | | |
|---|---|---|
| | STOT RE 1<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H372 (blood)<br>H400<br>H410 |
| **Specific Conc. Limits, M-factors** | Repr. 1A; H360D: C ≥ 0,003%<br>STOT RE 1; H372 (blood): C ≥ 0,02 %<br>STOT RE 2; H373 (blood): 0,002 % ≤ C < 0,02 %<br>M = 10<br>M = 10' | |

### 2.1.2.2. Candidate(s) for substitution

Brodifacoum is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012[1].

### 2.1.2.3. Qualitative and quantitative information on the composition of the biocidal product

| Common name | IUPAC name | Function | CAS number | EC number | Content (% w/w) |
|---|---|---|---|---|---|
| Brodifacoum | 3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.0023<br>(Pure active, 23 ppm)<br>0.0024<br>(technical active) |
| Remainder of the formulation | | | See Confidential Annex 3.6 | | |

### 2.1.2.4. Information on technical equivalence

The source of brodifacoum used in the product is the reference source.

### 2.1.2.5. Information on the substance(s) of concern

Not applicable, the formulation does not contain any substances of concern.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1381&from=EN

### 2.1.2.6. Type of formulation

RB: Ready-for-use pellet bait

### 2.1.3. Hazard and precautionary statements

**Classification and labelling of the product according to CLP**

| Classification | |
|---|---|
| **Hazard category** | STOT RE, Cat. 2 |
| **Hazard statement** | H373: Causes damage to organs (blood) through prolonged or repeated exposure |
| **Labelling** | |
| **Hazard Pictograms** |  |
| **Signal word** | Warning |
| **Hazard statements** | H373: Causes damage to organs (blood) through prolonged or repeated exposure |
| **Supplemental Hazard Statements** | None. |
| **Precautionary statements** | P101: If medical advice is needed, have product container or label at hand.<br>P102: Keep out of reach of children.<br>P103: Read label before use.<br>P260: Do not breathe dust.<br>P314: Get medical advice/attention if you feel unwell.<br>P501: Dispose of contents/ container in accordance with local/ regional/national/international regulations. |

## 2.1.4. Authorised use(s)

### 2.1.4.1. Use description

**Table 1 Use # 1 – General Public - Indoor - House mice and Brown rats**

| | |
|---|---|
| **Product Type** | PT14 - Rodenticides |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse-Adults and Juveniles<br><br>*Rattus norvegicus* - Brown rat-Adults and Juveniles |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application -<br>Ready-to-use pellet bait in presealed sachets (15g) to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Mice:<br>- Place 2-3 sachets (30-45 g) of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations and a maximum of 5m for low infestations.<br>Rats:<br>Place 3-4 sachets (45-60g) per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high nfestation and a maximum of 10m for low infestations. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Pack size: Min 30g to Max 150 g<br>Number of sachets per packaging: 2-10 sachets per box<br>Grams of bait per sachet: 15 g<br>Packaging material: Sachet: Paper/LLDPE(opaque); Outer box: Cardboard |

#### 2.1.4.1.1. Use-specific instructions for use

| |
|---|
| For use only in tamper-resistant bait stations. Do not open sachets.<br><br>The bait stations should be visited at least every 2 to 3 days for mice, and 5 to 7 days for rats at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact, and to remove rodent bodies. Re-fill bait when necessary. |

#### 2.1.4.1.2. Use-specific risk mitigation measures

| |
|---|
| See general directions for use. |

#### 2.1.4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See general directions for use. |

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

| |
|---|
| Use of gloves is recommended. |

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

| |
|---|
| See general directions for use. |

### Table 2 Use # 2 – General Public - Outdoor around buildings – House mice and Brown rats

| | |
|---|---|
| **Product Type** | PT14 - Rodenticides |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse-Adults and Juveniles<br>*Rattus norvegicus* - Brown rat - Adults and Juveniles |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait application -<br>Ready-to-use pellet bait (15 g) in presealed sachets to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Mice: |

| | |
|---|---|
| | - Place 2-3 sachets (30-45 g) of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations and a maximum of 5m for low infestations.<br>Rats:<br>-Place 3-4 sachets (45-60g) per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestation and a maximum of 10m for low infestations. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Pack size: Min 30 g to Max 150 g<br>Number of sachets per packaging: 2-10 sachets per box<br>Grams of bait per sachet: 15 g<br>Packaging material: Sachet: Paper/LLDPE (opaque); Outer box: Cardboard |

Use-specific instructions for use

| |
|---|
| For use only in tamper-resistant bait stations. Do not open sachets.<br>Place the bait stations in areas not liable to flooding.<br>Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.<br>The bait stations should be visited at least every 2 to 3 days for mice , and 5 to 7 days for rats at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

### 2.1.4.1.6. Use-specific risk mitigation measures

| |
|---|
| See general directions for use. |

### 2.1.4.1.7. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See general directions for use. |

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

| |
|---|
| Use of gloves is recommended. |

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

| |
|---|
| See general directions for use. |

## Table 3 Use # 3 – Professionals – Indoor -House mice and Brown rats

| | |
|---|---|
| **Product Type** | PT14 – Rodenticides |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse - Adults and Juveniles<br>*Rattus norvegicus* - Brown rat - Adults and Juveniles |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application -<br>Ready-to-use pellet bait to be used in tamper-resistant bait stations |
| | |
| **Application rate(s) and frequency** | Mice: 30-50 g per bait station;<br>Rats: 50-75g per bait station<br>Mice:<br>30-50g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations and 5m for low infestations.<br>Rats:<br>50-75g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestations and 10m for low infestations. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Pack size: 3 kg, 5 kg, 8 kg, 10 kg<br>Loose bait packed in: Tub/Pouch<br>Packaging material: PP (opaque). |

### 2.1.4.1.10. Use-specific instructions for use

For use only in tamper-resistant bait stations.

The bait stations should be visited at least every 2 to 3 days for mice, and 5 to 7 days for rats at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

[When available] Follow any additional instructions provided by the relevant code of best practice.

### 2.1.4.1.11. Use-specific risk mitigation measures

See general directions for use.

### 2.1.4.1.12. 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 stations close to water drainage systems, ensure that bait contact with water is avoided.

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

See general directions for use.

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

See general directions for use.

### Table 4 Use # 4 – Professionals - Outdoor around buildings – House mice and Brown rats

| | |
|---|---|
| **Product Type** | PT14 - Rodenticides (Pest control) |
| **Where relevant, an exact description of the authorised use** | not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse - Adults and Juveniles<br>*Rattus norvegicus* - Brown rat - Adults and Juveniles |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait application - |

| | |
|---|---|
| | Ready-to-use pellet bait to be used in tamper-resistant bait stations. |
| **Application rate(s) and frequency** | Mice: 30-50g per bait station; Rats: 50-75g per bait station<br>Mice:<br>30-50g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations and 5m for low infestations.<br>Rats:<br>50-75g per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestations and 10m for low infestations. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Pack size: 3 kg, 5 kg, 8 kg, 10 kg<br>Loose bait packed in: Tub/Pouch<br>Packaging material: PP (opaque) |

### 2.1.4.1.15. Use-specific instructions for use

For use only in tamper-resistant bait stations.

Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

The bait stations should be visited only 2-3 days for mice and 5-7 days for rats after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

[When available] Follow any additional instructions provided by the relevant code of best practice.

### 2.1.4.1.16. Use-specific risk mitigation measures

Do not apply this product directly in the burrows.

To protect the environment do not place bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems to prevent flushing away of bait due to high rainfall events and flooding.

### 2.1.4.1.17. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

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

| |
|---|
| See general directions for use. |

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

| |
|---|
| See general directions for use. |

### Table 5 Use # 5 – Trained Professionals – Indoor - House mice and Brown rats

| | |
|---|---|
| **Product Type** | PT14 - Rodenticides (Pest control) |
| **Where relevant, an exact description of the authorised use** | not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse - Adults and Juveniles<br>*Rattus norvegicus* - Brown rat - Adults and Juveniles |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application -<br>Ready-to-use pellet bait to be used in tamper-resistant bait stations or at covered and protected bait points |
| **Application rate(s) and frequency** | Mice: 30-50g per bait station or bait point;<br>Rats: 50-75g per bait station or bait point<br><br>Mice:<br>30-50g per bait station/bait point. If more than one bait station/point is needed, the minimum distance between bait stations/points should be 2m for high infestations and a 5m for low infestations.<br><br>Rats:<br>50-75g per bait station/bait point. If more than one bait station/point is needed, the minimum distance between bait stations/points should be 5m for high infestations and 10m for low infestations. |
| **Category(ies) of users** | Trained professional |
| **Pack sizes and packaging material** | Pack size: 3 kg, 5 kg, 8 kg, 10 kg<br>Loose bait packed in: Box/Tub/Pouch<br>Packaging material: Box: Cardboard; Tub/Pouch: PP (opaque) |

### 2.1.4.1.20. Use-specific instructions for use

For use only in tamper resistant bait stations and covered/protected bait points.

The bait stations should be visited at least every 2 to 3 days for mice, and 5 to 7 days for rats at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

Remove the remaining product at the end of treatment period.

[When available] Follow any additional instructions provided by the relevant code of best practice.

### 2.1.4.1.21. Use-specific risk mitigation measures

Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].

Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

Do not use the product in pulsed baiting treatments.

### 2.1.4.1.22. 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 stations close to water drainage systems, ensure that bait contact with water is avoided.

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

See general directions for use.

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

See general directions for use.

**Table 6 Use # 6 – Trained Professionals – Outdoor around buildings – House mice and Brown rats**

| | |
|---|---|
| **Product Type** | PT14 - Rodenticides (Pest control) |
| **Where relevant, an exact description of the authorised use** | not relevant for rodenticides |
| **Target organism (including development stage)** | *Mus musculus* - House mouse - Adults and Juveniles<br>*Rattus norvegicus* - Brown rat - Adults and Juveniles |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait application -<br>-Ready-to-use pellet bait to be used in tamper-resistant bait stations,<br>-Covered and protected bait points<br>-Direct application of ready – to-use bait into the burrow . |
| | |
| **Application rate(s) and frequency** | Mice: 30-50g per bait station or bait point;<br>Rats: 50-75g per bait station or bait point, 50 g per burrow<br>Mice:<br>30-50g per bait station/bait point. If more than one bait station/point is needed, the minimum distance between bait stations/points should be 2m for high infestations 5m for low infestations.<br>Rats:<br>50-75g per bait station/bait point. If more than one bait station/point is needed, the minimum distance between bait stations/points should be 5m for high infestations 10m for low infestations.<br>50 g of bait per burrow |
| **Category(ies) of users** | Trained professional |
| **Pack sizes and packaging material** | Pack size: 3 kg, 5 kg, 8 kg, 10 kg<br>Loose bait packed in: Box/Tub/Pouch/<br>Packaging material: Box: Cardboard; Tub/Pouch: PP (opaque) |

## 2.1.4.1.25. Use-specific instructions for use

| |
|---|
| For use in tamper-resistant bait stations, covered/protected bait points or in burrows. |
| Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding. |
| Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt. |
| Remove the remaining product at the end of treatment period |
| Baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species |
| -Burrow baits must be placed to minimise the exposure to non-target species and children. |
| -Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled. |

| |
|---|
| [When available] Follow any additional instructions provided by the relevant code of best practice. |

### 2.1.4.1.26. Use-specific risk mitigation measures

| |
|---|
| Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].<br>Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.<br>To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.<br>Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.<br>Do not use the product in pulsed baiting treatments.<br><br>To protect the environment do not place bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems to prevent flushing away of bait due to high rainfall events and flooding. |

### 2.1.4.1.27. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

| |
|---|
| See general directions for use. |

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

| |
|---|
| See general directions for use. |

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

| |
|---|
| See general directions for use. |

## 2.1.5. General directions for use

| |
|---|
| General Public: |

-Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

- Remove 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.

- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

- Where possible, bait stations must be fixed to the ground or other structures.

- Do not open the sachets containing the bait.

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- Do not place bait stations near water drainage systems where they can come into contact with water.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- Remove the remaining bait or the bait stations at the end of the treatment period.

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

(Trained) Professionals:

-Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

-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.

-Remove 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.

-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.

-Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of re-invasion.

-The product should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

-Where possible, bait stations must be fixed to the ground or other structures.

-Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.

- *[If national policy or legislation require it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

-Bait should be secured so that it cannot be dragged away from the bait station.

-Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

-Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

-When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

-If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation.

-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 rodents 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.

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

-Place the loose pellets in the baiting point by using a dosage device. Specify the methods to minimise dust (e.g. wet wiping).

Only for trained professionals:

The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

### 2.1.5.1. Risk mitigation measures

General Public:

-Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

-Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

-To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week).

-Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

-The product information (i.e. label and/or leaflet) shall clearly show that:

the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

Users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").

-Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

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

Professionals:

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".

- To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

- Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- The product information (i.e. label and/or leaflet) shall clearly show that:

the product shall not be supplied to the general public (e.g. "for professionals only").

the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").

- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- Do not wash the bait stations with water between applications.

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

Trained professionals:

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".

- 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".

- Do not use in areas where resistance to the active substance can be suspected.

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment *[unless authorised for permanent baiting treatments]*.

- 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.

- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.

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

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

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.

Note to Physician: Antidote - Vitamin K1 administered by medical/veterinary personnel only.

General: Have the product container, label or Safety Data Sheet with you when calling the emergency number, a poison control centre or physician, or going for treatment.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Contact a veterinary surgeon in case of ingestion by a pet.

Hazardous to wildlife

Bait stations must be labelled with the following information: "Do not move or open"; "Contains a rodenticide"; "Product name or authorisation number"; "Active substance(s)" and "In case of incident, call a poison centre [insert national phone number]

National Poison Centre: [Insert organisation name and contact information]

### 2.1.5.3. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose 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]*.

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

Store in a dry, cool and well ventilated place.

Keep in original container. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

Shelf life: 2 years

### 2.1.6. Other information

Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

### 2.1.7. Other information

Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.

Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

This product contains a bittering agent and a dye.

### 2.1.8. Packaging of the biocidal product

| User | Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---|---|---|---|---|---|
| Non-professional | Sachet | 15g | Paper/ LLDPE (product is in contact with LLPDE),<br>LDPE | Heat sealed bag | Yes |
| | Outer packaging (sachet): Box; | Box:<br>Min. 30g to max. 150g<br>i.e. 2-10 sachets per box | Box: Cardboard | N/A | Not applicable (secondary packaging material) |
| Professional & Trained Professional | Loose bait contained in: Box Tub/Pouch | Box:<br>3, 5, 8, 10 kg<br>Tub/pouch:<br>3, 5, 8, 10 kg | Box: Cardboard<br>Tub/pouch: PP | Tub: peel-off PP lid<br>Pouch: heat sealed | Yes |

### 2.1.9. Documentation

#### 2.1.9.1. Data submitted in relation to product application

See list of references, Annex 3.1.

#### 2.1.9.2. Access to documentation

Syngenta Crop Protection AG (Syngenta) is the owner and submitter of the files, data, studies, summaries and assessments that relate to the biocidal product and active substance dossier in support of the authorisation for the biocidal product under EU Regulation 528/2012 as a PT14 rodenticide.

## 2.2. Assessment of the biocidal product

### 2.2.1. Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

**Table 7 Use # 1 – General Public/Amateur/non-Professional – House mice and/or rats in and around buildings**

| | |
|---|---|
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Rodenticide |
| **Category(ies) of users** | General Public/Amateur/non-Professional |
| **Target organism (including development stage)** | ***Rats***<br>Scientific name: *Rattus norvegicus*<br>Common name: Norway rat or Brown rat<br>Development stage: Adults and juveniles<br><br>***Mice***<br>Scientific name: *Mus musculus*<br>Common name: House mouse<br>Development stage: Adults and juveniles |
| **Field of use** | In and around buildings |
| **Application method(s)** | Ready-to-use bait (15g) in pre-sealed sachets used in tamper-resistant bait stations. |

| Application rate(s) and frequency | | | | |
|---|---|---|---|---|
| **Target Organism** | **Area of use** | **Dosage** | **Recommended distance between bait stations (m)*** | **Application method** |
| Mice<br>*M. musculus*<br>*(House mouse)* | Indoor | 1 sachet (15 g) per bait station | 5 (low infestation)<br>2 (high infestation) | Tamper-resistant bait stations |
| Rats<br>*R. norvegicus*<br>(Brown rat). | Indoor or outdoor around buildings | 1-3 sachets (15-45 g) bait per bait station | 10 (low infestation)<br>5 (high infestation) | Tamper-resistant bait stations |
| * Where more than one bait station is required | | | | |

| | |
|---|---|
| **Frequency** | An initial inspection of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed, 1-3 times per week until infestation is controlled (max 5 weeks). Replace any bait that has been eaten by rodents, damaged by water or contaminated by dirt. |
| **Pack sizes and packaging material** | See section 2.1.8, packaging. |

## Table 8 Use # 2 – Professionals – House mice and/or rats in and around buildings

| | |
|---|---|
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Rodenticide |
| **Category(ies) of users** | Professional |
| **Target organism (including development stage)** | ***Rats***<br>Scientific name: *Rattus norvegicus*<br>Common name: Norway rat or Brown rat<br>Development stage: Adults and juveniles<br><br>***Mice***<br>Scientific name: *Mus musculus*<br>Common name: House mouse<br>Development stage: Adults and juveniles |
| **Field of use** | In and around buildings |
| **Application method(s)** | Ready-to-use bait used in tamper-resistant bait stations |

**Application rate(s) and frequency**

| Target Organism | Area of use | Dosage | Recommended distance between bait stations (m)* | Application method |
|---|---|---|---|---|
| Mice<br>*M. musculus*<br>*(House mouse)* | Indoor or outdoor around buildings | 5-15 g bait per bait station | 5 (low infestation)<br>2 (high infestation) | Tamper-resistant bait stations |
| Rats<br>*R. norvegicus*<br>(Brown rat). | Indoor or outdoor around buildings | 20-50 g bait per bait station | 10 (low infestation)<br>5 (high infestation) | Tamper-resistant bait stations |

* Where more than one bait station is required

| | |
|---|---|
| **Frequency** | An initial inspection of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed, 1-3 times per week until infestation is controlled (max 5 weeks). Replace any bait that has been eaten by rodents, damaged by water or contaminated by dirt. |
| **Pack sizes and packaging material** | See section 2.1.8, packaging. |

## Table 9 Use # 3 – Trained Professionals – House mice and/or rats in and around buildings and in burrows

| | |
|---|---|
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Rodenticide |
| **Category(ies) of users** | Trained professional |
| **Target organism (including development stage)** | ***Rats***<br>Scientific name: *Rattus norvegicus*<br>Common name: Norway rat or Brown rat<br>Development stage: Adults and juveniles<br><br>***Mice***<br>Scientific name: *Mus musculus*<br>Common name: House mouse<br>Development stage: Adults and juveniles |
| **Field of use** | In and around buildings<br>Outdoor, burrows |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations or covered/protected bait points and in burrows. |

**Application rate(s) and frequency**

| Target Organism | Area of use | Dosage | Recommended distance between bait stations (m)* | Application method |
|---|---|---|---|---|
| Mice<br>*M. musculus*<br>*(House mouse)* | Indoor and outdoor around buildings | 5-15 g bait per bait station or bait point | 5 (low infestation)<br>2 (high infestation) | Tamper-resistant bait stations or covered and protect bait points |
| Rats<br>*R. norvegicus*<br>(Brown rat). | Indoor and outdoor around buildings | 20-50 g bait per bait station or bait point | 10 (low infestation)<br>5 (high infestation) | Tamper-resistant bait stations or covered and protect bait points |
| | Outdoor<br>(burrows) | 20-50 g bait per burrow | N/A | Burrow baiting |

* Where more than one bait station is required

| | |
|---|---|
| **Frequency** | An initial inspection of bait points after 3 or 4 days is recommended. Replace any bait that has been consumed, 1-3 times per week until infestation is |

| | |
|---|---|
| | controlled (max 5 weeks). Replace any bait that has been eaten by rodents, damaged by water or contaminated by dirt. |
| **Pack sizes and packaging material** | See section 2.1.8, packaging. |

## 2.2.2. Physical, Chemical and Technical Properties

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| ***3.1*** | ***Appearance*** | | | | | | |
| 3.1.1 | Physical state at 20 °C and 101.3 kPa | Visual inspection | Content of Brodifacoum 0.002466% w/w | Solid | - | Y | [redacted] 2018a |
| 3.1.3 | Colour at 20 °C and 101.3 kPa | Visual description | | Pink | - | Y | [redacted] 2018a |
| 3.1.3 | Odour at 20 °C and 101.3 kPa | Comparison to other characteoristics odours | | Medium grain | - | Y | [redacted] 2018a |
| ***3.2*** | ***Acidity/alkalinity*** | | | | | | |
| 3.2.1 | pH 1% dispersion at 21.8°C | CIPAC MT 75.3 | Content of Brodifacoum 0.002466% w/w | 6.5 | - | Y | [redacted] 2018a |
| 3.2.2 | Acidity/alkalinity | - | | - | Not required, as pH of a 1% solution is >4 and <10 | - | - |
| ***3.3*** | ***Relative density (liquids) and bulk, tap density (solids)*** | | | | | | |
| 3.3.1 | Relative density | - | - | - | Not required. The product is a solid. | - | - |
| 3.3.2 | Pour density | CIPAC MT186 (Bulk density) | Content of Brodifacoum 0.002466% w/w | 0.607 g/ml | - | Y | [redacted] 2018a |
| 3.3.2 | Tap density: | CIPAC MT186 (Bulk density) | | 0.647 g/ml | - | Y | [redacted] 2018a |
| ***3.4.1.1*** | ***Accelerated storage tests*** | | | | | | |
| 3.4.1.1.1 | Accelerated storage (54°C for 14 days in PP | CIPAC MT 46.3 | | **Parameter** / **Initial** / **2 weeks at 54°C** | | Y | [redacted] 2018a |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | | | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | bucket packaging), 2 test items | | Content of Brodifacoum 0.002466% w/w | *Brodifacoum content (%) (HPLC-UV)* | 0.002466 | 0.002445<br>Decrease: 0.85% | eCA remark:<br>Acceptable<br>The parameters remained within acceptable limits and active substance content was determined using method MV171. This is the validated method (see section 2.2.4). | | |
| | | | | *Physical state (Visual method)* | Pellets | Pellets | | | |
| | | | | *Colour (Visual method)* | Pink | Slightly brownish-orange | | | |
| | | | | *Odour (Comparison)* | medium grain | medium grain | | | |
| | | | | *Weight loss (%)* | - | 0.1 – 1.2 | | | |
| | | | | *Packaging* | H 14.1 cm<br>W 15.5 cm<br>L 23.4 cm | H 14.4 cm<br>W 15.6 cm<br>L 23.4 cm | | | |
| | | | | *Packaging stability* | Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed, the label is intact | Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed, the label is intact | | | |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | | | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | *pH of a 1% solution* *(CIPAC MT 75.3)* | 6.5 (T=21.8 °C) | 6.5 (T=21.0 °C) | | | |
| | | | | *Attrition resistance (%)* *(CIPAC MT 178)* | Mean: 99.85 | Mean: 99.81 | | | |
| | | | | *Dust content (optical dust factor)* *(CIPAC MT 171.1)* | 1.72 (nearly dust-free) | 2.04 (nearly dust-free) | | | |
| | | | | *Sieve analysis* *(CIPAC MT 170)* | Rx ≥ 90%: 2000 µm<br>Rx ≤ 10%: 2000 µm | Rx ≥ 90%: 2000 µm<br>Rx ≤ 10%: 2000 µm | | | |
| 3.4.1.1.2 | Accelerated storage (54°C for 14 days in bag made of paper/PE packaging), 20 test items | CIPAC MT 46.3 | Content of Brodifacoum 0.002291% w/w | **Parameter** | **Initial** | **2 weeks at 54°C** | - eCA remark: Acceptable The applicant confirmed that the bags are made of LLDPE/paper, with the product being in contact with LLDPE. The parameters remained within acceptable limits | Y | [redacted] 2018b |
| | | | | *Brodifacoum content (%)* *(HPLC-UV)* | 0.002291 | 0.002320 Increase: 1.3% | | | |
| | | | | *Physical state* *(Visual method)* | Pellets | Pellets | | | |
| | | | | *Colour* *(Visual method)* | Pink | Pink | | | |
| | | | | *Odour* *(Comparison)* | Weak grain | Weak grain | | | |

<table>
<tr><th>BPR Endpoint</th><th>Property</th><th>Guideline or Method</th><th>Purity of the test substance (% (w/w)</th><th colspan="3">Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Weight loss (%)</td><td>-</td><td>6.94 – 7.92</td><td rowspan="4">and active substance content was determined using method MV171. This is the validated method (see section 2.2.4).</td><td rowspan="4"></td><td rowspan="4"></td></tr>
<tr><td></td><td></td><td></td><td></td><td>Packaging</td><td>H 11.4 mm<br>W 75 mm<br>L 90 mm</td><td>H 10.3 mm<br>W 75 mm<br>L 88 mm</td></tr>
<tr><td></td><td></td><td></td><td></td><td>Packaging stability</td><td>Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed</td><td>Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed</td></tr>
<tr><td></td><td></td><td></td><td></td><td>pH of a 1% solution<br>(CIPAC MT 75.3)</td><td>6.3<br>(T=19.5 °C)</td><td>6.3<br>(T=19.6 °C)</td></tr>
<tr><td>3.4.1.2</td><td>Long term storage at ambient temperature (24 months at 20°C in PP Buckets packaging) 5 test items</td><td>-</td><td>Content of Brodifacoum 0.002466% w/w</td><td colspan="3">Two year ambient study.<br><table><tr><th>Parameter</th><th>Initial</th><th>24 months at 20°C</th></tr><tr><td>Brodifacoum content (%)<br>(HPLC-UV)</td><td>0.002466</td><td>0.002362<br>Decrease: 4.2%</td></tr><tr><td>Physical state<br>(Visual method)</td><td>Pellets</td><td>Pellets</td></tr></table></td><td>-</td><td>Y</td><td>[redacted]<br>2018b</td></tr>
</table>

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | | | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | *Colour (Visual method)* | Pink | Pink | | | |
| | | | | *Odour (Comparison)* | medium grain | medium grain | | | |
| | | | | *Weight loss (%)* | - | 0.20 | | | |
| | | | | *Packaging* | H 14.1 cm<br>W 15.5 cm<br>L 23.4 cm | H 14.0 cm<br>W 16.9 cm<br>L 24.1 cm | | | |
| | | | | *Packaging stability* | Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed, the label is intact | Test item in sound condition, sealed and without leakages; no panelling or ballooning was observed, the label is intact | | | |
| | | | | *pH of a 1% solution (CIPAC MT 75.3)* | 6.5 (T=21.8 °C) | 6.8 (T=20°C) | | | |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | *Attrition resistance (%)* *(CIPAC MT 178)*: Mean: 99.85; Mean: 99.82<br>*Dust content (optical dust factor)* *(CIPAC MT 171.1)*: 1.72 (nearly dust-free); 0.07 (nearly dust-free)<br>*Sieve analysis* *(CIPAC MT 170)*: Rx ≥ 90%: 2000 µm; Rx ≤ 10%: 2000 µm; Rx ≥ 90%: 2000 µm; Rx ≤ 10%: 2000 µm<br>Note: The efficacy study (please refer to efficacy section 6.7, study by Prescott, 2017) was conducted with the aged product. At the start point of the study the formulated product (Batch EN04G21184) was 22 month old. The study demonstrates that the product maintained its palatability for two years and supports a two year shelf life. | | | |
| 3.4.1.3 | Low temperature stability test for liquids | - | - | - | Not applicable. The product is not a liquid. | - | - |
| ***3.4.2*** | ***Effects on content of the active substance and technical characteristics of the biocidal product*** | | | | | | |
| 3.4.2.1 | Light | - | - | - | Not required, as the commercial packaging precludes light and | - | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | | the active substance and coformulants are not known to be photosensitive. | | |
| 3.4.2.2 | Temperature and humidity | - | - | - | The effects of temperature are addressed in the accelerated storage stability studies.<br>In all conducted storage stability studies (please refer to both accelerated storage stability studies and the ongoing for 1 year long term storage stability study ) no influence of the moisture from the air on the packaging material and the formulated product was observed.<br>Both test item andits packaging remained in sound conditions. No increase of the weight of the test item and its packaging was | - | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | | noticed, what theoretically can be considered as a sign of the negative effect of the humidity of the products packaged in paper bags or buckets.<br><br>eCA remark:<br>The effect of humidity on the product stored in cardboard boxes were not addressed. However, the storage conditions indicate that the product should be kept dry. Cardboard boxes are therefore acceptable as well. | | |
| 3.4.2.3 | Reactivity towards container material | - | - | - | See storage stability studies for reactivity towards container material. | - | - |
| ***3.5*** | ***Technical Characteristics*** | | | | | | |
| 3.5.1 | Wettability | - | - | - | The product is not intended to be dispersed in water. | - | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| 3.5.2 | Suspensibility and spontaneity and dispersion stability | - | - | - | Not applicable. The product is a ready for use formulation and is not sprayed nor dispersed in water.. | - | - |
| 3.5.3 | Wet sieve test/Dry sieve analysis | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.4 | Emulsifiability, re-emulsifiability and emulsion stability | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.5 | Disintegration time | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.6 | Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 170 | - | Rx ≥ 90%: 2000 µm<br>Rx ≤ 10%: 2000 µm | eCA remark:<br>Acceptable<br>Six sieves were used, whereby the sieve with the largest preferred hole size (3350 µm) was omitted. It can be concluded that the biocidal product consists for >99.5% of pellets over 2 mm. The particle size is therefore | - | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | | addressed sufficiently. | | |
| 3.5.6.1 | Attrition and friability | CIPAC MT 178 (Attrition resistance) | Content of Brodifacoum 0.002466% w/w | Attrition resistance: 99.82%. | - | Y | [redacted] 2018a |
| 3.5.7 | Persistent foaming | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.8.1 | Flowability / Pourability / Dustability | CIPAC MT 172 (Flowability) | Content of Brodifacoum 0.002466% w/w | Only a small amount of sample dropped spontaneously through the sieve.<br>Mean after 5 liftings: 44.95g remained on the sieve.<br>Mean after 20 liftings: 44.6g remained on the sieve. | eCA remark:<br>Acceptable<br>This end point is not required for products of formulation type RB. | Y | [redacted] 2018a |
| 3.5.8.2 | Pourability | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.8.3 | Dustability | CIPAC MT 171.1 | Content of Brodifacoum 0.002466% w/w | 1.72 (nearly dust-free) | | Y | [redacted] 2018a |
| 3.5.9 | Burning rate - smoke generators | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.10 | Burning completeness - smoke generators | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.11 | Composition of smoke - smoke generators | - | - | - | Not applicable to a ready for use solid bait. | - | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| 3.5.12 | Spraying pattern - aerosols | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.5.13 | Other technical characteristics | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| ***3.6*** | ***Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised*** | | | | | | |
| 3.6.1 | Physical compatibility | - | - | - | The product is not intended to be authorised for use with other products. | - | - |
| 3.6.2 | Chemical compatibility | - | - | - | The product is not intended to be authorised for use with other products. | - | - |
| 3.7 | Degree of dissolution and dilution stability | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.8 | Surface tension | - | - | - | Not applicable to a ready for use solid bait. | - | - |
| 3.9 | Viscosity | - | - | - | Not applicable to a ready for use solid bait. | - | - |

**Conclusion on the physical, chemical and technical properties of the product**

The product is a pink wheat based pellet (RB) formulation containing 23 ppm of brodifacoum. There was an acceptable retention of the physical and chemical properties after accelerated storage at 54°C in both the professional (PP) and consumer packaging presentations (paper/LLDPE). The long-term storage stability studies at ambient temperatures show that the product is stable for the 24 months. Palatability was acceptable after 24 months. Hence, shelf life is 2 years.

## 2.2.3. Physical Hazards and Respective Characteristics

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| 4.1 | Explosives | EC A.14 | Content of Brodifacoum 0.002466% w/w | The test item has no explosive properties.<br>Since the heat of decomposition of the test item was above 500 J/kg, the main tests were conducted:<br>- mechanical sensitivity: no explosion of the test item occurred within 6 tests using a pinload of 360 N (friction) and using a mass of 10 kg failing from a height of 0.4 m (shock)<br>- thermal sensitivity: the test carried out with a nozzle with a diameter of 2.0 mm showed no explosion | - | Y | [redacted], 2018a |
| | | UN Test 1(c) / 2(c) / C.1 Time-pressure-test | Content of Brodifacoum 0.002390% w/w | The result of the Time-Pressure-Test for the test item was evaluated as negative according to UN-tests 1(c), 2(c) and C.1:<br>UN-Tests 1(c) and 2(c): "-"<br>UN-Test C.1: "no" | - | Y | [redacted] 2019 |
| | | UN Test Koenen-Test | | The result of the Koenen-Test for the test item was evaluated as negative according to UN-tests 1(b), 2(b) and E.1:<br>UN-Tests 1(b) and 2(b): "-" | - | - | [redacted]2019b |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | UN-Test E.1: “no“<br><br>Final conclusion:<br>Due to the results presented above from the UN-tests 1(b) and 1(c) the test item can be excluded from classification in class 1 (explosives) according to series 1 of the UN Recommendations on Transport of Dangerous Goods - Manual of Test and Criteria, rev. 6 (2015).- | | | |
| 4.2 | Flammable gases | - | - | - | Not applicable to a solid. | - | - |
| 4.3 | Flammable aerosols | - | - | - | Not applicable to a solid. | - | - |
| 4.4 | Oxidising gases | - | - | - | Not applicable to a solid. | - | - |
| 4.5 | Gases under pressure | - | - | - | Not applicable to a solid. | - | - |
| 4.6 | Flammable liquids | - | - | - | Not applicable to a solid. | - | - |
| 4.7 | Flammable solids | UN Manual of test and criteria, rev.6<br>UN test N.1 | Content of Brodifacoum 0.002466% w/w | The test item coud not be ignited and is thus not flammable | - | Y | [redacted], 2018b |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| 4.8 | Self-reactive substances and mixtures | - | - | - | None of the components of the product are classified as self-reacting substances.- | - | - |
| 4.9 | Pyrophoric liquids | - | - | - | Not applicable to a solid. | - | - |
| 4.10 | Pyrophoric solids | - | - | - | None of the components of the product are classified as pyrophoric. Experience in the use of the product does not indicate that the product will be pyrophoric | - | - |
| 4.11 | Self-heating substances and mixtures | UN Manual of test and criteria, rev.6<br>UN test N.4 | Content of Brodifacoum 0.002466% w/w | The test item does not undergo dangerous self-heating when tested at 140°C and is thus not classified as a self-heating substance. | - | Y | [redacted] 2018e |
| 4.12 | Substances and mixtures which in contact with water emit flammable gases | UN Manual of test and criteria, rev.6<br>UN test N.5 | Content of Brodifacoum 0.002466% w/w | The test item in contact with water showed no evolution of gas and no spontaneous igniton was observed and is thus not classified as mixture which in contact with water emit flammable gases<br>The test item is not classified as a substance which on contact | - | Y | [redacted] 2018c |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | with water emits flammable gases. | | | |
| 4.13 | Oxidising liquids | - | - | | Not applicable to a solid. | | |
| 4.14 | Oxidising solids | UN Manual of test and criteria, rev.6<br>UN test O.1 | Content of Brodifacoum 0.002466% w/w | The test item with cellulose burned slower than the slowest reference mixture and thus is not classified as an oxidising solid<br>The test item is not classified as an oxidising solid. | - | Y | [redacted] 2018d |
| 4.15 | Organic peroxides | - | - | - | None of the components of the product are known to be organic peroxides | - | - |
| 4.16 | Corrosive to metals | - | - | - | None of the components of the product are known to be corrosive to metal. Experience in the use of the product does not indicate that the product will react with metal. The product is a solid | - | - |
| 4.17.1 | Auto-ignition temperatures of products (liquids and gases) | - | - | - | Not applicable to a solid. | - | - |
| 4.17.2 | Relative self-ignition temperature for solids | - | - | Covered by Self-heating substances and mixtures. | None of the components of the | | - |

| BPR Endpoint | Property | Guideline or Method | Purity of the test substance (% (w/w) | Results | Remarks/ Justification | GLP (Y/N) | Reference |
|---|---|---|---|---|---|---|---|
| | | | | Please refer to point 4.11 | product are known to be self-heating. Experience in the use of the product does not indicate that the product is self-heating. | | |
| 4.17.3 | Dust explosion hazard | - | - | .- | Not required, as none of the components of the product are classified as explosive and there is no risk of dust being present | - | - |

| Conclusion on the physical hazards and respective characteristics of the product |
|---|
| Following a review of the components of the product and based on the experiments conducted it can be concluded that the product is not explosive, flammable, self-reactive, pyrophoric, self-heating, substances which emit flammable gases in contact with water, oxidising or corrosive to metals. The product does not require classification under Regulation (EC) No 1272/2008 for physical hazards. |

## 2.2.4. Methods for detection and identification

The active substance content in the test item has been determined by high performance liquid chromatography (HPLC) with UV detection.

The sample of test item solution has been grinded. Approximately 20g was weighted into 250 mL conical flask. 50 mL of solvent mix was added and the sample was refluxed for 30 minutes. After acclimatization the sample was filtered before vialing.

Chromatographic conditions:

| | |
|---|---|
| Column: | Nucleosil 120-5 $C_{18}$ (Particle Size: 5 µm, Length: 250 mm, I.D.: 4 mm) |
| Flow: | 1.0 mL/min |
| Eluent: | A: 3.85 g Ammoniumacetate / 2mL Acetic acid / 2 mL Triethylamine fill to 1000 mL with water, B: Methanol |
| Injector volume: | 1.0 mL/min |
| Temperature: | 20°C |
| Detection: | UV 254 nm |
| Retention time: | approx. 13 min Brodifacoum |

**Analytical methods for the analysis of the product**

| Analyte (type of analyte e.g. active substance) | Analytical method | Linearity | Specificity | Precision (% RSD) | Recovery rate (%) | | | Limit of quant. (LOQ) | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Range | Mean (%) | RSD | | |
| Brodifacoum | HPLC-UV (MV 171) | 3 concentrations<br>0.0077 – 0.0143 mg/mL, triple injections,<br><br>$Y=18.09*10^{3}x-16.46$<br><br>r = 1.00 | No interfering peaks were observed in blank control samples | 0.83 (n=6), $RSD_r$= 6.69, thus RSD<$RSD_r$ | 70%<br>100%<br>130% | 90.6 (n=3)<br>93.9 (n=3)<br>96.9 (n=3) | 1.6<br>0.2<br>0.9 | 0.00161 % w/w (70% of nominal) | [redacted] 2017a [redacted], 2017b, Validation of Method MV171: SYN: HPLC - Determination of Brodifacoum in Baits |

**Conclusion on the methods for detection and identification of the product**

A HPLC-UV method for the determination of brodifacoum in the product is available and has been fully validated in accordance with SANCO/3030/99 rev. 4.

### 2.2.4.1. Analytical methods for monitoring

### 2.2.4.2. Analytical methods for soil, water and air

Methods of analysis for the determination of brodifacoum residues in environmental matrices have previously been evaluated at EU level and accepted for inclusion in the Union list of approved active substances.

### 2.2.4.3. Analytical methods for animal and human body fluids and tissues

Methods of analysis for the determination of brodifacoum residues in animals and human body fluids and tissues have previously been evaluated at EU level and accepted for inclusion in the Union list of approved active substances.

### 2.2.4.4. Analytical methods for monitoring of active substances and residues in food and feeding stuff

Not applicable. Exposure to food and feeding stuffs is not expected to occur.

## 2.2.5. Efficacy against target organisms

### 2.2.5.1. Function and field of use

The product is a ready-to-use pellet bait for use in tamper-resistant bait stations and protected or covered bait points. The product is a rodenticide for the control of brown rats (*R. norvegicus*) and mice (*M. musculus*) in and around buildings and in burrows. User categories are the general public (non-professionals), professionals and trained professionals.

Application rates

General public

| User Group | Application rate | | Frequency |
|---|---|---|---|
| | Mice | Rats | |
| General public (non-professional) | Place 2 to 3 sachets (30 – 45 g) per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2m for high infestations and 5m for low infestations. | Place 3 to 4 sachets (45 – 60 g) per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestation and 10m for low infestations. | An initial inspection of bait points after 2-3 days for mice and 5-7 days for rats is recommended. Replace any bait that has been consumed 1-3 times per week until the infestation is controlled (max. 5 weeks). Replace contaminated or spoiled bait. |

Professional

| User Group | Application rate | | Frequency |
|---|---|---|---|
| | Mice | Rats | |
| Professional | Place 30 – 50 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be 2 meters for high infestations and 5m for low infestations. | Place 50 – 75 g bait per bait station bait point. If more than one bait station is needed, the minimum distance between bait stations should be 5m for high infestation and 10m for low infestations | An initial inspection of bait points after 2-3 days for mice and 5-7 days for rats is recommended. Replace any bait that has been consumed 1-3 times per week until the infestation is controlled (max. 5 weeks). Replace contaminated or spoiled bait. |

Trained Professional

| User Group | Application rate | | Frequency |
|---|---|---|---|
| | Mice | Rats | |
| Trained Professional | Place 30 - 50 g bait per bait station or covered/protected bait point. If more than one bait point is needed, the minimum distance between bait stations should be 2 meters 2m for high infestation and 5 m for low infestations ( | Place 50– 75 g bait per bait station or covered/protected bait point. If more than one bait point is needed, the minimum distance between bait stations should be 5m for high infestation and 10m for low infestations | An initial inspection of bait points after 2-3 days for mice and 5-7 days for rats is recommended. Replace any bait that has been consumed 1-3 times per week until the infestation is controlled (max. 5 weeks). Replace contaminated or spoiled bait. |
| | - | Burrows: 50g per burrow | - |

### 2.2.5.2. Organisms to be controlled and products, organisms or objects to be protected

For the control of brown rats (*R. norvegicus*) and mice (*M. musculus*)

The purpose of Klerat® Pellets XT includes:

Prevention of infestations of rodents known to transmit diseases;

Prevention of degradation or contamination of food and feeding stuffs and other materials, with urine, faeces and rodent hairs, at all stages of their production, storage and use;

Protection of buildings and structures including pipes, cables and overall integrity;

Protection of livestock, wild and domestic;

Prevention of social abhorrence.

### 2.2.5.3. Effects on target organisms, including unacceptable suffering

Rodents typically ingest the bait repeatedly over one to three days before first symptoms of poisoning occur. The biocidal effect appears between 4 and 10 days after ingestion of the baits.

Typical symptoms are general weakness, anorexia, and reduced locomotion.

According to the BPC opinion on brodifacoum (ECHA/BPC/113/2016): It is recognised that slow acting anticoagulant rodenticides like Brodifacoum do cause pain for several days in rodents and are generally not considered as a humane method to control 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.

### 2.2.5.4. Mode of action, including time delay

Brodifacoum acts by inhibiting vitamin K epoxide reductase in the vitamin K1-epoxide cycle, impeding the cyclic regeneration of vitamin K1, resulting in hypoprothrombinemia. Under physiological conditions, the oxidation of vitamin K in the hepatocyte is coupled to a carboxylation step essential for activation of prothrombin factors from inactive precursors. Brodifacoum produces hypoprothrombinaemia because the coupled carboxylation reaction is inhibited.

If therapeutic doses of vitamin K1 are given, additional substrate becomes available to resume the cycle and continue the carboxylation process, reversing the hypoprothrombinaemia.

### 2.2.5.5. Efficacy data

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects, mode of action, resistance</th><th>Author</th></tr>
<tr><td>A21479A (containing 23ppm of Brodifacoum)<br><br>For details on the formulation see confidential annex</td><td>House mouse (Mus musculus).<br><br>Population: approximately 37 mice estimated</td><td>Field Trial (Givors, France)<br><br>Census baiting technique.<br><br>19 baitboxes placed 2-15 m apart within a barn.<br>30 g bait per bait box.<br><br>-Pre-treatment census: 11 days, 30 g semolina per bait box<br><br>-Pre-treatment lag phase: 3 days, no bait<br><br>-Treatment census: 15 days, 30 g A214479 per bait box<br><br>-Post-treatment lag phase: 2 days, no bait<br><br>-Post-treatment census: 7 days, 30 g semolina per bait box<br><br>Test period: 26 Sept- 4 Nov 2016</td><td>In order to calculate the treatment efficacy of A21479A, the consumption plateau (stable consumption) in the pre-baiting period was used for calculation. This is considered to be reached after 11 d between the 4th and the 7th of October (190g/day, 194g/day and 358g in the last 2 days). The mean daily consumption at the plateau is 185.5g/day ((190+194+358)/4 days)). The mean daily consumption in the post-baiting period is 11.0g/day.<br><br>The efficacy of A21479A (pink pellets containing 23ppm of BRODIFACOUM) rodenticide in this mouse population: ((185.5-11.0)/ 185.5) *100 = 94.07 % efficacy.<br><br>When the whole pre-baiting phase would be taken into account the efficacy would be 91.5% ((129.6-11.0)/ 129.6) *100 = 91.5).<br><br>Table 1: Synthesis of results from pre-treatment to post-treatment in the site.<br><br><table><tr><th>Trial Phase</th><th>Mean Daily Consumption (g)</th><th>%</th></tr><tr><td>Pre-baiting (whole phase)</td><td>129.6</td><td>100</td></tr><tr><td>Pre-baiting (plateau phase)</td><td>185.5</td><td></td></tr><tr><td>Baiting</td><td>58.3</td><td>44.9</td></tr><tr><td>Post-baiting</td><td>11.0</td><td>8.5</td></tr></table><br>During the whole trial no dead mice were found.</td><td>[redacted] (2016)</td></tr>
</table>

**Experimental data on the efficacy of the biocidal product against target organism(s)**

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|
| A21479A (containing 23ppm of Brodifacoum)<br>Batch EN04G21184<br><br>22 months old product tested. | House mouse (*Mus musculus*)<br><br>laboratory House mice (homozygous for the VKORC1 mutation Y139C) | Choice feeding laboratory test<br><br>5 males<br>5 females<br>4 d test period (A22414A + RM3 ground laboratory diet as challenge diet), Both A22414A and challenge diet were provided at libitum.<br>14 d observation period (RM3 ground laboratory diet only)<br>Daily recording of individual bait consumption<br>Documentation of mortality / survival at end of observation period | The house mice consumed between 6.7 and 22.1g of the formulation, which is equivalent to an active ingredient intake of between 3.85 and 11.82 mg/kg.<br>Palatability: 73.7%<br>Mortality: 4.7 days average<br><br>**Table 1**: Overall results obtained with Klerat Pellets (Batch EN04G21184) | [redacted] (2016) |

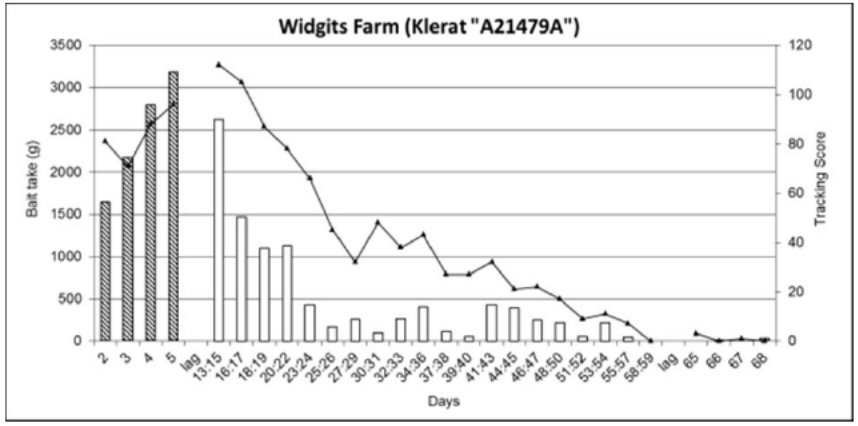
| Animal # | Sex | Initial Weight | Final Weight | Day of death | Dose mg/kg | Treated Consumption | Control | % Acceptance |
|---|---|---|---|---|---|---|---|---|
| 1 | F | 36.5 | 32.6 | 5 | 10.71 | 17.0 | 5.6 | 75.2 |
| 2 | F | 38.8 | 33.1 | 5 | 10.73 | 18.1 | 5.0 | 78.4 |
| 3 | F | 34.0 | 29.2 | 5 | 10.35 | 15.3 | 2.6 | 85.5 |
| 4 | F | 36.7 | 30.0 | 6 | 8.34 | 13.3 | 5.3 | 71.5 |
| 5 | F | 43.0 | 36.9 | 6 | 11.82 | 22.1 | 2.5 | 89.8 |
| 6 | M | 40.0 | 37.6 | 4 | 3.85 | 6.7 | 11.7 | 36.4 |
| 7 | M | 41.6 | 39.0 | 4 | 6.80 | 12.3 | 4.7 | 72.4 |
| 8 | M | 40.8 | 39.5 | 4 | 8.46 | 15.0 | 5.4 | 73.5 |
| 9 | M | 38.6 | 37.4 | 4 | 8.58 | 14.4 | 5.2 | 73.5 |
| 10 | M | 39.7 | 36.1 | 4 | 8.81 | 15.2 | **3.7** | 80.4 |
| **Total** | | | | | | **149.4** | **51.7** | |
| **Average** | | 39.0 | 35.1 | 4.7 | 8.84 | | | 73.7 |
| **Std deviation** | | | | | 2.30 | | | 14.4 |

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|
| A21479A (containing 23ppm of Brodifacoum)<br>Batch EN04G21184 was produced in July 2014.<br><br>30 months old product tested. | Norway or brown rat (*Rattus norvegicus*, CSL Berkshire.<br>Norway rats (homozygous for the VKORC1 mutation L120Q) | Choice feeding laboratory test.<br><br>5 males<br>5 females<br>4 d testing period (A21479A + RM3 ground laboratory diet as challenge diet). Both A21479A and challenge diet were provided at libitum.<br>14 d observation period (RM3 ground laboratory diet only)<br>Daily recording of individual bait consumption<br>Documentation of mortality / survival at end of observation period | The Norway rats consumed between 37.3 g and 75.5 g of the formulation, which is equivalent to an active ingredient intake of between 3.41 and 8.06 mg/kg.<br><br>Palatability: 76.9%<br>Mortality: 5.4 days average<br><br>**Table 1**: Overall results obtained with Klerat Pellets (Batch EN04G21184) | [redacted] (2017) |

| Animal Number | Sex | Initial Weight | Final Weight | Day of death | Dose mg/kg | Treated Consumption (g) | Control Consumption (g) | Acceptance |
|---|---|---|---|---|---|---|---|---|
| 1 | F | 205.0 | 185.0 | 7 | 6.93 | 61.8 | 17.4 | 78.0 |
| 2 | F | 198.0 | 200.0 | 5 | 8.06 | 69.4 | 4.6 | 93.8 |
| 3 | F | 199.0 | 187.0 | 10 | 6.10 | 52.8 | 15.8 | 77.0 |
| 4 | F | 204.0 | 195.0 | 5 | 7.82 | 69.4 | 8.1 | 89.5 |
| 5 | F | 208.0 | 182.0 | 7 | 6.67 | 60.3 | 10.9 | 84.7 |
| 6 | M | 315.0 | 302.0 | 4 | 4.15 | 56.9 | 23.2 | 71.0 |
| 7 | M | 296.0 | 287.0 | 4 | 3.41 | 43.9 | 24.0 | 64.7 |
| 8 | M | 326.0 | 328.0 | 4 | 3.99 | 56.5 | 32.3 | 63.6 |
| 9 | M | 211.0 | 205.0 | 4 | 4.07 | 37.3 | 29.4 | 55.9 |
| 10 | M | 238.0 | 238.0 | 4 | 7.30 | 75.5 | 7.7 | 90.7 |
| Total | | | | | | **583.8** | **173.4** | |
| Average | | 240.0 | 230.9 | 5.4 | 5.85 | | | **76.9** |
| Std deviation | | | | | 1.77 | | | 12.9 |

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|
| A21479A (containing 23ppm of Brodifacoum) | Norway or brown rat (*Rattus norvegicus*, | Field trial (livestock holding near Bramley, Hampshire, UK) | **Table 1.** Occurrence of the VKORC1 mutation L120Q in Norway rats obtained from the trial site. | [redacted] (2017b) |

| Norway rats Analysed | Wild Type Susceptible | L120Q Heterozygous | L120Q Homozygous | DNA Extraction Failure |
|---|---|---|---|---|

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|
| | possessing the VKORC1 mutation L120Q),<br><br>Population: >159 rats estimated | Census baiting technique (in combination with burrow baiting from day 43 to 54)<br><br>90 initial census bait points(reduced to 75 on day 36)<br>50 g bait per bait point<br>Additional tracking activity measurement<br><br>-Survey and placement of census bait and tracking patches: 12 d (day -11 - 0)<br>-Pre-treatment census: 4 d (day 1-5), whole dry wheat<br>-Pre-treatment lag phase: 5 d (day 6-11), no bait<br>-Treatment census: 47 d (day 12-59) 50 g A21479A per bait box (day 12-59) and per burrow (day 43-54).<br>-Post-treatment lag phase: 5 d (day 59-64), no bait<br>-Post-treatment census: 4 d (day 64-68), whole dry wheat<br><br>Test period: 5 Oct - 23 Dec 2016 (day -11 – 68) | <table><tr><td>10</td><td>0</td><td>5</td><td>4</td><td>1</td></tr></table><br>**Figure 1** – Summary of census bait takes and Klerat (A21479A) takes with tracking data overlaid (Hatched bars - census bait consumption, Unfilled bars - test bait consumption, Lines - tracking data)<br>  <br><br>**Table 2. Summary of Census Data**<br><table><tr><td>**Pre-treatment census, initiated 17/10/16**</td><td>**Post-treatment census** for the whole test period (including time period with</td></tr></table> | |

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|

| | | | additional burrow baiting), **initiated 19/12/2016** | | | | |
|---|---|---|---|---|---|---|---|
| | census bait | | | | census bait | | |
| **date** | weight of bait eaten (g) | no. of points with take | track score | **date** | weight of bait eaten (g) | no. of points with take | track score |
| **17-Oct** | 1639 | 22 | 81 | **19-Dec** | 0 | 0 | 3 |
| **18-Oct** | 2168 | 27 | 71 | **20-Dec** | 13 | 1 | 0 |
| **19-Oct** | 2795 | 22 | 88 | **21-Dec** | 0 | 0 | 1 |
| **20-Oct** | 3180 | 23 | 96 | **22-Dec** | 32 | 3 | 0 |
| **totals** | **9782** | **94** | **336** | **totals** | **45** | **4** | **4** |

Bait consumption by non-target rodents (indicated by the presence of droppings) was noted and removed from dataset.

During the fourth week of treatment, remaining rat activity, locally restricted to the poultry pens, was observed on tracking patches while the takes of poisoned bait were low. Therefore, on day 43 of the treatment, 41 burrows were repeatedly baited with 50 g of the test substance per burrow until day 54.

**Table 3.** Estimates of treatment efficacy for the Widgets Farm trial, using 'highest recorded daily census bait consumption' and 'highest recorded daily track score' as measures of pre-treatment and post-treatment rodent activity for the whole test period (including time period with additional burrow baiting).

| | **Pre-treatment** | **Post-treatment** | **Efficacy (at day 64)** |
|---|---|---|---|

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|

| | | | |
|---|---|---|---|
| **Census Bait Consumption** | 3,180 | 32 | **99.0%** |
| **Track Score** | 96 | 3 | **96.9%** |

**Table 4.** Estimates of treatment efficacy for the Widgets Farm trial, using 'highest recorded daily census bait consumption' and 'highest recorded daily track score' as measures of rodent activity for the test period until day 40 (not considering time period with additional burrow baiting).

| | Pre-treatment | treatment (at day 40) | Efficacy (at day 40) |
|---|---|---|---|
| **Census Bait Consumption** | 3,180 | 55.4 | **98.3%** |
| **Track Score** | 96 | 9 | **90.6%** |

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects, mode of action, resistance</th><th>Author</th></tr>
<tr>
<td>Klerat Pellets XT<br><br>A22414A (containing 23 ppm of Brodifacoum)<br>In plastic sachets (15 g)</td>
<td>Albino House mouse (Mus musculus).<br><br>Albino Norway or brown rat (Rattus norvegicus)</td>
<td>Choice feeding laboratory test.<br><br>Per target species:<br>5 males<br>5 females<br>4 d testing period (A22414A + RM3 ground laboratory diet as challenge diet). Both A22414A and challenge diet were provided at libitum.<br><br>14 d observation period (ground laboratory diet only)<br>Daily recording of individual bait consumption<br>Documentation of mortality / survival at end of observation period</td>
<td>Table 1: Klerat Pellets (A22414A) containing 23ppm brodifacoum, tested against albino house mice in a choice test where RM3 Ground Laboratory Diet was the challenge diet.<br><br>
<table>
<tr><th>Animal Number</th><th>Sex</th><th>Initial Weight (g)</th><th>Final Weight (g)</th><th>Day of Death</th><th>Dose mg/kg</th><th>Treated Consumption (g)</th><th>Control Consump (g)</th><th>Acceptance</th></tr>
<tr><td>1</td><td>F</td><td>22.9</td><td>20.9</td><td>6</td><td>18.98</td><td>18.9</td><td>2.6</td><td>87.9</td></tr>
<tr><td>2</td><td>F</td><td>23.7</td><td>22.5</td><td>6</td><td>14.56</td><td>15.0</td><td>6.5</td><td>69.8</td></tr>
<tr><td>3</td><td>F</td><td>24.3</td><td>23.8</td><td>4</td><td>5.40</td><td>5.7</td><td>7.8</td><td>42.2</td></tr>
<tr><td>4</td><td>F</td><td>22.3</td><td>20.6</td><td>7</td><td>13.00</td><td>12.6</td><td>3.9</td><td>76.4</td></tr>
<tr><td>5</td><td>F</td><td>24.6</td><td>20.9</td><td>16</td><td>6.45</td><td>6.9</td><td>15.6</td><td>30.7</td></tr>
<tr><td>6</td><td>M</td><td>28.1</td><td>25.9</td><td>4</td><td>6.55</td><td>8.0</td><td>7.1</td><td>53.0</td></tr>
<tr><td>7</td><td>M</td><td>31.6</td><td>28.2</td><td>6</td><td>11.65</td><td>16.0</td><td>6.3</td><td>71.7</td></tr>
<tr><td>8</td><td>M</td><td>28.6</td><td>27.0</td><td>4</td><td>5.71</td><td>7.1</td><td>8.2</td><td>46.4</td></tr>
<tr><td>9</td><td>M</td><td>31.1</td><td>28.9</td><td>6</td><td>10.50</td><td>14.2</td><td>5.5</td><td>72.1</td></tr>
<tr><td>10</td><td>M</td><td>33.0</td><td>33.0</td><td>3</td><td>5.16</td><td>7.4</td><td>6.6</td><td>52.9</td></tr>
<tr><td>Total</td><td></td><td></td><td></td><td></td><td></td><td>111.8</td><td>70.1</td><td></td></tr>
<tr><td>Average</td><td></td><td>27.0</td><td>25.2</td><td>6.2</td><td>9.79</td><td>11.18</td><td>7.01</td><td>60.3</td></tr>
<tr><td>Std Error</td><td></td><td></td><td></td><td></td><td>1.49</td><td>1.48</td><td>1.10</td><td>5.66</td></tr>
</table>
<br>In the above test, the mean acceptance of this formulation was 60.3% (SE 5.66) against albino house mice, and mortality was 100%. House mice consumed between 6.9 g and 18.9 g of formulation.</td>
<td>[redacted] (2017c)</td>
</tr>
</table>

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|

**Mice:**

Palatability: 60.3%

Mortality: 6.2 days average

Table 2: Klerat Pellets (A22414A) containing 23 ppm brodifacoum, tested against albino Norway rats in a choice test where RM3 Ground Laboratory Diet was the challenge diet

| Animal Number | Sex | Initial Weight (g) | Final Weight (g) | Day of Death | Dose mg/kg | Treated Consump (g) | Control Consump (g) | % Acceptance |
|---|---|---|---|---|---|---|---|---|
| 1 | F | 144.0 | 154.0 | 3 | 3.63 | 22.7 | 18.5 | 55.1 |
| 2 | F | 162.0 | 186.0 | 5 | 5.42 | 38.2 | 40.8 | 48.4 |
| 3 | F | 137.0 | 139.0 | 4 | 3.78 | 22.5 | 34.9 | 39.2 |
| 4 | F | 140.0 | 155.0 | 4 | 7.18 | 43.7 | 19.0 | 69.7 |
| 5 | F | 157.0 | 180.0 | 4 | 7.00 | 47.8 | 33.7 | 58.7 |
| 6 | M | 165.0 | 213.0 | 3 | 1.95 | 14.0 | 70.7 | 16.5 |
| 7 | M | 173.0 | 194.0 | 4 | 3.72 | 28.0 | 32.6 | 46.2 |
| 8 | M | 166.0 | 189.0 | 4 | 5.15 | 37.2 | 41.1 | 47.5 |
| 9 | M | 144.0 | 165.0 | 6 | 7.27 | 45.5 | 45.1 | 50.2 |
| 10 | M | 160.0 | 189.0 | 4 | 5.84 | 40.6 | 49.8 | 44.9 |
| **Total** | | | | | | 340.2 | 386.2 | |
| **Average** | | 154.8 | 176.4 | 4.1 | 5.09 | 34.02 | 38.62 | 47.6 |
| **Std** | | | | | 0.57 | 3.63 | 4.80 | 4.37 |

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Author |
|---|---|---|---|---|
| | | | <table><tr><td>**Error**</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table><br>**<u>Rats</u>**:<br>Palatability: 47.6%<br>Mortality: 4.1 days average<br><br>In the above test, the mean acceptance of this formulation was 47.6% (SE 4.37) against albino Norway rats, and mortality was 100%. The Norway rats consumed between 14.0g and 47.8g of formulation.<br><br>The results of these tests show that Klerat Pellets (A22414A) sealed within these sachets are likely to be efficacious when used for the control of Norway rats and house mice in the presence of alternative sources of rodent food. | |

| Conclusion on the efficacy of the product |
|---|
| Five studies were submitted investigating the efficacy of the product against brown rats (*R. norvegicus*) and the House mouse (*M. musculus*). One formulation (internal company development code A21479A) used for testing has a slightly lower level of denatonium benzoate than the formulation for which authorisation is sought (internal company development code A22414A). A comparison of the two formulations is presented in confidential Annex 3.6 of this PAR. The very minor differences in levels of coformulants between the formulations are not expected to have any effect on the palatability or performance[2]. Read-across from the studies with these products is therefore considered to be acceptable.<br><br>For an evaluation of the label claims, see section 2.2.5.8.<br><br>It is considered that the data package demonstrates that the product is sufficiently efficacious against the brown rat (*R. norvegicus*) and House mouse (*Mus musculus*) and the efficacy data supports a two year shelf-life. |

## 2.2.5.6. Occurrence of resistance and resistance management

Resistance is characterized by the ability of individuals within a rodent population in the field to continue feeding on the anticoagulant bait over many weeks, without being killed. Continuous feeding from anticoagulant baits may not only be due to resistance, but may also be caused by under-baiting or immigration. However, once these alternatives have been eliminated the probability that the cause of the continued feeding activity is anticoagulant resistance is high. The Rodenticide Resistance Action Committee (RRAC) of Crop Life International published a Technical Monograph (RRAC, Ed., 2016[3]) in which anticoagulant resistance management strategies are proposed on the best knowledge of rodent control.

### Strategies to avoid resistance in susceptible populations

To ensure proper use, the following standard sentences to reduce the possible development of resistance (CA-Nov16-Doc.4.1.b-final) are applicable for this product.

Non-professionals:
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

(Trained) Professionals:
- 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.

- 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 rodents 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.

- Remove the remaining bait or the bait stations at the end of the treatment period.

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[2] Kaukeinen, D. E. and Buckle, A. P., Evaluations of aversive agents to increase the selectivity of rodenticides, with emphasis on denatonium benzoate (Bitrex®) bittering agent (1992). In Borrrecco, J.E. and Marsh, R.E. (eds). Proceedings of the 15th Vertebrate Pest Conference 1992. http://digitalcommons.unl.edu/vpc15/42/

[3] http://www.rrac.info/content/uploads/RRAC_Guidelines_Resistance.pdf

- Do not use in areas where resistance to the active substance can be suspected.

- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.

- 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.

## Treatment of rodent infestations containing resistant individuals

Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.

Alternatively use an acute or sub-acute but non anticoagulant rodenticide. In both cases it essential that a complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.

Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).

Do not use anticoagulant rodenticides as permanent baits routinely.

Record details of treatment

Where there are indications that resistance may be more extensive than a single infestation, apply area control or block control rodent programmes.

The area under such management should extend at least to the boundaries of the area of known resistance and ideally beyond.

These programmes must be effectively coordinated and should encompass the procedures identified above.

In the last decades many tests have been developed to identify anticoagulant-resistant rats. In a Technical Monograph of the Rodenticide Resistance Action Committee of Crop Life International (RRAC) several standard methodologies are provided (RRAC 2003b: A Reappraisal of Blood Clotting Response Tests for Anticoagulant Resistance and a Proposal for a Standardised BCR Test Methodology. Technical Monograph, Brussels, Belgium.). Blood clotting response (BCR) resistance tests are available for a number of anticoagulant rodenticides. The published protocol (RRAC 2003)[4] can be used to provide information on the incidence and degree of resistance in a particular rodent population and to provide a simple comparison of resistance factors between active ingredients, thus giving clear information about cross resistance for any given strain. The introduced methodology has a sound statistical basis in being based on the EC50 response, and requires many fewer animals than the resistance tests in current use. The tests presented in RRAC (2003b) can be used to give a clear indication of the likely practical impact of the resistance on field efficacy.

## 2.2.5.7. Known limitations

None.

[4] http://www.rrac.info/releases/technical-monographs/

## 2.2.5.8. Evaluation of the label claims

The product is a rodenticide against both brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*).In total, 5 studies were provided to demonstrate the efficacy of the product against both brown rats (*Rattus norvegicus*) and house mice (*Mus musculus*).

Three laboratory choice feeding tests (palatability tests) and two field tests in rural areas were provided. For animal welfare reasons, the number of animals in the laboratory tests was reduced to a reasonable minimum. The chosen population size of 10 animals (5 males and 5 females) is thereby considered to be sufficient according to the recommendations in appendix 13 of the "Guidance on the Biocidal Products Reglation, Vol. II Efficacy – Assessment and Evaluation", especially since no contradicting results were observed within the populations. In all cases, the product was shown to be sufficiently palatable and efficacious against both rodent species:

Laboratory tests:

1. An acceptance of 73.7% (SE=4.55) was demonstrated with 22 months old product versus RM3 laboratory diet for house mice homozygeous for the Y139C mutation in the VKORC1 gene. This mutation is one of two most frequent amino acid substitutions in the VKORC1 gene which occurs in house mice in the UK and other European countries and is linked to resistance developmentagainst first-generation anticoagulant rodenticides (FGARs) and to one or more of the second-generation anticoagulants (SGARs, e.g. Bromadialone).

   The house mice consumed between 6.7 and 22.1 g of the formulation, which is equivalent to an active ingredient intake of between 3.85 and 11.82 mg/kg. These values are considerably greater than the brodifacoum acute LD50 for house mice (0.40 mg/kg) and 100% mortality occurred after an average of 4.7 days. The amount of consumed bait as well as the occurred mortality of 100% show that the bait is sufficiently palatable for a lethal dose to be ingested. Additionally, the results confirm that the formulation is efficacious against house mice with one of the most common VKORC1 gene mutations.

2. An acceptance of 76.9% (SE=4.08) was demonstrated with 30 months old product versus RM3 laboratory diet for brown rats carrying the VKORC1 L120Q mutation, with 100% mortality after 5.4 days average. The VKORC1 mutation L120Q confers resistance in brown rats to the first-generations anticoagulants (FGARs) and to one or more of the second-generation anticoagulants (SGARs, e.g. Bromadialone). Homozygeous carriers of this mutation are considered to have the most severe form of resistance to anticoagulant rodenticides. The core area of occurrence for this mutation has been demonstrated to be primarily in the UK, but isolated occurrences of this mutation have also been reported in France and Belgium.

   The brown rats consumed between 37.3 g and 75.5 g of the formulation, which is equivalent to an active ingredient intake of between 3.41 and 8.06 mg/kg. These values are considerably greater than the brodifacoum acute LD50 for Norway rats (0.22 – 0.26 mg/kg). The amount of consumed bait as well as the occurred mortality of 100% show that the bait is sufficiently palatable for a lethal dose to be ingested. Additionally, the results confirm that the formulation is efficacious against brown rats with the most severe VKORC1 gene mutation.

3. For albino brown rats the mean acceptance was 47.6% (SE 4.37) with 100% mortality after 4.1 days average. The brown rats consumed between 14.0 g and 47.8 g of formulation, which is equivalent to an active ingredient intake of between 1.95 and 7.27 mg/kg. These values are greater than the acute brodifacoum LD50 for Norway rats (0.22 – 0.26 mg/kg).

   For albino house mice the mean acceptance was 60.3% (SE 5.66) with 100% mortality after 6.2 days average. House mice consumed between 6.9 g and 18.9 g of formulation, which is equivalent to between 5.16 and 18.98 mg/kg of active ingredient. The brodifacoum intake of the tested house mice was greater than the brodifacoum acute LD50 for house mice of 0.40 mg/kg. The amount of consumed bait as well as the occurred mortality of 100% show that the sachet packaging does not effect the palatability and efficacy of the product.

Field tests:

1. A field test against brown rats (*Rattus norvegicus*) was conducted in a rural area (Widgits Farm, Bramley, Hampshire, UK) on a site with a population known to be resistant against first-generation anticoagulant rodenticides (VKORC1 mutation L120Q). The census baiting technique was used as main baiting technique and combined with burrow baiting for a specific time period (day 43-54).
   In the beginning (day 13-30) of the treatment period there was a good bait uptake and a rapid reduction in bait uptake and in track score. However during day 30-45 bait uptake was low and the tracking activity did not

lower. It seemed likely that the rats were avoiding the bait and ate the abundantly available alternate food sources on site. For this reason, the applicant decided to add burrow baiting, which seemed to be successful. The product showed sufficient control of the rat population under field conditions with 50 g of product per bait point. Over the whole testperiod the reduction in the rat population was over 95% (96.9 % reduction in track score-99 % reduction in bait consumption). When only the census baiting period without burrow baiting was taken into account (day 1-42), reduction in the rat population was over 90% (90.6% reduction in track score - 98.3% reduction in bait consumption). The latter is a low estimate since there was no lag period. Animals, poisoned during census baiting period, could die after day 42, but are not taken into account since there is no lag period and it could be a combined effect of census and burrow baiting. When (trained) professional users use a product they can assess during the use period whether it seems to be working or whether adjustments need to be made. In this case it took a bit longer but with the adjustments made by the applicant efficacy was in the end >95%. This test demonstrates efficacy of the product against brown rats under use conditions when 50 g bait per bait box is applied.

2. A field test against house mice (*Mus musculus*) was conducted in an agricultural building in Givors (France) using the census baiting technique. The product showed sufficient control of the mice population under field conditions (efficacy 94.07%) if provided in bait boxes (30 g of test product per bait box) placed 2-15 m apart.Unlike other anticoagulant rodenticide products, the product is specifically formulated as a 'lower' concentration bait. However, as can be seen from the results, this provides for a very high bait acceptance by both rats and mice (greater than 70%) and results in excellent effectiveness (greater than 90% mortality) under challenging field conditions (i.e. where resistance to anticoagulant rodenticides is known to exist).

Therefore, it is considered that the product is sufficiently effective against brown rats and mice to enable authorisation of the product.

As 50 g of the test product was tested in the field trial against brown rats, the claimed minimal application rate for (trained) professional users is 50 g per bait station or bait point. As the product is produced in 15 g sachets for non-professional users and non-professional users will in practice use the product against less severe infestations, 45 g is considered to be sufficiently efficacious for this use category. As demonstrated in the two laboratory studies against brown rats, the lowest amount of test product taken was 3.4 mg/kg body weight and 1.95 mg/kg. In comparison to the acute brodifacoum LD50 for Norway rats (0.22 – 0.26 mg/kg), this equals the 13 -15.5 fold and 7.5 – 8.8 fold of the acute LD50 dosis. The reduction of 5% in the amount of bait applied is therefore considered to be negligible. In case of a more severe rat problem, the non-professional user can use the higher amount of the 45g-60g range or get help from a professional.

Klerat Pellets XT is effective in controlling *Mus musculus* "In and around buildings" when used at 30 - 45 grams of bait per bait station or covered and protected bait points with bait points spaced 2-5 m.

Klerat Pellets XT is effective in controlling *Rattus norvegicus* "In and around buildings" when used at a dosage of 45 - 60 grams of bait per bait station for non-professional users and at a dosage of 50 -75 grams of bait per bait sation or covered and protected bait point with bait points spaced 5-10 m for (trained) professional users.

Although for mice only 22 months old product is tested instead of 24 months (2 years) the palatability of the aged product is very high (73.7%) and is not expected to go below the required 20% palatability within 2 months. Furthermore, for rats a 30 months old product is tested, also with a high palatability (76.9%). Therefore, the eCA considers a shelf life of 2 years for this product acceptable.

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

Not applicable, the product is not intended for use with other biocidal products.

## 2.2.6. Risk Assessment for human health

### 2.2.6.1. Assessment of effects on human health

#### 2.2.6.1.1. Skin corrosion and irritation

| Conclusion used in Risk Assessment – Skin corrosion and irritation | |
|---|---|
| **Value/conclusion** | The product does not require classification for skin irritation according to Regulation (EC) No 1272/2008. |
| **Justification for the value/conclusion** | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin irritation/corrosion hazards by calculation. In accordance with Section 3.2.3.3.1 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for skin irritation/corrosion. Table 3.2.3 contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin.<br>Details of the product composition are presented in Confidential Annex 3.6. There are no components of the product classified for skin irritation/corrosion hazards. The product does not, therefore, require classification for skin irritation/corrosion according to Regulation (EC) No 1272/2008.<br>A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP** | Not classified |

#### 2.2.6.1.2. Eye irritation

| Conclusion used in Risk Assessment – Eye irritation | |
|---|---|
| **Value/conclusion** | The product does not require classification for eye irritation/serious eye damage according to Regulation (EC) No 1272/2008. |
| **Justification for the value/conclusion** | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for eye irritation/serious eye damage by calculation. In accordance with Section 3.3.3.3.1 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for eye irritation/corrosion. Table 3.3.3 contains the generic concentration limits to be used to determine if a mixture is considered to cause irreversible or reversible eye effects.<br>Details of the product composition are presented in Confidential Annex 3.6. There are no components of the product classified for eye irritation/serious eye damage at a concentration that triggers classification. The product does not, therefore, require classification for eye irritation/serious eye damage according to Regulation (EC) No 1272/2008. |

| Conclusion used in Risk Assessment – Eye irritation | |
|---|---|
| | A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP** | Not classified |

### 2.2.6.1.3. Respiratory tract irritation

| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
|---|---|
| **Justification for the conclusion** | No data on respiratory irritation are provided. The product is not considered to be an irritant with respect to dermal or eye corrosion/irritation. |
| **Classification of the product according to CLP** | The product does not require classification for respiratory tract irritation according to Regulation EC 1272/2008. |

### 2.2.6.1.4. Skin sensitization

| Conclusion used in Risk Assessment – Skin sensitisation | |
|---|---|
| **Value/conclusion** | Based on the classification of the components, the product requires no classification in accordance with Regulation (EC) 1272/2008. |
| **Justification for the value/conclusion** | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin sensitisation by calculation. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient has been classified as a skin sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 or is present at or above the concentration limit for sensitised individuals presented in Table 3.4.6.<br>There are no components of the product that are classified for skin sensitisation or require a labelling phrase for elicitation. Consequently no classification or labelling for skin sensitisation is required according to Regulation (EC) No 1272/2008.<br>It is therefore considered that a study is not required, nor an appropriate use of animals. |
| **Classification of the product according to CLP** | Not classified. |

### 2.2.6.1.5. Respiratory sensitization (ADS)

| Conclusion used in Risk Assessment – Respiratory sensitisation | |
|---|---|
| **Value/conclusion** | The product does not require classification for respiratory sensitisation according to Regulation (EC) No 1272/2008. |
| **Justification for the value/conclusion** | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for respiratory sensitisation by calculation. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is |

| | |
|---|---|
| | necessary if it contains at least one ingredient classified as a respiratory sensitizer and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 and for individuals who are already sensitised to the substance or mixture refer to Table 3.4.6.<br><br>There are no components of the product classified for respiratory sensitisation. The product does not therefore require classification for respiratory sensitisation. A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP** | The product does not require classification for respiratory sensitisation according to Regulation (EC) No 1272/2008. |

### 2.2.6.1.6. Acute toxicity

**Acute toxicity by oral route**

| Value used in the Risk Assessment – Acute oral toxicity | |
|---|---|
| **Value** | The product does not require classification for acute oral toxicity according to Regulation (EC) No 1272/2008. |
| **Justification for the selected value** | No product data are available. Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute oral toxicity by calculation. The acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.<br><br>In accordance with Section 3.1.3.3 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a reason to suspect that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for acute toxicity.<br><br>Details of the product composition are presented in Confidential Annex 3.6. There are no components of the product classified for oral toxicity. The product does not, therefore, require classification for dermal toxicity according to Regulation (EC) No 1272/2008.<br><br>A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP** | Not classified. |

## acute toxicity by inhalation

| Value used in the Risk Assessment – Acute inhalation toxicity | |
|---|---|
| **Value** | Based on the classification of the components, the product does not requires classification in accordance with Regulation (EC) 1272/2008. |
| **Justification for the selected value** | No product data are available. Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation. The acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.<br><br>In accordance with Section 3.1.3.3 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a reason to suspect that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for acute toxicity.<br><br>Details of the product composition are presented in Confidential Annex 3.6. There are two components of the product classified for inhalation toxicity, which are contained at a concentration < 0.01% each. Therefore, the product does not require classification for inhalation toxicity according to Regulation (EC) No 1272/2008.<br><br>A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP** | Not classified. |

## Acute toxicity by dermal route

| Value used in the Risk Assessment – Acute dermal toxicity | |
|---|---|
| **Value** | The product does not require classification for acute dermal toxicity according to Regulation (EC) No 1272/2008. |
| **Justification for the selected value** | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute dermal toxicity by calculation. The acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.<br><br>Details of the product composition are presented in Confidential Annex 3.6. There are no components of the product classified for dermal toxicity. The product does not, therefore, require classification for dermal toxicity according to Regulation (EC) No 1272/2008.<br><br>A study is not required, nor considered an appropriate use of animals. |
| **Classification of the product according to CLP and DSD** | Not classified |

### 2.2.6.1.7. Information on dermal absorption

A dermal absorption study [redacted] 2003) has been conducted on the formulation Klerat Pellets (A10976C) – see confidential Annex 3.6 for comparison of the compositions. Apart from a small change in concentration of 1 inert and a lower level of brodifacoum (0.005% vs 0.0023% w/w), the formulations are identical. The study was previously submitted and a figure of 3% dermal absorption was derived by the Italian and Irish CAs (for active substance approval and product authorisation respectively). However, as the concentration of the a.s. brodifacoum in the b.p. Klerat® Pellets XT is lower compared to the tested formulation, a pro-rata correction was applied to account for potential higher dermal absorption of the a.s. from the b.p., resulting in a dermal absorption value of 6.5%.

| Value(s) used in the Risk Assessment – Dermal absorption | |
|---|---|
| Substance | Brodifacoum |
| Value | 6.5% (Based on default value for brodifacoum (Renewal AR) with pro-rata correction for the lower content of brodifacoum) |
| Justification for the selected value | The mean recovery from the skin washes was 108%. Recovery from all other compartments (receptor fluid, epidermis, stratum corneum etc.) was found to be below the limit of quantification. High recovery at skin wash suggests that dermal absorption is negligible. However, as a worst case, it has been assumed that the absorbed dose is equivalent to the limit of quantification for the receptor fluid (< 3.5%), giving a dermal absorption value of 3%. Considering the lower content of brodifacoum in Klerat Pellets XT compared to the tested formulation, a pro-rata correction was applied to the dermal absorption to account for the effects on dermal absorption at lower concentrations ((0.005/0.0023)x3% = 6.5%). |
| eCA note | Dermal absorption of rodenticides was discussed at the WGIV-2020 and WG-I-2021 meeting. Pro-rata approach was considered as not justified in the common active substance concentration range of these biocidal products due to the high variability, uncertainty of dermal absorption values derived from *in-vitro* studies, and other scientific considerations.<br><br>Moreover, as the Health Working Group meeting WG-I-2021 agreement on acceptance of pro-rata is valid since 1 June 2021, it is not obligatory for the applicant to apply this agreement for this authorization.<br><br>Therefore, as this will not impact the risk assessment (gloves required for primary use), the PAR is not amended. |

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

According to Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR), an ED hazard assessment of the b.p. needs to be performed. To comply with this information requirement, the co-formulants contained in the b.p. were screened for indications of potential ED properties. The active substance does not have to be screened as there is information available in the assessment report. The AR for renewal of the authorization of Brodifacoum (Sept 2016, the Netherlands and Italy) indicates that *"no new information is available. Brodifacoum is not considered to have endocrine disrupting properties*".

For one co-formulant, an ED alert was identified. However, for this co-formulant CA NL concludes that we have to await the discussions at EU level. See the confidential annex for more specific information.

In conclusion, based on available information, it is not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties of this co-formulant is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

Details on the ED screening of the co-formulants and its results are provided in the confidential Annex.

#### 2.2.6.1.9. Available toxicological data relating to a mixture

Not applicable.

#### 2.2.6.1.10. Repeated Specific Target Organ Toxicity

Brodifacoum is classified as STOT-RE Cat 1 for blood with a specific concentration limits of

STOT RE 1; H372 (blood): C ≥ 0.02 %

STOT RE 2; H373 (blood): 0,002 % ≤ C < 0.02 %

Since the concentration of brodifacoum is 0.0023% w/w, the product is classified as STOT RE2 and labelled with H373 (blood).

#### 2.2.6.1.11. Reproductive Toxicity

Brodifacoum is classified as Repr, 1A; H360D, with a specific concentration limits of

Repr. 1A; H360D: C ≥ 0.003 %

Since the concentration of brodifacoum is 0.0023% w/w, the product is NOT CLASSIFIED for reproductive toxicity.

### 2.2.6.2. Exposure assessment

The product, containing brodifacoum 0.0023% w/w (23 mg/kg), is a ready for use (RB) pellet formulation which is used to control rats and mice in and around buildings. Treatments are made by professional and trained professional pest control operators and non-professional (consumer/amateur) users. Professionals and trained professionals are expected to decant pellets from large sacks into a bucket to make movement between bait boxes/bait stations easier, load tamper proof bait boxes with pellets and clean some bait boxes. For non-professional use, the product is supplied in ready to use sachets which are placed directly into tamper resistant bait stations. Non-users are not expected to be present during application. The application rate is described in Section 2.1.4.

Brodifacoum has a low vapour pressure (1 × 10-6 Pa). Therefore, inhalation exposure to vapour released from the product is expected to be negligible. Professionals and trained professionals will decant the pellets from large sacks into buckets, which will produce some dust in the breathing zone. To protect the professional user from inhalatory exposure to dust, the following precautionary statement was added to the label: do not breathe dust.

Dermal exposure is the primary route of exposure for professional and trained professional users to brodifacoum, since the pellets are administered by hand. Professionals and trained professional users are expected to wear suitable PPE such as gloves. For non-professional use the product is supplied in ready to use sachets which are placed directly into tamper proof bait boxes. Therefore, non-professional dermal exposure during application is expected to be negligible. All user groups are not anticipated to handle dead rodents directly. Even in the event that rodents are found, this is not likely to be a source of exposure in the case of the product because (1) the bait works by ingestion, so there is likely to be no active substance on the outer surface of the rodent and thus, there is no source for dermal exposure and (2) users are averse to handling dead animals and so will do so carefully and only while wearing gloves to help protect against rodent-borne diseases. Therefore, potential exposure to brodifacoum associated with handling dead rodents is negligible. Non-users are not expected to be present during application and will not have access to the pellets following application because they are administered in tamper proof bait boxes.

The product is not likely to be ingested by users. Therefore, the risk during use is considered to be negligible. A possible acute oral exposure scenario for children is via incidental ingestion of the product. Apart from this acute scenario, the risk of oral exposure to all non-users is considered unlikely.

### 2.2.6.2.1. Identification of main paths of human exposure towards the active substance and substances of concern from its use in the biocidal product

| 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. | negligible | negligible | n.a. | no | no | n.a. |
| Dermal | n.a. | yes | yes | n.a. | no | no | n.a. |
| Oral | n.a. | no | no | n.a. | no | yes (accidental) | n.a. |

### 2.2.6.2.2. List of scenarios

| Summary table: scenarios | | | |
|---|---|---|---|
| Scenario number | Scenario (e.g. mixing/ loading) | Primary or secondary exposure<br>Description of scenario | Exposed group |
| 1. | Decanting | Primary - Decanting pellets from large bag into a bucket for the control of rats | (trained) prof |
| 2. | Decanting | Primary - Decanting pellets from large bag into a bucket for the control of mice | (trained) prof |
| 3. | Filling bait boxes | Primary - Scooping bait from bucket into bait boxes for the control of rats and mice | (trained) prof |
| 4. | Cleaning | Primary - Cleaning of used bait boxes for the control of rats and mice | (trained) prof |
| 5. | Filling bait boxes | Primary - Filling bait boxes for the control of rodents | (trained) prof and non-prof |
| 6. | Cleaning | Primary - Cleaning of used bait boxes for the control of rodents | (trained) prof and non-prof |
| 7. | Ingestion of pellets | Secondary - Infants ingesting bait | General public |

### 2.2.6.2.3. Industrial exposure

Not applicable.

### 2.2.6.2.4. Trained Professional and Professional exposure

eCA note: According to HEEG opinion 9 – Default protection factors for protective clothing and gloves, for solids a glove protection factor of 95% should be used. However, the conclusion of the assessment will not change whether a protection factor of 90% or 95% is used. Therefore, eCA NL decided not to correct the assessment.

**Scenario 1, Decanting pellets from large bag into a bucket for the control of rats**

| Description of Scenario 1 | | |
|---|---|---|
| For the control of rats, trained professional and professional users are expected to decant pellets from large bag into a bucket. Exposure during this task has been estimated according to HEEG Opinion 12. | | |
| | Parameters | Value |
| Tier 1 | Number of bait boxes filled | 63 manipulations/day |
| | Amount of bait used | 75 g product/bait box |
| | Dermal exposure | 93 mg product/3 kg decanted pellets |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Time for decanting | 3 min/decant |
| | inhalation rate | 1.25 $m^3$/hour |
| | concentration in air | 9.62 mg product/$m^3$ |
| | inhalation absorption | 100% |
| | Body weight | 60 kg |
| Tier 2 (gloves) | glove protection factor | 90% |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from trained professional and professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 1 | 1 - no PPE | $4.61 \times 10^{-7}$ | $3.65 \times 10^{-6}$ | n.a. | $4.11 \times 10^{-6}$ |
| | 2 - Gloves | $4.61 \times 10^{-7}$ | $3.65 \times 10^{-7}$ | n.a. | $8.26 \times 10^{-7}$ |

**Scenario 2, Decanting pellets from large bag into a bucket for the control of mice**

| Description of Scenario 2 | | |
|---|---|---|
| For the control of mice, trained professional users and professional users are expected to decant pellets from large bag into a bucket. Exposure during this task has been estimated according to HEEG Opinion 12. | | |
| | Parameters | Value |
| Tier 1 | Number of bait boxes filled | 63 manipulations/day |
| | Amount of bait used | 50 g product/bait box |
| | Dermal exposure | 93 mg product/3 kg decanted pellets |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Time for decanting | 3 min/decant |
| | Inhalation rate | 1.25 $m^3$/hour |
| | Concentration in air | 9.62 mg product/$m^3$ |
| | Inhalation absorption | 100% |
| | Body weight | 60 kg |
| Tier 2 | Glove protection factor | 90% |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from trained professional and professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 2 | 1 - no PPE | $4.61 \times 10^{-7}$ | $2.43 \times 10^{-6}$ | n.a. | $2.89 \times 10^{-6}$ |
| | 2 - Gloves | $4.61 \times 10^{-7}$ | $2.43 \times 10^{-7}$ | n.a. | $7.04 \times 10^{-7}$ |

**Scenario 3, Application: loading and placing bait boxes for the control of rats and mice**

| Description of Scenario 3 | | |
|---|---|---|
| Trained professional and professional users are expected to scoop pellets from a bucket into bait boxes. Exposure during this task has been estimated according to HEEG Opinion 12. | | |
| | Parameters | Value |
| Tier 1, no PPE | Number of bait boxes filled | 63 manipulations/day |
| | Dermal exposure | 2.04 mg product/bait box |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Body weight | 60 kg |
| Tier 2, gloves | Glove protection factor | 90% |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from trained professional and professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 3 | 1 - no PPE | negligible | $3.20 \times 10^{-6}$ | n.a. | $3.20 \times 10^{-6}$ |
| | 2 - Gloves | negligible | $3.20 \times 10^{-7}$ | n.a. | $3.20 \times 10^{-7}$ |

**Scenario 4, Cleaning of used bait boxes for the control of rats and mice**

| Description of Scenario 4 | | |
|---|---|---|
| Trained professional and professional users are expected to clean bait boxes. Exposure during this task has been estimated according to HEEG Opinion 12. | | |
| | Parameters | Value |
| Tier 1, no PPE | Number of bait boxes cleaned | 16 manipulations/day |
| | Dermal exposure | 3.79 mg product/bait box |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Body weight | 60 kg |
| Tier 2, gloves | Dermal exposure | 0.379 mg product/bait box |
| | glove protection factor | 90% |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from trained professional and professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 4 | 1 - no PPE | negligible | $1.51 \times 10^{-6}$ | n.a. | $1.51 \times 10^{-6}$ |
| | 2 - Gloves | negligible | $1.51 \times 10^{-7}$ | n.a. | $1.51 \times 10^{-7}$ |

**Further information and considerations on Scenarios 1-4**

The product is not classified for local effects. Therefore, there is no need to consider local effects separately.

**Combined scenarios**

For the control of rats, trained professional and professional users will decant pellets from a large bag into a bucket (Scenario 1), fill bait stations (Scenario 3) and clean bait stations (Scenario 4).

For the control of mice, trained professional and professional users will decant pellets from a large bag into a bucket (Scenario 2), fill bait stations (Scenario 3) and clean bait stations (Scenario 4).

| Summary table: combined systemic exposure from trained professional and professional uses | | | | |
|---|---|---|---|---|
| **Scenarios combined** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenarios 1,3,4 (Tier 1) | $4.61 \times 10^{-7}$ | $8.36 \times 10^{-6}$ | n.a. | $8.82 \times 10^{-6}$ |
| Scenarios 1,3,4 (Tier 2) | $4.61 \times 10^{-7}$ | $8.36 \times 10^{-7}$ | n.a. | $1.30 \times 10^{-6}$ |
| Scenarios 2,3,4 (Tier 1) | $4.61 \times 10^{-7}$ | $7.15 \times 10^{-6}$ | n.a. | $7.61 \times 10^{-6}$ |
| Scenarios 2,3,4 (Tier 2) | $4.61 \times 10^{-7}$ | $7.15 \times 10^{-7}$ | n.a. | $1.18 \times 10^{-6}$ |

### 2.2.6.2.5. Non-professional exposure (consumer)

**Scenario 5, Filling bait boxes for the control of rodents**

| Description of Scenario 5 | | |
|---|---|---|
| Non-professional users will fill bait boxes with pre-wrapped ready to use bait packages. There is no requirement to undo these packages. Inhalation exposure will be negligible. Dermal exposure during this task has been estimated according to HEEG Opinion 10, which is considered a worst case, as the baits are pre-wrapped so that dermal exposure of the non-professional can be expected to be minimal. | | |
| | Parameters | Value |
| Tier 1 | Number of bait boxes filled | 5 manipulations/day |
| | Dermal exposure | 2.04 mg product/bait box |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Body weight | 60 kg |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from non-professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 5 | 1 - no PPE | negligible | $2.54 \times 10^{-7}$ | n.a. | $2.54 \times 10^{-7}$ |

**Scenario 6, Cleaning of used bait boxes for the control of rodents**

| Description of Scenario 6 | | |
|---|---|---|
| Non-professional users are expected to clean bait boxes. Exposure during this task has been estimated according to HEEG Opinion 12. | | |
| | Parameters | Value |
| Tier 1 | Number of bait boxes cleaned | 5 manipulations/day |
| | Dermal exposure | 3.79 mg product/bait box |
| | Concentration | 0.0023% a.s. w/w |
| | Dermal absorption | 6.5% |
| | Body weight | 60 kg |

For details on calculation please refer to Annex 3.2.

| Summary table: estimated exposure from non-professional uses | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 6 | 1 - no PPE | negligible | $4.72 \times 10^{-7}$ | n.a. | $4.72 \times 10^{-7}$ |

**Further information and considerations on Scenario 5-6**

The product is not classified for local effects. Therefore, there is no need to consider local effects separately.

**Combined scenarios**

Non-professional users are expected to load (Scenario 5) and clean (Scenario 6) bait stations.

| Summary table: combined systemic exposure from non-professional uses | | | | |
|---|---|---|---|---|
| **Scenarios combined** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenarios 5,6 | negligible | $7.26 \times 10^{-7}$ | n.a. | $7.26 \times 10^{-7}$ |

### 2.2.6.2.6. Exposure of the general public

**Scenario 7, Ingestion of pellets**

| **Description of Scenario 7** | | |
|---|---|---|
| Oral exposure assessment for toddlers based on default values:<br>The exposure concentration via oral uptake is assumed to be equivalent to be 5 g is for products without a human aversive (bittering) agent (TNsG User Guidance, version 1, p. 70) and 10 mg of the bait (toddlers) for transient mouthing of poison bait treated with repellent (TNsG 2002, Part 3, Appendix 7.2.1, p58). | | |
| | Parameters | Value |
| Tier 1 | Amount ingested | 5 g product (User Guidance, bait without aversive (bittering) agent)<br>10 mg product (TNsG) |
| | Concentration of brodifacoum | 0.0023% w/w |
| | Oral absorption | 100% |
| | Body weight | 10 kg |

**Calculations for Scenario 7**

An infant is assumed to ingest 10 mg of bait (0.23 µg brodifacoum), by accident. Complete absorption of ingested bait is assumed. For an infant body weight of 10 kg, this corresponds to an estimated acute dose of $2.3 \times 10^{-5}$ mg brodifacoum/kg bw. It is extremely unlikely that this scenario would occur, however, because the product is placed in tamper proof bait stations that are to be placed where access is not likely and because the human taste deterrent included in the product will ensure that the infant will expel the product from the oral cavity rather than swallow and ingest it.

eCA note: We agree with the applicant that it is unlikely that an infant will ingest 5 grams of the biocidal product. However, as it has been assessed for similar products, we consider the ingestion of 5 grams as a very worst case, moreover, it is not possible to rule out that all people will respond to the bittering agent. Therefore, in a very worst case, the calculations of a toddler ingesting 5 grams biocidal product has been considered and added to the calculations. 5 grams of biocidal product corresponds to 0.115 mg brodifacoum (0.0023% brodifacoum). It is assumed 100% oral absorption. Therefore, the total brodifacoum ingested by a toddler of 10 kg will results in an internal dose of $1.15 \times 10^{-2}$ mg brodifacoum / kg bw.

| Summary table: systemic exposure from ingestion | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** [mg a.s./kg bw/day] | **Estimated dermal uptake** [mg a.s./kg bw/day] | **Estimated oral uptake** [mg a.s./kg bw/day] | **Estimated total uptake** [mg a.s./kg bw/day] |
| Scenario 7 User guidance, bait without aversive (bittering agent | 1/none | n.a. | n.a. | $1.15 \times 10^{-2}$ | $1.15 \times 10^{-2}$ |
| Scenario 7 TNsG | 1/none | n.a. | n.a. | $2.3 \times 10^{-5}$ | $2.3 \times 10^{-5}$ |

**Further information and considerations on scenario 7**

The product is not classified for local effects. Therefore, there is no need to consider local effects separately.

**Combined scenarios**

There are no combined scenarios. The primary exposure scenario is for adults applying the product. The secondary exposure scenario is for children (toddlers) ingesting the pellets. Therefore there is no realistic scenario where primary and secondary exposure could occur to the same individual.

**Monitoring data**

Not applicable.

**Dietary exposure**

Not applicable, exposure to food, drinking water or livestock is not foreseen.

**Information of non-biocidal use of the active substance**

Not applicable. The are no other non-biocidal uses.

**Estimating Livestock Exposure to Active Substances used in Biocidal Products**

Not applicable, exposure to food, drinking water or livestock is not foreseen as the following risk mitigation measures are applied which are stated in the instructions for use:

- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Tamper resistant bait stations must be used by professional users.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Remove the remaining bait or the bait stations at the end of the treatment period.
- The biocidal product contains a bittering/aversive agent.

**Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)**

Not applicable, exposure to food, drinking water or livestock is not foreseen.

**Estimating transfer of biocidal active substances into foods as a result of non-professional use**

Not applicable, exposure to food, drinking water or livestock is not foreseen.

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

Production and formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not under repeated under regulation 528/2012 (this principle was agreed at Biocides TMI/06).

**Aggregated exposure**

Not applicable.

#### 2.2.6.2.7. Summary of exposure assessment

| Scenarios and values to be used in risk assessment | | | |
|---|---|---|---|
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** mg a.s./kg bw/day |
| 1,3,4 | trained professional + professional | 1 - no PPE | $8.82 \times 10^{-6}$ |
| 1,3,4 | trained professional + professional | 2 - gloves | $1.30 \times 10^{-6}$ |
| 2,3,4 | trained professional + professional | 1 - no PPE | $7.61 \times 10^{-6}$ |
| 2,3,4 | trained professional + professional | 2 - gloves | $1.18 \times 10^{-6}$ |
| 5,6 | non-professional | 1 - no PPE | $7.26 \times 10^{-7}$ |
| 7 | Secondary, ingestion of pellets | 1 - no PPE | 10 mg ingestion: $2.30 \times 10^{-5}$ 5 g ingestion: $1.15 \times 10^{-2}$ |

### 2.2.6.3. Risk characterisation for human health

#### 2.2.6.3.1. Reference values to be used in Risk Characterisation

| Reference | Study | NOAEL (LOAEL) | AF | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| $AEL_{short\text{-}term}$ | rat developmental | 0.001 mg/kg bw/day | 300 | no | $3.3 \times 10^{-6}$ mg/kg bw/day |
| $AEL_{medium\text{-}term}$ | rabbit developmental | 0.002 mg/kg bw/day | 300 | no | $6.7 \times 10^{-6}$ mg/kg bw/day |
| $AEL_{long\text{-}term}$ | rat reproductive 2-generation study | 0.001 mg/kg bw/day | 300 | no | $3.3 \times 10^{-6}$ mg/kg bw/day |

#### 2.2.6.3.2. Maximum residue limits or equivalent

Not applicable.

#### 2.2.6.3.3. Specific reference value for groundwater

Not applicable.

### 2.2.6.3.4. Risk for industrial users

Not applicable.

### 2.2.6.3.5. Risk for trained professional and professional users

Trained professional and professional users are expected to use the product daily. Therefore, the estimated uptakes have been assessed against the $AEL_{long\text{-}term}$.

**Combined scenarios**

All identified tasks are expected to be carried out in combination. Therefore, only the combined scenarios have been considered as these represent the worst case.

| Scenarios combined | Tier | Systemic NOAEL mg/kg bw/d | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 1,3,4 | 1 | 0.001 | $3.3 \times 10^{-6}$ | $8.82 \times 10^{-6}$ | 267 | no |
| 1,3,4 | 2 | 0.001 | $3.3 \times 10^{-6}$ | $1.3 \times 10^{-6}$ | 39 | yes |
| 2,3,4 | 1 | 0.001 | $3.3 \times 10^{-6}$ | $7.61 \times 10^{-6}$ | 231 | no |
| 2,3,4 | 2 | 0.001 | $3.3 \times 10^{-6}$ | $1.18 \times 10^{-6}$ | 36 | yes |

**Local effects**

The product is not classified for local effects. Therefore there is no need to consider local effects separately.

**Conclusion**

For the control of rats, when decanting, loading and cleaning tasks are combined, the exposure is predicted to be below the $AEL_{long\text{-}term}$ with the use of proper PPE (gloves). For the control of mice, when decanting, loading and cleaning tasks are combined, exposure is predicted to be below the $AEL_{long\text{-}term}$ with the use of proper PPE (gloves).

### 2.2.6.3.6. Risk for non-professional users

Non-professional users are expected to use the product less frequently than trained professional or professional users. Therefore, the estimated uptakes have been assessed against the $AEL_{short\text{-}term}$ of $3.3 \times 10^{-6}$ mg/kg bw/day. Only combined scenarios have been characterized. See next section.

**Combined scenarios**

All identified tasks are expected to be carried out in combination. Therefore, only the combined scenarios have been considered and these represent the worst case.

| Scenarios combined | Tier | Systemic NOAEL mg/kg bw/d | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ AEL (%) | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| 5,6 | 1 | 0.001 | $3.3\times10^{-6}$ | $7.26 \times 10^{-7}$ | 22 | yes |

**Local effects**

The product is not classified for local effects. Therefore there is no need to consider local effects separately.

**Conclusion**

Exposure of non- professional users is predicted to be below the $AEL_{short\text{-}term}$ without the use of PPE (gloves).

### 2.2.6.3.7. Risk for the general public

The product is supplied in pre-wrapped ready-to-use packaging. In addition, bait stations are tamper proof. Therefore, the general public is only expected to be exposed during exceptional circumstances. As such, the estimated uptake has been assessed against the $AEL_{short\text{-}term}$.

**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) |
|---|---|---|---|---|---|---|
| 7 | 1 | 0.001 | $3.3\times10^{-6}$ | $2.30 \times 10^{-5}$ | 697 | No |
| 7 | 1 | 0.001 | $3.3\times10^{-6}$ | $1.15 \times 10^{-2}$ | 348485 | No |

**Local effects**

The product is not classified for local effects. Therefore there is no need to consider local effects separately.

**Conclusion**

Exposure for infants ingesting bait exceeds the $AEL_{short\text{-}term}$ (10 mg= 697%, 5g = 348485). However, it is extremely unlikely that this scenario would occur. The product is placed in tamper proof bait stations that are to be placed where access is not likely, in accordance with the label. In addition, the human taste deterrent (denatonium benzoate) included in the product will ensure that the infant will expel the product from the oral cavity rather than swallow and ingest it in the unlikely circumstances that the bait station was accessed. Furthermore, the symptoms of ingestions of AVK rodenticides are well known, and an antidote is readily available.

In order to prevent accidential ingestion of bait by toddlers, the following risk mitigation measures are applied as stated in the instructions for use:

- The product is to be applied in tamper resistant bait stations by non-professional and professional users.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- This product contains a bittering agent.

- Store in places prevented from the access of children, birds, pets and farm animals.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- If the product was ingested accidentially, the following instructions are provided on the label/instructions for use:
    - Note to Physician: Antidote: Vitamin K1 administered by medical personnel only.
    - General: Have the product container, label or Safety Data Sheet with you when calling the emergency number, a poison control centre or physician, or going for treatment.
- Bait stations must be labelled with the following information:
    - Do not move or open
    - Contains a rodenticide
    - Product name or authorisation number
    - Active substance
    - In case of incident, call a poison centre [insert national phone number and name of the organisation].

#### 2.2.6.3.8. Risk for consumers via residues in food

Food, drinking water or livestock exposure is not foreseen as the product should not be applied to areas where food utensils or food preparation surfaces may become contaminated and should only be applied to areas inaccessible to pets.

To prevent accidental exposure of consumers via residues in food, the following risk mitigation measures apply which are stated on the label/instructions for use:

- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

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

Indirect exposure via the environment is considered to be negligible. The active substance is used as a rodenticide only and so there will be no additional exposure through use in other biocidal products.

### 2.2.7. Risk assessment for animal health

No livestock exposure is foreseen as the product is not intended to be applied to areas where livestock are present or may become exposed. To mitigate the risk of secondary animal exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

- Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry);

  Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

## 2.2.8. Risk assessment for the environment

The product is a ready to use rodenticide, available in the form of pellets, containing 0.0023% w/w (23 mg/kg) brodifacoum. It is placed in tamper resistant refillable bait boxes (by amateur and professional users) or covered/protected bait points (by trained professionals), in and around buildings (including burrows), for the control of rats (*Rattus norvegicus*) and mice (*Mus musculus*).

For the control of rats, a maximum of 75 g of product is applied per bait point, every 5-10 metres; and for the control of mice, a maximum of 50 g of product is applied per bait point, every 2-5 metres. In both instances, baits must be replaced one to three times a week until infestation is controlled, up to a maximum of five weeks. Therefore, each bait station or bait box will be inspected and replenished a maximum of 12 times over the five week period (day 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31 and 34). For burrow baiting, the maximum applied amount of product per rat burrow is 50 g.

See section 2.1.4 for application rates.

The following environmental exposure assessment was based on the Brodifacoum Assessment Report[5] and the ESD for PT14. Note that the ESD for PT14 was updated after the submittion of the CAR (submittion of the CAR was in March 2018). The relevant changes will be indicated later in the document. In addition, the calculations with updated ESD and ECHA sheets with default values for PT14 are performed, and presented in Annex (3.7).

### 2.2.8.1. Effects assessment on the environment

PNEC values agreed for brodifacoum under the EU review programme and detailed in the finalised Assessment Report are presented in the following table.

### 2.2.8.2. PNEC values for brodifacoum

| Compartment | PNEC | Units | Justification |
|---|---|---|---|
| $PNEC_{STP}$ | 0.0038 | mg/L | Calculated applying an assessment factor of 1 to the conservative estimate of EC10 > 0.0038 mg/L. (Due to the lack of measured values of test substance concentration, the EC10 was conservatively set greater than Brodifacoum's water solubility). |
| $PNEC_{aquatic, freshwater}$ | 4.00E-05 | mg/L | Derived from the algae endpoint (72h ErC50 = 0.04 mg/L) and the application of an AF=1000. |
| $PNEC_{sediment, freshwater}$ | 4.00E-06 | mg/L | As no specific data are available, the risk posed by Brodifacoum to sediment-dwelling organisms is covered by the risk to the aquatic organisms. Since the log $K_{ow}$ is 6.12 (higher than 5), a factor of 10 is applied to the PEC/PNEC ratio calculated for the aquatic organisms, to take into account the possible higher hazard to the ingestion of contaminated sediments. |

[5] Brodifacoum, Product-type 14 (Rodenticide). Assessment Report. (17 September 2009) revised 16 December 2010.

| Compartment | PNEC | Units | Justification |
|---|---|---|---|
| $PNEC_{terrestrial}$ | 0.88 | $mg/kg_{wwt}$ | Calculated applying a conversion factor of 1000 to a 14-d LC50 > 879.6 $mg/kg_{wwt}$. |
| $PNEC_{oral, bird}$ | 1.28E-05 | mg/kg diet | Based on a NOEL of 3.85E-04 mg Brodifacoum/kg bw/d, a NOEC = 0.0038 mg *Brodifacoum*/kg/diet and an AF of 30. |
| | 1.28E-05 | mg/kg bw/d | |
| $PNEC_{oral, mammal}$ | 2.22E-04 | mg/kg diet | Derived from a $NOEC_{mammal,food}$ of 0.02 mg/kg food, a NOAEL of 0.001 mg/kg bw/day and an AF of 90. |
| | 1.1 E-05 | mg/kg bw | |

### 2.2.8.2.1. Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

In accordance with the Guidance on the BPR (Volume IV. Part A Chapter II: Requirements for Active Substances Version 1.1 November 2014), and based on the data available on each of the components in the mixture, classification of the mixture has been made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Only one component of the formulation (Brodifacoum) is classified (H400 and H410 with an M factor of 10 for acute and chronic hazard according to ATP 09 of the harmonised classification - Annex VI of Regulation (EC) No 1272/2008), however as the concentration present in the product (0.0023% w/w) is less than 0.1% w/w divided by the M-factor the product does not require to be classified according to CLP Regulation 1272/2008.

### 2.2.8.2.2. Further Ecotoxicological studies

All information on the ecotoxicology of the product can be extrapolated from the information on the active substance and co-formulants. Ecotoxicity data for the active substance are summarised in the Competent Authority Report. No additional testing with the product is, therefore, considered necessary.

Endocrine disruption activity of non-active substances

According to Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR), an ED hazard assessment of the b.p. needs to be performed. To comply with this information requirement, the co-formulants contained in the b.p. were screened for indications of potential ED properties.

Since the identity of co-formulants is confidential information, details on the ED screening approach of the co-formulants and its results are provided in the confidential Annex.

For the co-formulants the databases as stated the confidential Annex are considered, as well as additional databases relevant for non-target organisms including:

- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
- UN factsheet (https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
- Denmark EPA (http://cend.dk/files/DK_ED-list-final_2018.pdf)
- Japan ED database (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.htm)

For one co-formulant, an ED alert was identified. However, for this co-formulant CA NL concludes that we have to await the discussions at EU level. See the confidential annex for more specific information.

In conclusion, based on available information, it is not possible to conclude whether the non-active substance should be considered to have ED properties before the expiration of the legal deadline in the BPR and therefore the process will be concluded at the post-authorisation stage. Once the conclusion regarding ED properties of this co-formulant is available, the applicant must inform the eCA. If needed, the conditions of authorization shall be revised.

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### 2.2.8.2.3. Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No further studies have been submitted or required.

### 2.2.8.2.4. Supervised trials to assess risks to non-target organisms under field conditions

No further studies have been submitted or required.

### 2.2.8.2.5. Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No further studies have been submitted or required.

### 2.2.8.2.6. Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant as the products are not intended for treating a large proportion of a specific habitat.

### 2.2.8.2.7. Foreseeable routes of entry into the environment on the basis of the use envisaged

Based on the intended use, direct exposure to soil and groundwater can be expected however exposure to the aquatic compartment and the atmosphere are not considered relevant. There is potential for primary and secondary poisoning however if the rodenticide application is performed according to the product label's instructions (i.e. pellets/wax blocks placed hidden and safe, in sturdy bait stations and inaccessible to non-target organisms), the risk of primary and secondary exposure of non-target mammals and birds are minimized.

### 2.2.8.2.8. Further studies on fate and behaviour in the environment (ADS)

No further studies have been submitted or required.

### 2.2.8.2.9. Leaching behaviour (ADS)

No further studies have been submitted or required.

### 2.2.8.2.10. Testing for distribution and dissipation in soil (ADS)

No further studies have been submitted or required.

### 2.2.8.2.11. Testing for distribution and dissipation in water and sediment (ADS)

No further testing is considered necessary to determine the distribution and degradation characteristics of the product.

#### 2.2.8.2.12. Testing for distribution and dissipation in air (ADS)

No further data are required.

#### 2.2.8.2.13. If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant. The product is not a spray and is for use in and around buildings only. Therefore no spraying near surface waters will take place.

#### 2.2.8.2.14. If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant. The product is not a spray and is for use in and around buildings only. Therefore no spraying near surface waters will take place.

### 2.2.8.3. Exposure assessment

For the control of rats, a maximum of 75 g of product is applied per bait point, every 5-10 metres; and for the control of mice, a maximum of 50 g of product is applied per bait point, every 2-5 metres. For burrow baiting, the maximum amount of products applied per rat burrow is 50 g. The baiting of mice burrows is not an intended use.

In both instances, baits must be replaced one to three times a week until infestation is controlled, up to a maximum of five weeks. Therefore, each bait station or bait box will be inspected and replenished a maximum of 12 times over the five week period (day 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31 and 34). The data on replacement, inspection and replenishment are from the applicant; note that the frequency (Nappl) is thus 12 and is higher than default value in ESD, which is 5; as more conservative it is accepted by NL CA.

See section 2.2.5.1 for application rates.

An environmental risk assessment based on the realistic worst case scenarios and product-specific uses has been performed in the following sections, for the control of rats (Scenario 1.a and 2.a) and the control of mice (Scenario 1.b).

No risk characterisation was performed for metabolites as no major metabolites were identified in soil and water (Assessment Report, 2010).

#### 2.2.8.3.1. General information

| | |
|---|---|
| Assessed PT | PT 14: Rodenticides |
| Assessed scenarios | Scenario 1.a: In and around buildings – rat control *<br>Scenario 1.b: In and around buildings – mouse control *<br>Scenario 2.a: Burrow baiting- rat control |
| ESD(s) used | Revised emission scenario document for product type 14. Rodenticides. European Chemicals Agency, Report no. ECHA-18-H-23-EN, Helsinki, Finland, August 2018. |
| Approach | The exposure scenarios are suggested based on the scenarios where the highest release to the environment is expected to take place (in accordance to the ESD PT14 default values and product-specific label instructions). The contribution to regional release is considered negligible. |
| Distribution in the environment | Calculated based on the ESD PT14 (ECHA, 2018) and on the BPR Guidance (Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017). |
| Groundwater simulation | Yes (higher tier modelling with PEARL 4.4.4 is performed for the burrow baiting scenario) |
| Confidential Annexes | No |
| Life cycle steps assessed | The environmental exposure scenarios are based on the potential releases of rodenticides from application, use and disposal.<br>Production: No<br>Formulation: No<br>Use: Yes<br>Service life: Yes |
| Remarks | According to the TAB ENV 180, (November 2021) calculations of the “bank slopes” scenario should be evaluated when the use in and around building is claimed. These calculations are included in the assessment. |

### 2.2.8.4. Emission estimation

If areas in and around buildings are treated, baits must be placed in bait stations or in other ways covered or hidden to minimise access of non-target animals. Besides spills, exposure of the environment is also expected from urine, faeces and carcasses of the target animals when poisoned rodents enter the outdoor environment (ECHA ESD, 2018). This sub-scenario is limited to rat control campaigns since rats often have their nesting sites outdoors and switch between in- and outdoors.

#### 2.2.8.4.1. Emission to sewage treatment plant

Exposure of rodenticides after treatment in or around houses to STP is only relevant for indoor application of liquid poisons, residues from mixing and cleaning (ECHA ESD, 2018). Thus the pathway is considered negligible for the application of the rodenticide in bait boxes.

#### 2.2.8.4.2. Emission to soil

According to the ECHA ESD (2018) the main exposure of environment is expected to be soil. Soil can be exposed directly or indirectly via spills, faeces, urine, and carcasses of the target animals. Emissions to soil may furthermore occur by indoor poisoned rats and mice dying outside buildings. This scenario however, will not be considered with reference to groundwater concentration since the main exposure to soil takes place if rodents are controlled outside buildings and baits are placed on bare soil.

In order to estimate the total concentration in the soil around the bait box (taking into account both direct and indirect or disperse releases), the realistic worst case scenario (presented in the ESD for a rodent infested farm) was considered, using the highest product application frequency and the active substance in-use concentration stated in the product label; therefore the assumptions used in the calculations are in-line with the worst case uses for the product. For burrow baiting, the scenario described in the ESD for PT 14 (2018) is used to estimate soil concentrations. The default assumptions used in the ESD are considered for the assessment. For application in and around buildings, the realistic worst case scenario described by the ESD assumes that the bait stations are placed within a 10-metre zone around a farm (that is 55 m long and 10 m wide), as it is the most frequented zone for the rodents. The directly exposed area is assumed to be 10 cm around the bait box (30x20 cm) with its back against the building wall and the mixing soil depth and wet density are assumed to be 10 cm and 1700 $kg.m^{-3}$ respectively. The area indirectly exposed to rodenticide is assumed to be 550 $m^2$ and the area directly exposed to rodenticide (around the box) is 0.09 $m^2$.

For rat control 10 bait points are placed 5 m apart as per the ESD assumptions, and for mouse control 27 bait points are placed 2 m apart. (Note: it is assumed that a 5 m gap (for rat control) or a 2 m gap (for mouse control) is left between the corner of a building and the first bait). Therefore the number of bait points used for the mouse control represents a worst-case scenario since it is higher than the default assumption used in the ESD.

In both control operations, each bait point is inspected and replenished a maximum of 12 times (day 1, 4, 7, 10, 13, 16, 19, 22, 25, 28, 31 and 34). It is also assumed that by the end of the campaign all of the bait has been eaten, that direct release to the environment during application and use is 1% and that 90% of the ingested rodenticide is released via urine and faeces.

In accordance to this, the input parameters, included in the following table, were used for calculating the emissions to soil. Standard default parameters, from the ESD for PT14, are presented unless stated otherwise. The resulting $PEC_{soil}$ is included in the 'Calculated PEC Values' section.

## Scenario: In and around buildings – rat and mouse control

| Input parameters for calculating the local emission | | | | | |
|---|---|---|---|---|---|
| **Variable/Parameter** | **Symbol** | **Scenario 1.a** Rat control | **Scenario 1.b** Mouse control | **Unit** | **Remark** |
| ***Input*** | | | | | |
| Amount of product used at each refilling in the control operation for each bait box | $Q_{prod}$ | 75 | 50 | g | S |
| Fraction of active substance in product | $FC_{product}$ | 0.000023 | 0.000023 | [-] | S |
| Number of application sites | $N_{sites}$ | 10 | 27 | [-] | D (Rat)/S (Mouse) |
| Number of applications (initial baiting+refillings) | $N_{appl}$ | 12 | 12 | [-] | S (ESD default is 5) |
| Fraction of product released directly to soil | $F_{released\text{-}D,\ soil}$ | 0.01 | 0.01 | [-] | D |
| Area directly exposed to rodenticide (around the box) | $AREA_{exposed\text{-}D}$ | 0.09 | 0.09 | $m^2$ | D |
| Depth of exposed soil | $DEPTH_{soil}$ | 0.1 | 0.1 | m | D |
| Density of exposed soil | $RHO_{soil}$ | 1700 | 1700 | $kg.m^{-3}$ | D |
| Fraction of active ingredient metabolised | $F_{metab}$ | 0 | 0 | [-] | S |
| Fraction released indirectly to soil | $F_{released\text{-}D,soil}$ | 0.9 | 0.9 | [-] | D |
| Area indirectly exposed to rodenticide | $AREA_{exposed\text{-}ID}$ | 550 | 550 | $m^2$ | D |
| ***Output*** | | | | | |
| Local direct emission rate of active substance to soil from a campaign | $Elocal_{soil\text{-}D\text{-}campaign}$ | 2.07E-03 | 3.73E-03 | g | O |
| Local concentration in soil due to direct release after a campaign | $Clocal_{soil\text{-}D}$ | 1.35E-02 | 9.02E-03 | $mg/kg_{wwt}$ | O |
| Concentration in soil due to indirect (disperse) release after a campaign | $Clocal_{soil\text{-}ID}$ | 1.97E-03 | 3.56E-03 | $mg/kg_{wwt}$ | O |

Note: in the revised Emission Scenario Document for Product Type 14 (August 2018) the emission scenarios for the application in and around buildings are calculated separately for indoor use and outdoor use around buildings. Here it is calculated together; this does not impact the conclusions.

Calculations

**$Elocal_{soil\text{-}D\text{-}campaign}$** = $Q_{prod} * Fc_{prod} * N_{sites} * N_{appl} * F_{released\text{-}D,soil}$

**$Clocal_{soil\text{-}D}$** = $Elocal_{soil\text{-}D\text{-}campaign} * 10^3 / (AREA_{exposed\text{-}D} * DEPTH_{soil} * RHO_{soil} * N_{sites})$

**$Clocal_{soil\text{-}ID}$** = $Q_{prod} * Fc_{prod} * N_{sites} * N_{appl} * 10^3 * F_{released\text{-}ID,soil} * (1- F_{released\text{-}D,soil}) / (AREA_{exposed\text{-}D} * DEPTH_{soil} * RHO_{soil})$

**$Clocal_{soil}$** = $Clocal_{soil\text{-}D}$ + $Clocal_{soil\text{-}ID}$

**Scenario: Burrow baiting – rat control**

| Input parameters for calculating the local emission | | | | |
|---|---|---|---|---|
| **Variable/Parameter** | **Symbol** | **Scenario 2.a** Rat control | **Unit** | **Remark** |
| ***Input*** | | | | |
| Amount of product used at each refilling in the control operation | $Q_{prod}$ | 50 | g | S |
| Fraction of active substance in product | $FC_{product}$ | 0.000023 | [-] | S |
| Number of application sites | $N_{sites}$ | 1 | [-] | D |
| Number of applications | $N_{appl}$ | 3 | [-] | D |
| Fraction of product released to soil during application | $F_{released\text{-}D,\ soil,\ appl}$ | 0.05 | [-] | D |
| raction of product released to soil during use | $F_{released\text{-}D,\ soil,\ use}$ | 0.2 | [-] | D |
| Density of exposed soil | $RHO_{soil}$ | 1700 | $kg.m^{-3}$ | D |
| Soil volume exposed to rodenticide | $Vsoil_{exposed}$ | 0.0085 | $m^3$ | D |
| ***Output*** | | | | |
| Local direct emission rate of active substance to soil from a campaign | $Elocal_{soil\text{-}D\text{-}}$ | 8.63E-04 | g | O |
| Local concentration in soil resulting from direct exposure | $Clocal_{soil\text{-}D}$ | 0.06 | $mg/kg_{wwt}$ | O |

Scenario: Bank slope treatment – rat control

| Parameters | Symbol | Value | Unit | Origin |
|---|---|---|---|---|
| **Input** | | | | |
| Amount of product used for one bait station/box | Qprod | 50 | [g] | S |
| Fraction of active substance in the product | Fcproduct | 0.00023 | [-] | S |
| Number of application sites | Nsites | 12 | [-] | D/S |
| Number of applications | Napp | 1 | [-] | D |
| Fraction of active ingredient released directly | Frelease-D,water | 0.4 | [-] | D |
| Water volume of channel | Vchannel | 450,000 | [L] | D |
| **Output** | | | | |
| Local direct emission of substance to water | $Elocal_{water-D}$ | 3.86E-02 | g | O |
| Local concentration in channel water | Clocalwater-D | 8.59E-08 | [g.L-1] | O |
| **Calculation** | | | | |
| Clocalwater-D = Qprod • Fcproduct • Napp • Nsites • Frelease-D,water / Vchannel (3.34) | | | | |

### 2.2.8.4.3. Emission to groundwater

The product is intended to be used within enclosed bait stations (by amateurs) or covered/hidden bait points (by professionals) in and around buildings. Rodenticide active substances might be vertically transported to aquifers or even groundwater when entering the soil compartment.

The assessment of groundwater concentrations has to be conducted for the application of solid and liquid baits. The $PEC_{groundwater}$ is calculated according to equation 68, chapter 2.3.8.6, Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B (2015) as a first worst-case estimation. Initial Tier 1 $PEClocal_{soil,porew}$ calculations (based on the BPR guidance, Equation # 70) are included in the 'Calculated PEC Values' section.

### 2.2.8.4.4. Fate and distribution in exposed environmental compartments

Based on the intended use and the physico-chemical properties of the active substance and product, direct exposure to soil and indirect exposure to groundwater can be expected. Exposure to air is considered negligible since Brodifacoum is a non-volatile substance (with a low vapour pressure of <<1E-06 Pa at 20°C) and the product comes in the form of a solid formulation. Exposure to the STP and fresh-water compartments is also considered not relevant, according to the ESD for PT14, for the scenario 'in and around buildings'. There is potential for primary and secondary poisoning however if the rodenticide application is done according to the product label's instructions (i.e. pellets/wax blocks placed hidden and safe, in sturdy bait stations and inaccessible to non-target organisms), the risk of primary and secondary exposure of non-target mammals and birds is minimized.

| Identification of relevant receiving compartments based on the exposure pathway | | | | | | | |
|---|---|---|---|---|---|---|---|
| Scenario | Environmental compartments | | | | | | |
| | Air | STP | Soil | Surface water | Ground-water | Primary poisoning | Secondary poisoning |
| In and around buildings | (+) | (+) | ++ | (+) | + | ++ | + |
| Burrow baiting | - | - | ++ | - | + | ++ | + |
| Rat control for bank slopes | (+) | - | | ++ | + | ++ | + |

++ Compartment primarily exposed

\+ Compartment secondarily exposed

(+) Compartment potentially exposed, but not relevant according to the ESD for PT14

\- Compartment not exposed

The following table summarises the main Brodifacoum physico-chemical properties that were considered in this risk assessment; these were obtained from the Brodifacoum PT14 Final Assessment Report.

| Brodifacoum physico-chemical properties relevant to the environmental risk assessment | | | |
|---|---|---|---|
| **Physico-chemical property** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 523.4 | g/mol | - |
| Melting point | 232 | °C | - |
| Vapour pressure (at 20°C) | 2.6E-22 | Pa | - |
| Water solubility (at 20°C) | 5.8E-05 | mg/L | |
| Octanol/water partition coefficient | 4.92 | Log 10 | at pH7 and 20°C |
| Organic carbon/water partition coefficient (Koc) | 9155 | L/kg | - |
| Henry's Law Constant (at 20°C) | 2.18E-03 | $Pa/m^3/mol$ | - |
| Biodegradability | Not biodegradable | - | - |
| DT50 soil (at 12°C) | 298 | d | - |

### 2.2.8.4.5. Calculated PEC values

The following table includes the $PEC_{soil}$ and $PEClocal_{soil,porew}$ values calculated for the realistic worst-case rat and mouse control operations (i.e. Scenarios 1.a and 1.b, respectively) and the application by burrow baiting (i.e. Scenario 2.a).

$PEC_{soil}$ represents the total concentration in the soil around the bait box taking into account both direct and disperse releases; it is referred to in the ESD as $Clocal_{soil}$ and it was calculated using the following equation (taken from the ESD): $Clocal_{soil}$ = $Clocal_{soil\text{-}D}$ + $Clocal_{soil\text{-}ID}$(not relevant for burrow baiting). The $PEClocal_{soil,porew}$ was calculated based on the BPR guidance (v.2.0, Oct 2017) Equation # 70: $PEClocal_{soil}$ * $RHO_{soil}$ / $K_{soil\text{-}water}$ * 1000.

| Summary table on calculated PEC values | | |
|---|---|---|
| **Scenario** | **$PEC_{soil}$** | **$PEClocal_{soil,porew}$** |
| | [$mg/kg_{wwt}$] | [mg/L] |
| 1.a Rat control in and arround the house | 1.55E-02 | 9.59E-05 |
| 1.b Mouse control in and arround the house | 1.26E-02 | 7.79E-05 |
| 2.a Rat control in burrows | 0.06 | 3.71E-04 |
| | $PEC_{water}$ | - |
| | [mg/L] | |
| 3. Rat control for bank slopes | 1.29E-04 | |

## 2.2.8.5. Primary and secondary poisoning

**Qualitative Risk Assessment**

Appendix 5 of the addendum of the BPR Guidance (Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017) for PNECoral derivation of anticoagulant rodenticides proposes a qualitative approach for the acute poisoning situation, due to the lack of guidance for calculating an acute PNECoral.

In the following sections, qualitative assessments have been performed for use of the product in and around buildings, as outlined in the guidance document.

Object of a qualitative risk assessment should be:

- Primary poisoning:
    - Tier 2 for 1 day exposure with and without excretion, where the $PEC_{oral}$ is the expected concentration of the active substance in the non-target animal after 1 day exposure (single meal) [mg/kg bw]. A default excretion factor of 0.3 (for birds and mammals) should be used in case no data is available.
- Secondary poisoning:
    - Tier 1, where the $PEC_{oral}$ is the concentration in the rodent immediately after a last meal on day 5 [mg/kg food]. For a short-term exposure PD is 1 (rodents have fed entirely on rodenticide) and $F_{rodent}$ = 1 (non-target animals consume 100 % of their daily intake on poisoned rodents). For comparison, calculations with PD = 0.5 and PD = 0.2 could also be included.

Primary Poisoning Acute – Tier 1 (Steps 1 & 2)

The primary poisoning acute Tier 1 assessment includes two scenarios; Step 1 and Step 2.

In Step 1, which is a worst case scenario, birds are assumed to consume only bait during one day and mammals are expected to eat 600 g of bait (AV, PT and PD are all set to 1). The expected concentration of active substance (EC) in the animal is calculated (as shown in the ESD (ECHA, 2018)), with and without excretion (metabolism of Brodifacoum is not considered to be significant and therefore has not been included in the calculations) by the following equation:

EC = ETE x (1-EI)

The estimated daily uptake of a compound (ETE) is given by the following equation:

ETE = (FIR/BW) * C * AV * PT * PD (mg/kg bw/day)

Where FIR is the food intake rate of the indicator species, BW is the indicator species body weight, C is the concentration of the active substance in fresh diet, AV is the avoidance factor, PT is the fraction of diet obtained in treated area and PD is the fraction of the food type in the diet.

In Step 2, which is a refined scenario, the fraction of the diet from the treated area (PT) is set to 0.9 and the avoidance (AV) of mammals is set to 0.8. The fraction of the food type in the diet (PD) is set to 1.

**Primary Poisoning – Acute, Tier 1 - Estimated Daily Uptake for Non-Target Mammals and Birds Ingesting Product Containing Brodifacoum**

| Species | Body Weight (g) BW | Daily Mean Food Intake (g) FIR | Rodenticide Consumption (g) | Concentration of Brodifacoum after a single meal (one day) (mg/kg) ETE | |
|---|---|---|---|---|---|
| | | | | Step 1 | Step 2 |
| | | | | EI = 0 | EI= 0 |
| Dog | 10000 | 600 | 600 | 1.38 | 0.99 |
| Pig | 80000 | 600 | 600 | 0.17 | 0.12 |
| Young Pig | 25000 | 600 | 600 | 0.55 | 0.40 |
| Tree Sparrow | 22 | 7.6 | 7.6 | 7.95 | 5.72 |
| Chaffinch | 21.4 | 6.42 | 6.42 | 6.89 | 4.97 |
| Wood Pigeon | 490 | 53.1 | 53.1 | 2.49 | 1.79 |
| Pheasant | 953 | 102.7 | 102.7 | 2.48 | 1.78 |

EI= Excretion Factor

Secondary Poisoning – Acute – Tier 1

A Tier 1 qualitative acute assessment has been made where the $PEC_{oral}$ is the concentration in the rodent immediately after the last meal on day 5 [mg/kg food]. PD is 1 (rodents have fed entirely on rodenticide) and $F_{rodent}$ = 1 (non-target animals consume 100% of their daily intake on poisoned rodents) as a realistic worst case. For comparison calculations with PD = 0.5 and PD = 0.2 have also be included (intermediate and normal case, respectively).

**Secondary Poisoning, Acute, Tier 1 - $PEC_{oral}$ Predator**

| Parameter | Realistic worst case (100%) | Intermediate (50%) | Normal case (20%) |
|---|---|---|---|
| Concentration of product in fresh diet ((C); mg/kg) | 23 | 23 | 23 |
| Avoidance factor (1 = no avoidance; 0 = complete avoidance) (AV) | 1 | 1 | 1 |
| Fraction of diet obtained in treated area (PT) | 1 | 1 | 1 |
| Fraction of food type (treated bait) in diet (PD) | 1 | 0.5 | 0.2 |
| Fraction of daily uptake eliminated (EI) | 0 | 0 | 0 |
| Fraction of poisoned rodents in predator's diet ($F_{rodent}$ acute = 1) | 1 | 1 | 1 |
| Days the rodent is feeding on rodenticide until caught by predator (N) | 5 | 5 | 5 |

| | | | |
|---|---|---|---|
| Estimated daily uptake of a compound in the rodent (mg/kg bw) | 2.30 | 1.15 | 0.46 |
| **Normal non-resistant rodent which stops eating on day 5 estimated concentration** | **11.50** | **5.75** | **2.30** |

**Quantitative Risk Assessment**

Appendix 5 of the addendum of the BPR Guidance (Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017) defines the objective of a quantitative risk assessment as follows:-

Object of a quantitative risk assessment should be:

- Primary poisoning:
  - Tier 1 where the $PEC_{oral}$ is the concentration of the active substance in the food (bait) [mg/kg food]
  - Tier 2 for 5 days exposure, considering excretion, where the $PEC_{oral}$ is the expected concentration of the active substance in the non-target animal after 5 days exposure [mg/kg bw]. A default excretion factor of 0.3 (for birds and mammals) should be used in case no data are available. As a worst case, the parameter AV, PT and PD are all 1.
- Secondary poisoning:
  - Tier 1 for a long-term exposure. The $PEC_{oral}$ is the concentration in the rodent immediately after a last meal on day 5 [mg/kg food]; PD = 1 and $F_{rodent}$ = 0.5 (non-target animals consume 50 % of their daily intake on poisoned rodents). For comparison, calculations with PD = 0.5 and PD =0.2 could also be included.
  - Tier 2 for a long-term exposure. The $PEC_{oral}$ is the concentration in non-target animals after a single day of exposure [mg/kg bw]; PD = 1 and $F_{rodent}$ = 0.5.

Primary Poisoning – Tier 1

The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the bait. The worst case Step 1 $PEC_{oral}$ is therefore **23 mg/kg food** (Brodifacoum present at 0.0023% w/w).

Primary Poisoning – Long-term, Tier 2

Long term primary poisoning has been calculated based on a mammal or bird eating the bait for 5 consecutive days. As indicated elsewhere, excretion (metabolism of Brodifacoum is not considered to be significant) has not been included in the calculations.

The worst case scenario exists if AV, PT and PD are all set to 1 (step 1). $EC_x$ is calculated with the formulat $EC_x = EC_{(x-1)} + ETE)*(1-EL)$.

**Primary Poisoning - Long-term, Tier 2, Step 1 - $PEC_{oral}$ expressed as mg/kg BW for Non-Target Mammals and Birds Accidentally Exposed to Brodifacoum for 5 consecutive days In and Around Buildings**

| | Dog | Pig | Young Pig | Tree Sparrow | Chaffinch | Wood Pigeon | Pheasant |
|---|---|---|---|---|---|---|---|
| ETE | 1.38 | 0.17 | 0.55 | 7.95 | 6.89 | 2.49 | 2.28 |
| EC2 | 1.38 | 0.17 | 0.55 | 7.95 | 6.89 | 2.49 | 2.28 |
| EC3 | 2.76 | 0.34 | 1.10 | 15.9 | 13.8 | 4.98 | 4.95 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| EC4 | 4.13 | 0.52 | 1.65 | 23.8 | 20.7 | 7.46 | 7.42 |
| EC5 | 5.51 | 0.69 | 2.20 | 31.7 | 27.5 | 9.94 | 9.89 |
| EC6 | 6.88 | 0.86 | 2.75 | 39.6 | 34.4 | 12.4 | 12.4 |

For a more realistic worst case AV = 0.9, PT = 0.8 and PD = 1 (step 2).

**Primary Poisoning – Long-term, Tier 2, Step 2 - $PEC_{oral}$ expressed as mg/kg BW for Non-Target Mammals and Birds Accidentally Exposed to Brodifacoum for 5 consecutive days In and Around Buildings**

| | Dog | Pig | Young Pig | Tree Sparrow | Chaffinch | Wood Pigeon | Pheasant |
|---|---|---|---|---|---|---|---|
| ETE | 0.99 | 0.12 | 0.40 | 5.72 | 4.97 | 1.79 | 1.78 |
| EC2 | 0.99 | 0.12 | 0.40 | 5.72 | 4.97 | 1.79 | 1.78 |
| EC3 | 1.98 | 0.25 | 0.79 | 11.4 | 9.92 | 3.58 | 3.56 |
| EC4 | 2.97 | 0.37 | 1.19 | 17.1 | 14.9 | 5.37 | 5.34 |
| EC5 | 3.96 | 0.50 | 1.59 | 22.8 | 19.8 | 7.16 | 7.12 |
| EC6 | 4.95 | 0.62 | 1.98 | 28.5 | 24.8 | 8.95 | 8.90 |

Secondary poisoning Long-term, Tier 1

**Secondary Poisoning, Long-term, Tier 1 - $PEC_{oral}$ Predator – terrestrial exposure**

| Parameter | Realistic worst case (100%) | Intermediate (50%) | Normal case (20%) |
|---|---|---|---|
| Concentration of product in fresh diet ((C); mg/kg) | 23 | 23 | 23 |
| Avoidance factor (1 = no avoid, 0 = complete avoid.) (AV) | 1 | 1 | 1 |
| Fraction of diet obtained in treated area (PT) | 1 | 1 | 1 |
| Fraction of food type (treated bait) in diet (PD) | 1 | 0.5 | 0.2 |
| Fraction of daily uptake eliminated (EI) | 0 | 0 | 0 |
| Fraction of poisoned rodents in predator's diet (chronic = 0.5) | 0.5 | 0.5 | 0.5 |
| Days the rodent is feeding on rodenticide until caught by predator (N) | 5 | 5 | 5 |

| | | | |
|---|---|---|---|
| Predicted environmental concentration of a.i. in food of predator on day N ('chronic') | 5.75 | 2.88 | 1.15 |

**Secondary Poisoning – Long-term, Tier 2 - terrestrial exposure**

Concentrations resulting from a single day exposure assuming that predators feed 50% on poisoned rodents fed on rodenticide 5, 7 or 14 days with PD (fraction of food) 1, 0.5 and 0.2 are shown below.

**Secondary Poisoning – Long-term, Tier 2 - Concentrations Resulting After a Single Day Exposure Assuming Predators Feed 50% on Poisoned Rodents Fed on Brodifacoum Bait**

| Non-Target Animals | Concentration in Non-Target Animal (mg/kg bw Predator) | | |
|---|---|---|---|
| | Rodent caught on day 5 after feeding | Rodent caught on day 7 after feeding | Rodent caught on day 14 after feeding |
| Barn owl *(Tyto alba)* | 1.14 | 1.43 | 3.99 |
| Kestrel *(Falco tinnunculus)* | 1.73 | 2.17 | 6.06 |
| Little owl *(Athene noctua)* | 1.30 | 1.63 | 4.56 |
| Tawny owl *(Strix aluco)* | 1.05 | 1.31 | 3.67 |
| Fox *(Vulpes vulpes)* | 0.42 | 0.52 | 1.47 |
| Polecat *(Mustela putorius)* | 0.87 | 1.09 | 3.06 |
| Stoat *(Mustela erminea)* | 1.25 | 1.56 | 4.37 |
| Weasel *(Mustela nivalis)* | 1.80 | 2.25 | 6.31 |
| Dog *(Canis familiaris)* | 0.21 | 0.26 | 0.73 |

**Scenario 3: Secondary poisoning for fish eating birds and mammals – bank slope scenario**

Because the use on bank slopes has emission to surface water also secondary poisoning of birds and mammals has been determined in line with Vol IV part B&C.

| | |
|---|---|
| $PEC_{water}$ (mg/L)* | 1.29E-04 |
| BCF (L/kg wwt)** | 35645 |
| BMF** | 2 |
| $PEC_{oral,\ pred}$ (mg/kg wwt) | 4.60 |

* a correction of a factor 2 was applied to the PECwater to determine the PECoral considering that not all the food of the predator will be obtained from the treated area.
** derived from the CAR obtained from a log Kow of 4.92

## 2.2.8.6. Risk characterisation

### 2.2.8.6.1. Atmosphere

Brodifacoum has a low vapour pressure (2.6E-22 Pa, at 20°C) and a Henry's Law constant of <<2.18E-03 Pa/m$^3$/mol (at 20°C, pH 7). Based on this and on the fact that the product comes in the form of a solid formulation, release to air is expected to be negligible.

### 2.2.8.6.2. Sewage treatment plant (STP) / Aquatic compartment

Contamination of surface water and sediment following the placement of block baits in and around buildings is very unlikely, as stated in the ESD (ECHA, 2018).

Exposure to fresh water and sediment from the use of brodifacoum in the product, in and around buildings, is negligible according to the ESD for PT14. In line with TAB entry 180, however, emission to water from bank slope treatment has to be assessed.

| Calculated PEC/PNEC values | | | |
|---|---|---|---|
| **Scenario** | **$PEC_{water}$** | **$PNEC_{water}$** | **$PEC/PNEC_{water}$** |
| | [mg/L] | [$mg/kg_{wwt}$] | [-] |
| 3 Rat control on bank slopes | 1.29E-04 | 4E-05 | **3.23** |

From the data presented above, the use along bank slopes of brodifacoum in the product does pose an unacceptable risk to the aquatic environment as the $PEC/PNEC_{water}$ values are higher than 1.

### 2.2.8.6.3. Terrestrial compartment

| Calculated PEC/PNEC values | | | |
|---|---|---|---|
| **Scenario** | **$PEC_{soil}$** | **$PNEC_{soil}$** | **$PEC/PNEC_{soil}$** |
| | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [-] |
| 1.a Rat control | 1.55E-02 | 0.88 | 0.02 |
| 1.b Mouse control | 1.26E-02 | | 0.01 |
| 2.a Rat control | 0.06 | | 0.07 |

From the data presented above, the use of brodifacoum in the product does not pose an unacceptable risk to the terrestrial environment as the $PEC/PNEC_{soil}$ values are less than 1. Nevertheless, it is important to note that, the tier 1 risk assessment is very conservative as it neither takes into account the degradation of brodifacoum in the environment nor the fraction of active ingredient metabolised, hence exposure to the environment can be expected to be much lower. An acceptable risk to soil from the proposed uses can be concluded.

### 2.2.8.6.4. Groundwater

$PECloca l_{soil,porew}$ values for both scenarios (in and around buildings) were calculated based on the BPR guidance, Equation # 70. These $PECloca l_{soil,porew}$ values indicate an acceptable risk to the groundwater compartment as they are < 0.1 µg/L (or 1E-04 mg/L), the maximum permissible concentration by directive 2006/18/EC; therefore the risk to the groundwater environment for the use of Brodifacoum is acceptable.

For burrow baiting, the PEC in pore water of 0.371 µg/L amounts to >0.1 µg/L, which is the maximum admissible concentration for a single biocide in drinking water. The calculated pore water concentration for brodifacoum (as an indicator of the potential concentrations in groundwater) does not comply with this criterion. The exceedance of the groundwater threshold value can be considered as acceptable as the pore-water approach is overly conservative. Furthermore, the released amount of a.s. is in general very low and the application only takes place at a small scale.

However, FOCUS PEARL 4.4.4 is used to refine the groundwater concentrations. The application parameters as described in the revised ESD for PT 14 (2018) for open areas are applied. It is assumed that 100 bait points are applied per hectare (worst case for rat control; 50 g b.p. per baiting point). The application is done on day 1, 3 and 8 of a control campaign and 2 campaigns are performed per year (application dates: 15.03, 17.03., 22.03, 15.09, 17.09, 22.09). The release fractions to soil from the ESD PT 14 (2018) are considered for the application rates (0.25) resulting in a brodifacoum application amount of dosage of 2.88E-05 kg a.s./ha.

The application type is surface application and the crop type grass/alfalfa. The relevant input parameters are summarized in the following table.

| Parameter | Value |
|---|---|
| **Tab Scenario** | |
| Location | all 9 EU scenarios |
| Crop Calendar | Grass/alfalfa |
| Irrigation | no irrigation |
| Tillage | no tillage |
| Repeat interval for application events (years)- | 1 |
| Deposition | no deposition |
| **Tab Diffusion** | |
| Reference temperature for diffusion (°C) | 20 (default) |
| Reference diffusion coefficient in water ($m^2$/d) | 4.3E-5 (default) |
| Reference diffusion coefficient in air ($m^2$/d) | 0.43 (default) |
| **Tab Crop** | |
| Wash-off factor (/m) | 0.0001 |
| Canopy process option | Lumped |
| Half-life at crop surface (d) | 1000000 |
| Coefficient for uptake by plant (-) | 0 (no uptake by plants) |
| **Application** | |
| Application type | To the soil surface |
| Date: | 15.03.1901, 17.03.1901, 22.03.1901, 15.09.1901, 17.09.1901, 22.09.1901 |
| Dosage (kg/ha) | 2.88E-05 |
| **Substances** | |
| **Active substance** | |
| **Tab General** | |
| Molar mass (g· $mol^{-1}$) | 523.4 |
| Saturated vapour pressure (Pa) | 1E-05 |
| Measured at (°C) | 20 |
| Molar enthalpy of vaporisation (kJ/mol) | 95 |
| Solubility in water (mg/L) | 5.8E-05 |
| Measured at (°C) | 20 |

| | |
|---|---|
| Molar enthalpy of dissolution (kJ/mol) | 27 (default) |
| **Tab Freundlich sorption** | |
| Option | Kom, pH-independent |
| Kom | 5310.33 |
| Measured at (°C) | 20 |
| Molar enthalpy of sorption (kJ/mol) | 0 |
| Reference concentration in liquid phase (mg/L) | 1 (default) |
| Freundlich sorption exponent (-) | 1 (worst case) |
| Desorption rate coefficient(/d) | 0 (default) |
| Factor relating CofFreNeq and COFFreEql (-) | 0 (default) |
| **Tab Transformation** | |
| Half-life (d) | 298 |
| Measured at (°C) | 12 |
| Optimum moisture conditions (pF2 or wetter) | unchecked |
| Liquid content in incubation experiment (mg/kg) | 1 (default) |
| Exponent for the effect liquid (-) | 0.7 (default) |
| Molar activation energy (kJ/mol) | 54 (default) |

The FOCUS PEARL 4.4.4 calculation demonstrates groundwater values of <0.001 µg/L for all nine FOCUS scenarios, i.e., there is no risk for brodifacoum to be transported into groundwater when being applied in burrows.

### 2.2.8.6.5. Primary and secondary poisoning

Appendix 5 of the addendum of the BPR Guidance (Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017) describes that a qualitative description of the toxicity of the substance compared to the possible single uptake should be given instead of performing a quantitative risk assessment. Therefore in the following sections the risk assessments for both primary and secondary poisoning – acute will be based on the qualitative estimations whilst the primary and secondary - long term assessments are based on the quantitative assessments.

Primary poisoning - Qualitative Risk Assessment

**Qualitative Risk Characterisation Primary Poisoning – Acute, Tier 1, Step 2**

| Species | Concentration of Brodifacoum after a single meal (one day) (mg/kg bw) ETE, Step 2 | LD50 dose (mg/kg bw) | $PEC_{oral}$ Higher Than $LD_{50}$ (Y/N) |
|---|---|---|---|
| Dog | 0.99 | 0.4 | Y |
| Pig | 0.12 | 0.4 | N |
| Young Pig | 0.40 | 0.4 | Equal |
| Tree Sparrow | 5.72 | 0.31 | Y |
| Chaffinch | 4.97 | 0.31 | Y |
| Wood Pigeon | 1.79 | 0.31 | Y |
| Pheasant | 1.78 | 0.31 | Y |

Primary poisoning - Quantitative Risk Assessment

## Primary Poisoning – Long-term - Tier 2 Step 2

| Species | PEC = EC (concentration of Brodifacoum / kg bw after one day of elimination) | PNEC dose (mg/kg bw) | PEC/PNEC |
|---|---|---|---|
| Dog | 0.99 | 1.10E-05 | 90000 |
| Pig | 0.12 | 1.10E-05 | 10909 |
| Young Pig | 0.40 | 1.10E-05 | 36364 |
| Tree Sparrow | 5.72 | 1.28E-05 | 520000 |
| Chaffinch | 4.97 | 1.28E-05 | 451818 |
| Wood Pigeon | 1.79 | 1.28E-05 | 162727 |
| Pheasant | 1.78 | 1.28E-05 | 161818 |

Conclusion for primary poisoning

It can be concluded that the qualitative and quantitative risk assessment indicates a concern from both acute and long-term consumption of Brodifacoum bait. If used in accordance with the label, primary poisoning incidents involving Klerat Pellets XT should be rare. However, when baits are located around buildings, there is a potential for similarly sized birds and mammals to access the baits. From the calculated results it can be seen that the effects from ingestion would be both lethal and sub-lethal. Therefore, risk mitigation measures are required. In NL this means a restriction to the use by (trained) professionals as part of Integrated Pest Management (IPM) principles. For further measures to protect animals and the environment we refer to the SPC which shall be duly taken into consideration for a clear labelling of the product. For other member states different mitigation measures may apply.

To reduce the risk of this occurring it is recommended that suitable bait containers such as tamper-resistant bait boxes are used.

Any remaining baits must be disposed of safely after a campaign has finished. Dead rodents should be disposed of in a similar manner, and care must be taken when handling carcasses. Rodenticide baits should be kept safely locked away.

Note from the eCA: there are at present indications that the RMMs undertaken do not result in a reduction in the exposure of predatory birds and mammals and other non target species.

Secondary poisoning - Qualitative Risk Assessment – terrestrial route

## Qualitative Risk Characterisation, Secondary Poisoning, Acute, Tier 1

| Non-target Animal | PD (%) | PEC (Conc. in food) mg/kg | PNEC (conc in food) mg/kg diet | PEC/PNEC |
|---|---|---|---|---|
| Birds | 20 | 2.3 | 1.30E-05 | 176923 |
| | 50 | 5.75 | 1.30E-05 | 441538 |
| | 100 | 11.5 | 1.30E-05 | 884615 |
| Mammals | 20 | 2.3 | 2.22E-04 | 10360 |
| | 50 | 5.75 | 2.22E-04 | 25856 |
| | 100 | 11.5 | 2.22E-04 | 51802 |

Secondary poisoning - Quantitative Risk Assessment – terrestrial route - long term

## Quantitative Risk Characterisation; Secondary Poisoning, Long term, Tier 2

| Non-Target Animals | Concentration in Non-Target Animal (mg/kg bw Predator) | | | PNEC | PEC/PNEC | | |
|---|---|---|---|---|---|---|---|
| | Rodent caught on day 5 after feeding | Rodent caught on day 7 after feeding | Rodent caught on day 14 after feeding | | Rodent caught on day 5 after feeding | Rodent caught on day 7 after feeding | Rodent caught on day 14 after feeding |
| Barn owl *(Tyto alba)* | 1.14 | 1.43 | 3.99 | 1.28E-05 | 89063 | 111719 | 311719 |
| Kestrel *(Falco tinnunculus)* | 1.73 | 2.17 | 6.06 | 1.28E-05 | 135156 | 169531 | 473438 |
| Little owl *(Athene noctua)* | 1.30 | 1.63 | 4.56 | 1.28E-05 | 101563 | 127344 | 356250 |
| Tawny owl *(Strix aluco)* | 1.05 | 1.31 | 3.67 | 1.28E-05 | 82031 | 102344 | 286719 |
| Fox *(Vulpes vulpes)* | 0.42 | 0.52 | 1.47 | 1.10E-05 | 38182 | 47273 | 133636 |
| Polecat *(Mustela putorius)* | 0.87 | 1.09 | 3.06 | 1.10E-05 | 79091 | 99091 | 278182 |
| Stoat *(Mustela erminea)* | 1.25 | 1.56 | 4.37 | 1.10E-05 | 113636 | 141818 | 397273 |
| Weasel *(Mustela nivalis)* | 1.80 | 2.25 | 6.31 | 1.10E-05 | 163636 | 204545 | 573636 |
| Dog *(Canis familiaris)* | 0.21 | 0.26 | 0.73 | 1.10E-05 | 19091 | 23636 | 66364 |

Secondary poisoning - Quantitative Risk Assessment bank slope – aquatic route

| Calculated PEC/PNEC values | | | |
|---|---|---|---|
| **Scenario** | **$PEC_{oral}$** | **$PNEC_{oral}$** | **$PEC/PNEC_{water}$** |
| | **[mg/kg food]** | **[mg/kg food]** | **[-]** |
| 3 Rat control on bank slopes | | | |
| Fish eating birds | 4.60 | 1.28E-05 | **359235** |
| Fish eating mammals | 4.60 | 2.22E-04 | **20713** |

Due to the unacceptable risks identified when applying bait boxes on bank slopes “do not place bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems to prevent flushing away of bait due to high rainfall events and flooding.”

Conclusion for secondary poisoning

It can be concluded that the qualitative and quantitative risk assessment for the terrestrial exposure and for the aquatic exposure indicates a concern from both acute and long-term consumption of pray organisms contaminated with Brodifacoum.

Overall Conclusion: The conclusion of the qualitative and quantitative risk assessments is that there are in many cases unacceptable risks to non-target vertebrates *via* primary and secondary poisoning. Therefore, it would seem more appropriate to develop and validate risk management procedures than to refine the risk assessment procedures.

The applicant considers that provided that baits are deployed in accordance with the product labelling and other approved guidance on good practice, the primary poisoning risk to non-target mammals may be considered to be negligible.

The risk of secondary poisoning of the active substance to birds and small mammals are expected to be significantly reduced by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the blocks and removing dead and moribund rodents during a baiting campaign to minimise the opportunity secondary exposure. These mitigation measures are described in good practice guidance documents, in training material for pest control professionals and on the labels of the products.

The eCA, however, concludes that all risk quotients are far above 1, and several field studies have shown that predatory birds and mammals in the wild are poisoned with anticoagulants to a degree which does not comply with the criteria for authorisation in art. 19(1), b, iv. There are indications that the RMMs proposed do not reduce the exposure and the risk to an acceptable level.

### 2.2.8.6.6. Mixture toxicity

The product only contains a single active substance and no other relevant substance of concern. A mixture assessment is therefore unnecessary.

### 2.2.8.6.7. Aggregated exposure (combined for relevant emission sources)

An assessment on aggregated exposure has not been performed as only one treatment (between the rat and mouse control) is applicable per location. Therefore, as both treatments cannot be considered at the same time, aggregated exposure is not relevant.

| **Overall conclusion on the risk assessment for the environment of the product** |
|---|
| The risk to the environment for the use of brodifacoum in Klerat Pellets XT is unacceptable. The risk of primary poisoning to non-target mammals cannot be considered to be negligible. All risk quotients are far above 1, and several field studies have shown that predatory birds and mammals in the wild are poisoned with anticoagulants to a degree which does not comply with the criteria for authorisation in art. 19(1), b, iv. |

## 2.2.9. Measures to protect man, animals and the environment

See SPC and MSDS.

## 2.2.10. Assessment of a combination of biocidal products

Not relevant. The product is not intended to be authorised for the use with other biocidal products.

## 2.2.11. Comparative assessment

The NL CA for biocides has processed an application for the biocidal product Klerat Pellets XT which contains the active substance Brodifacoum. The active substance brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR.

Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Klerat Pellets XT 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'). These questions are also relevant now. 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 According to Article 1 of Commission Implementing Decision (EU) 2017/1532 the NL CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

**Conclusion**

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the NL 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 opinion also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which may provide sufficient efficacy in certain circumstances on their own or in a combination of them. However, there is insufficient scientific evidence to prove that those non-chemical alternatives are sufficiently effective according to the criteria established in agreed Union guidance 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 is granted for the product Klerat Pellets XT for 5 years.

# 3. ANNEXES

## 3.1. List of studies for the biocidal product

| IUCLID reference number | Author(s) | Year | Title<br>Source (where different from company)<br>Company, Report No<br>GLP or GEP (where relevant),<br>Published or No | Data Protection Claimed<br>Y/N | Owner |
|---|---|---|---|---|---|
| 3.1<br>3.2<br>3.3<br>3.4<br>3.5 | [redacted] | 2018a | Determination of Physico-Chemical Properties and Storage Stability Tests for Klerat Pellets: 2 weeks at 54°C, 8 weeks at 40C and up to 24 months at 20°C - 2 Weeks Interim Report Biogenius GmbH, Study No5831<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 3.4 | [redacted] | 2018b | Determination of Physico-Chemical Properties and Storage Stability Tests for Klerat Pellets: 2 weeks at 54°C, 8 weeks at 40C and up to 24 months at 20°C - 2 Weeks Interim Report.<br>Biogenius GmbH, Study Mo6014<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 4.1 | [redacted] | 2018a | Explosive Properties A.14,<br>Siemens AG, Report PS20170533-3<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 4.1 | [redacted] | 2019 | Explosive properties (UN Manual of Tests and Criteria, Time-Pressure-Test 1(c) / 2(c) / C.1)<br>Siemens AG, Report PS20190124-1<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| | [redacted] | 2019 | EXPLOSIVE PROPERTIES<br>(UN MANUAL OF TESTS AND CRITERIA, KOENEN.TEST<br>1(b)t(2(b)/E.r)<br>Siemens AG, Report P520190124-2<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 4.2 (4.7) | [redacted] | 2018b | Flammability (Solids) N.1,<br>Siemens AG, Report PS20170533-1<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 4.2 (4.12) | [redacted] | 2018c | Flammability (Contact with water) UN N.5,<br>Siemens AG, Report PS20170533-2<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |

| | | | | | |
|---|---|---|---|---|---|
| 4.4 (4.14) | [redacted] | 2018d | Oxidising Properties of Solids UN O.1,<br>Siemens AG, Report PS20170533-4<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 4.17 (4.11) | [redacted] | 2018e | Auto-flammability (UN N.4),<br>Siemens AG, Report PS20170533-5<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 5 | [redacted] | 2017a | SYN: HPLC - Determination of Brodifacoum in Baits.<br>Biogenius GmbH, Method MV171<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 5 | [redacted] | 2017b | Validation of Method MV171: SYN: HPLC - Determination of Brodifacoum in Baits.<br>Biogenius GmbH, Study Mo5507<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 5 | [redacted] | 2018c | Validation of Method: MV-187: HPLC-MS-Determination of Denatonium Benzoate in Klerat Pellets.<br>Biogenius GmbH, Study No5998<br>GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 6.7 | [redacted] | 2016 | Evaluation Of The Efficacy Of The A21479A Pellet (23ppm Brodifacoum Pellet Rodenticide) For The Control Of House Mouse Infestations In Agricultural Building. IZIPEST, France. Report number: 16SYN002. Non-GLP, Unpublished | Y | Syngenta Crop Protection AG |
| 6.7 | [redacted] | 2016 | Acceptance of Klerat Pellets containing 23ppm of brodifacoum (A21479A; Batch EN04G21184) vs RM3 ground lab diet, using resistant house mice homozygous for the VKORC1 mutation Y139C. Vertebrate Pests Unit, University of Reading, UK. Report No: VPU16/010. Non-GLP, Unpublished. | Y | Syngenta Crop Protection AG |
| 6.7 | [redacted] | 2017a | Acceptance of A21479A Klerat Pellets 23ppm (Batch EN04G21184) vs RM3, using CSL Berkshire Norway rats. Vertebrate Pests Unit, University of Reading, UK. Report No: VPU17/001. Non-GLP, Unpublished. | Y | Syngenta Crop Protection AG |

| | | | | | |
|---|---|---|---|---|---|
| 6.7 | [redacted] | 2017b | Field efficacy evaluation of Klerat (A21479A) pellet rodenticide bait, containing brodifacoum at 23ppm, for the control of wild Norway Rats (Rattus norvegicus) infesting an agricultural holding in Hampshire, known to possess the VKORC1 mutation L120Q.<br><br>Vertebrate Pests Unit, University of Reading, UK. Report No: VPU17/008. Non-GLP, Unpublished. | Y | Syngenta Crop Protection AG |
| 6.7 | [redacted] | 2017c | Efficacy of Klerat Pellets containing brodifacoum (23ppm) and bitrex (10ppm) (Formulation: A22414A) packaged in plastic sachets using RM3 Ground Laboratory Diet as the challenge diet, against albino house mice and albino Norway rats.<br><br>Vertebrate Pests Unit, University of Reading, UK. Report No: VPU17/028. Non-GLP, Unpublished. | Y | Syngenta Crop Protection AG |
| 8.6 | [redacted] | 2003 | Klerat Pellets: In Vitro Absorption Through Human Epidermis. Syngenta CTL Report No: CTL/JV1757. GLP, unpublished.<br><br>PP581/10463 | Y | Syngenta Crop Protection AG |

## 3.2. Output tables from exposure assessment tools

Human Health

Calculations for Scenario 1, Decanting pellets from large bag into a bucket for the control of rats

**Tier 1, no PPE**

Dermal

| | |
|---|---|
| Amount used per day | = 63 manipulations × 75 g/bait box = 4.725 kg |
| Exposure to b.p. | = 4.725 kg × 31 mg product/kg decanted = 146.49 mg product/day |
| Exposure to a.s. | = 146.49 mg product/day × 0.0023% w/w brodifacoum |
| | = $3.4 \times 10^{-3}$ mg a.s./day |
| Systemic dermal exposure | = $3.4 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw |
| | = $3.65 \times 10^{-6}$ mg a.s./kg bw/day |

Inhalation

| | |
|---|---|
| Number of decants | = 2 per day |
| Time spent decanting | = 2 per day × 3 min per decant = 0.1 h |
| Amount of air inhaled | = 0.1 h × 1.25 $m^3$/h = 0.125 $m^3$ |
| Amount of b.p. inhaled | = 0.125 $m^3$ × 9.62 mg product/$m^3$ = 1.203 mg product/day |
| Amount of a.s. inhaled | = 1.203 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.8 \times 10^{-5}$ mg a.s./day |
| Systemic exposure via | = $2.8 \times 10^{-5}$ mg a.s./day ÷ 60 kg bw |
| inhalation | = $4.61 \times 10^{-7}$ mg a.s./kg bw/day |

| | |
|---|---|
| Total exposure | = Dermal + Inhalation |
| | = $4.11 \times 10^{-6}$ mg a.s./kg bw/day |

**Tier 2, gloves**

Dermal

| | |
|---|---|
| Amount used per day | = 63 manipulations × 75 g/bait box = 4.725 kg |
| Exposure to b.p. | = 4.725 kg × 31 mg product/kg decanted = 146.49 mg product/day |
| Exposure to a.s. | = 146.49 mg product/day × 0.0023% w/w brodifacoum |
| | = $3.4 \times 10^{-3}$ mg a.s./day |
| Systemic dermal exposure | = $3.4 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption × 10% glove penetration ÷ 60 kg bw |
| | = $3.65 \times 10^{-7}$ mg a.s./kg bw/day |

Inhalation

| | |
|---|---|
| Number of decants | = 2 per day |

| | |
|---|---|
| Time spent decanting | = 2 per day × 3 min per decant = 0.1 h |
| Amount of air inhaled | = 0.1 h × 1.25 $m^3$/h = 0.125 $m^3$ |
| Amount of b.p. inhaled | = 0.125 $m^3$ × 9.62 mg product/$m^3$ = 1.203 mg product/day |
| Amount of a.s. inhaled | = 1.203 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.8 \times 10^{-5}$ mg a.s./day |
| Systemic exposure via | = $2.8 \times 10^{-5}$ mg a.s./day ÷ 60 kg bw |
| inhalation | = $4.61 \times 10^{-7}$ mg a.s./kg bw/day |
| | |
| Total exposure | = Dermal + Inhalation |
| | = $8.26 \times 10^{-7}$ mg a.s./kg bw/day |

**Calculations for Scenario 2, Decanting pellets from large bag into a bucket for the control of mice**

**Tier 1, no PPE**

Dermal

| | |
|---|---|
| Amount used per day | = 63 manipulations × 50 g/bait box = 3.15 kg |
| Exposure to b.p. | = 3.15 kg × 31 mg product/kg decanted = 97.66 mg product/day |
| Exposure to a.s. | = 97.66 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.25 \times 10^{-3}$ mg a.s./day |
| Systemic dermal exposure | = $2.25 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw |
| | = $2.43 \times 10^{-6}$ mg a.s./kg bw/day |

Inhalation

| | |
|---|---|
| Number of decants | = 2 per day |
| Time spent decanting | = 2 per day × 3 min per decant = 0.1 h |
| Amount of air inhaled | = 0.1 h × 1.25 $m^3$/h = 0.125 $m^3$ |
| Amount of b.p. inhaled | = 0.125 $m^3$ × 9.62 mg product/$m^3$ = 1.203 mg product/day |
| Amount of a.s. inhaled | = 1.203 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.8 \times 10^{-5}$ mg a.s./day |
| Systemic exposure via | = $2.8 \times 10^{-5}$ mg a.s./day ÷ 60 kg bw |
| inhalation | = $4.61 \times 10^{-7}$ mg a.s./kg bw/day |
| | |
| Total exposure | = Dermal + Inhalation |
| | = $2.89 \times 10^{-6}$ mg a.s./kg bw/day |

**Tier 2, gloves**

Dermal

| | |
|---|---|
| Amount used per day | = 63 manipulations × 50 g/bait box = 3.15 kg |
| Exposure to b.p. | = 3.15 kg × 31 mg product/kg decanted = 97.66 mg product/day |
| Exposure to a.s. | = 97.66 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.25 \times 10^{-3}$ mg a.s./day |
| Systemic dermal exposure | = $2.25 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption × 10% glove penetration ÷ 60 kg bw |
| | = $2.43 \times 10^{-7}$ mg a.s./kg bw/day |

Inhalation

| | |
|---|---|
| Number of decants | = 2 per day |
| Time spent decanting | = 2 per day × 3 min per decant = 0.1 h |
| Amount of air inhaled | = 0.1 h × 1.25 $m^3$/h = 0.125 $m^3$ |
| Amount of b.p. inhaled | = 0.125 $m^3$ × 9.62 mg product/$m^3$ = 1.203 mg product/day |
| Amount of a.s. inhaled | = 1.203 mg product/day × 0.0023% w/w brodifacoum |
| | = $2.8 \times 10^{-5}$ mg a.s./day |
| Systemic exposure via | = $2.8 \times 10^{-5}$ mg a.s./day ÷ 60 kg bw |
| inhalation | = $4.61 \times 10^{-7}$ mg a.s./kg bw/day |

| | |
|---|---|
| Total exposure | = Dermal + Inhalation |
| | = $7.04 \times 10^{-7}$ mg a.s./kg bw/day |

**Calculations for Scenario 3, Application: loading and placing bait boxes for the control of rats and mice**

**Tier 1, no PPE**

Dermal

| | |
|---|---|
| Number of manipulations | = 63 |
| Exposure to b.p. | = 63 manipulations × 2.04 mg product/bait box = 128.52 mg product/day |
| Exposure to a.s. | = 128.52 mg product/day × 0.0023% w/w brodifacoum |
| | = $3.0 \times 10^{-3}$ mg a.s./day |
| Systemic dermal exposure | = $3.0 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw |
| | = $3.20 \times 10^{-6}$ mg a.s./kg bw/day |

**Tier 2, gloves**

Dermal

| | |
|---|---|
| Number of manipulations | = 63 |
| Exposure to b.p. | = 63 manipulations × 2.04 mg product/bait box = 128.52 mg product/day |
| Exposure to a.s. | = 128.52 mg product/day × 0.0023% w/w brodifacoum |

= $3.0 \times 10^{-3}$ mg a.s./day

Systemic dermal exposure = $3.0 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption × 10% glove penetration ÷ 60 kg bw

= $3.20 \times 10^{-7}$ mg a.s./kg bw/day

**Calculations for Scenario 4, Cleaning of used bait boxes for the control of rats and mice**

**Tier 1, no PPE**

Dermal

Number of manipulations = 16

Exposure to b.p. = 16 manipulations × 3.79 mg product/bait box = 60.64 mg product/day

Exposure to a.s. = 60.64 mg product/day × 0.0023% w/w brodifacoum

= $1.4 \times 10^{-3}$ mg a.s./day

Systemic dermal exposure = $1.4 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw

= $1.51 \times 10^{-6}$ mg a.s./kg bw/day

**Tier 2, gloves**

Dermal

Number of manipulations = 16

Exposure to b.p. = 16 manipulations × 3.79 mg product/bait box = 60.64 mg product/day

Exposure to a.s. = 60.64 mg product/day × 0.0023% w/w brodifacoum

= $1.4 \times 10^{-3}$ mg a.s./day

Systemic dermal exposure = $1.4 \times 10^{-3}$ mg a.s./day × 6.5% dermal absorption × 10% glove penetration ÷ 60 kg bw

= $1.51 \times 10^{-7}$ mg a.s./kg bw/day

**Calculations for Scenario 5, Filling bait boxes for the control of rodents**

**Tier 1, no PPE**

Dermal

Number of manipulations = 5

Exposure to b.p. = 5 manipulations × 2.04 mg product/bait box = 10.2 mg product/day

Exposure to a.s. = 10.2 mg product/day × 0.0023% w/w brodifacoum

= $2.3 \times 10^{-4}$ mg a.s./day

Systemic dermal exposure = $2.3 \times 10^{-4}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw

= $2.54 \times 10^{-7}$ mg a.s./kg bw/day

**Calculations for Scenario 6, Cleaning of used bait boxes for the control of rodents**

**Tier 1, no PPE**

Dermal

Number of manipulations = 5

| | |
|---|---|
| Exposure to b.p. | = 5 manipulations × 3.79 mg product/bait box = 18.95 mg product/day |
| Exposure to a.s. | = 18.95 mg product/day × 0.0023% w/w brodifacoum |
| | = $4.4 \times 10^{-4}$ mg a.s./day |
| Systemic dermal exposure | = $4.4 \times 10^{-4}$ mg a.s./day × 6.5% dermal absorption ÷ 60 kg bw |
| | = $4.72 \times 10^{-7}$ mg a.s./kg bw/day |

## 3.3. New information on the active substance

None.

## 3.4. Residue behaviour

Not applicable.

## 3.5. Summaries of the efficacy studies

See IUCLID section 6.1 and Section 2.2.5 of the product assessment report.

## 3.6. Confidential annex

The confidential annex 3.6 has been submitted in a separate word document.

## 3.7. Other

Environmental exposure assessment:

During the RCOM NL CA received severeral comments, therefore calculated here also PECs with the updated ECHA sheets; for rats and mice, to show separately PECs around the buildings and in the buildings, as in the main text the emissions are shown together. In addition, default values as in the ECHA sheets are here used, as well the emissions “bank slopes’ has been added.

Note that this additional calculations in the Annex do not change the conclusions.

1) Exposure scenarios in and around buildings: rats (with default values): Rodenticide emissions to soil due to use around buildings on unpaved ground

**Input**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Rodent to be controlled | | Rat | | | |
| Type of bait formulation | | Bagged baits, drinking through | | | |
| Amount of product used at each refill for one bait station/box | $Q_{prod}$ | 75 | g | S | |
| Fraction of substance in product | $Fc_{prod}$ | 0.000023 | [-] | S | |
| Number of application sites | $N_{sites}$ | 10 | [-] | D | |
| Number of applications (initial baiting+refillings) | $N_{appl}$ | 5 | | | |
| Fraction of substance released directly to soil | $F_{released-D,soil}$ | 0.01 | [-] | D | |
| Fraction of substance metabolised | $F_{metab}$ | 0 | [-] | S | |
| Fraction of substance released indirectly to soil | $F_{released-ID,soil}$ | | | | |
| a) no data on metabolism | | 0.9 | [-] | D | |
| b) data on metabolism present | | ?? | [-] | O | $\mathbf{F_{released-ID,soil}} = 0.9 * (1 - F_{metab})$ |
| **Additional parameters needed to calculate concentrations in soil** | | | | | |
| Soil area exposed directly | $AREA_{exposed-D}$ | 0.09 | $m^2$ | D | |
| Soil area exposed indirectly | $AREA_{exposed-ID}$ | 550 | $m^2$ | D | |
| Depth of exposed soil | $DEPTH_{soil}$ | 0.1 | m | D | |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg_{wwt}.m^{-3}$ | D | |

**Output**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Local direct emission of substance to soil from a campaign | $Elocal_{soil-D-campaign}$ | 8.63E-05 | g | O | $\mathbf{Elocal_{soil-D-campaign}} = Q_{prod} * Fc_{prod} * N_{appl} * F_{released-D,soil}$ |
| Local indirect emission of substance to soil from a campaign | $Elocal_{soil-ID-campaign}$ | #WAARDE! | g | O | $\mathbf{Elocal_{soil-ID-campaign}} = Q_{prod} * Fc_{prod} * N_{sites} * N_{appl} * F_{released-ID,soil}$ |
| **Concentrations** | | | | | |
| Local concentration in soil resulting from direct exposure | $Clocal_{soil-D}$ | 5.64E-03 | $mg.kgwwt^{-1}$ | O | $\mathbf{Clocal_{soil-D}} = Elocal_{soil-D-campaign} * 10^3 / (AREA_{exposed-D} * DEPTH_{soil} * RHO_{soil})$ |
| Local concentration in soil resulting from indirect exposure | $Clocal_{soil-ID}$ | ?? | $mg.kgwwt^{-1}$ | O | $\mathbf{Clocal_{soil-ID}} = Elocal_{soil-ID-campaign} * 10^3 / (AREA_{exposed-ID} * DEPTH_{soil} * RHO_{soil})$ |
| Total local concentration in soil resulting from direct plus indirect exposure | $Clocal_{soil}$ | ?? | $mg.kgwwt^{-1}$ | O | $\mathbf{Clocal_{soil}} = \mathbf{Clocal_{soil-D}} + \mathbf{Clocal_{soil-ID}}$ |

*1) S: data set; D: default; O: output; P: pick list*

2) Exposure scenarios in and around buildings: rats (with default values): Rodenticide emissions to soil due to use in buildings and emissions to soil via rat carcasses, urine and faeces

**Input**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Type of bait formulation | | Solid baits, drinking through | | | |
| Amount of product used at each refill for one bait station/box (solid bait and drinking trough) /per building (contact formulation) | $Q_{prod}$ | 75 | g | S | |
| Fraction of substance in product | $Fc_{prod}$ | 0.000023 | [-] | S | |
| Number of application sites | $N_{sites}$ | 22 | [-] | D | |
| Number of applications (initial baiting+refillings) | $N_{appl}$ | 5 | [-] | D | |
| Fraction of active ingredient metabolised | $F_{metab}$ | 0 | [-] | S | |
| Fraction released indirectly to soil | $F_{released\text{-}ID\ soil}$ | | | | |
| a) no data on metabolism | | 0.5 | [-] | S | |
| b) data on metabolism present | | **0.5** | [-] | O | **$F_{released\text{-}ID,soil}$** = 0.5 * (1 - $F_{metab}$) |
| **Additional parameters needed to calculate concentrations in soil** | | | | | |
| Soil area exposed indirectly | $AREA_{exposed\text{-}ID}$ | 1800 | $m^2$ | D | |
| Depth of exposed soil | $DEPTH_{soil}$ | 0.1 | m | D | |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg_{wwt}.m^{-3}$ | D | |

**Output**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Local indirect emission of substance to soil from a campaign | $Elocal_{soil\text{-}ID\text{-}campaign}$ | **9.49E-02** | g | O | **$Elocal_{soil\text{-}ID\text{-}campaign}$** = $Q_{prod}$ * $Fc_{prod}$ * $N_{sites}$ * $N_{appl}$ * $F_{released\text{-}ID,soil}$ |
| **Concentrations** | | | | | |
| Local concentration in soil resulting from indirect exposure | $Clocal_{soil\text{-}ID}$ | **3.10E-04** | $mg.kgwwt^{-1}$ | O | **$Clocal_{soil\text{-}ID}$** = $Elocal_{soil\text{-}ID\text{-}campaign}$ * $10^3$ / ($AREA_{exposed\text{-}ID}$ * $DEPTH_{soil}$ * $RHO_{soil}$) |

*1) S: data set; D: default; O: output; P: pick list*

3. Exposure scenarios for bank slopes: rats (with default values):

| Input | | | | | |
|---|---|---|---|---|---|
| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
| Amount of product used at each application for one bait station/box | $Q_{prod}$ | 75 | g | S | |
| Fraction of substance in product | $Fc_{prod}$ | 0.000023 | [-] | S | |
| Number of application sites | $N_{sites}$ | 12 | [-] | D | |
| Number of applications | $N_{app}$ | 7 | [-] | D | |
| Fraction of substance released directly | $F_{released\text{-}D,water}$ | 0.4 | [-] | D | |
| **Additional parameters needed to calculate concentrations in water** | | | | | |
| Water volume of channel | $V_{channel}$ | 450000 | L | D | |

| Output | | | | | |
|---|---|---|---|---|---|
| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
| Local direct emission of substance to water | $Elocal_{water\text{-}D}$ | **5.80E-02** | g | O | **$Elocal_{water\text{-}D}$** = $Q_{prod}$ * $Fc_{prod}$ * $N_{app}$ * $N_{sites}$ * $F_{release\text{-}D,water}$ |
| Local concentration of substance in channel water | $Clocal_{water\text{-}D}$ | **1.29E-07** | $g.L^{-1}$ | O | **$Clocal_{water\text{-}D}$** = $Elocal_{water\text{-}D}$ / $V_{channel}$ |

*1) S: data set; D: default; O: output; P: pick list*

4) Exposure scenarios for in and around buildings: mice (with default values): Rodenticide emissions to soil due to use around buildings on unpaved ground

**Input**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Rodent to be controlled | | Mice | | | |
| Type of bait formulation | | Bagged baits, drinking through | | | |
| Amount of product used at each refill for one bait station/box | $Q_{prod}$ | 50 | g | S | |
| Fraction of substance in product | $Fc_{prod}$ | 0.000023 | [-] | S | |
| Number of application sites | $N_{sites}$ | 20 | [-] | D | |
| Number of applications (initial baiting+refillings) | $N_{appl}$ | 5 | | | |
| Fraction of substance released directly to soil | $F_{released-D,soil}$ | 0.01 | [-] | D | |
| Fraction of substance metabolised | $F_{metab}$ | 0 | [-] | S | |
| Fraction of substance released indirectly to soil | $F_{released-ID,soil}$ | | | | |
| a) no data on metabolism | | 0.9 | [-] | D | |
| b) data on metabolism present | | ?? | [-] | O | **$F_{released-ID,soil}$** = 0.9 * (1 - $F_{metab}$) |
| **Additional parameters needed to calculate concentrations in soil** | | | | | |
| Soil area exposed directly | $AREA_{exposed-D}$ | 0.09 | $m^2$ | D | |
| Soil area exposed indirectly | $AREA_{exposed-ID}$ | 550 | $m^2$ | D | |
| Depth of exposed soil | $DEPTH_{soil}$ | 0.1 | m | D | |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg_{wwt}.m^{-3}$ | D | |

**Output**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Local direct emission of substance to soil from a campaign | $Elocal_{soil-D-campaign}$ | 5.75E-05 | g | O | **$Elocal_{soil-D-campaign}$** = $Q_{prod}$ * $Fc_{prod}$ * $N_{appl}$ * $F_{released-D,soil}$ |
| Local indirect emission of substance to soil from a campaign | $Elocal_{soil-ID-campaign}$ | #WAARDE! | g | O | **$Elocal_{soil-ID-campaign}$** = $Q_{prod}$ * $Fc_{prod}$ * $N_{sites}$ * $N_{appl}$ * $F_{released-ID,soil}$ |
| **Concentrations** | | | | | |
| Local concentration in soil resulting from direct exposure | $Clocal_{soil-D}$ | 3.76E-03 | $mg.kgwwt^{-1}$ | O | **$Clocal_{soil-D}$** = $Elocal_{soil-D-campaign}$ * $10^3$ / ($AREA_{exposed-D}$ * $DEPTH_{soil}$ * $RHO_{soil}$) |
| Local concentration in soil resulting from indirect exposure | $Clocal_{soil-ID}$ | ?? | $mg.kgwwt^{-1}$ | O | **$Clocal_{soil-ID}$** = $Elocal_{soil-ID-campaign}$ * $10^3$ / ($AREA_{exposed-ID}$ * $DEPTH_{soil}$ * $RHO_{soil}$) |
| Total local concentration in soil resulting from direct plus indirect exposure | $Clocal_{soil}$ | ?? | $mg.kgwwt^{-1}$ | O | **$Clocal_{soil}$ = $Clocal_{soil-D}$ + $Clocal_{soil-ID}$** |

*1) S: data set; D: default; O: output; P: pick list*

5) Exposure scenarios for in and around buildings: mice (with default values): Rodenticide emissions to soil due to use in buildings and emissions to soil via rat carcasses, urine and faeces

**Input**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Type of bait formulation | | Solid baits, drinking through | | | |
| Amount of product used at each refill for one bait station/box (solid bait and drinking trough) /per building (contact formulation) | $Q_{prod}$ | 50 | g | S | |
| Fraction of substance in product | $Fc_{prod}$ | 0.000023 | [-] | S | |
| Number of application sites | $N_{sites}$ | 22 | [-] | D | |
| Number of applications (initial baiting+refillings) | $N_{appl}$ | 5 | [-] | D | |
| Fraction of active ingredient metabolised | $F_{metab}$ | 0 | [-] | S | |
| Fraction released indirectly to soil | $F_{released-ID,soil}$ | | | | |
| a) no data on metabolism | | 0.5 | [-] | S | |
| b) data on metabolism present | | 0.5 | [-] | O | **$F_{released-ID,soil}$** = 0.5 * (1 - $F_{metab}$) |
| **Additional parameters needed to calculate concentrations in soil** | | | | | |
| Soil area exposed indirectly | $AREA_{exposed-ID}$ | 1800 | $m^2$ | D | |
| Depth of exposed soil | $DEPTH_{soil}$ | 0.1 | m | D | |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg_{wwt}.m^{-3}$ | D | |

**Output**

| *Variable/parameter* | *Symbol* | *Value* | *Unit* | *S/D/O/P [1]* | *References / Calculation formulas / Explanations* |
|---|---|---|---|---|---|
| Local indirect emission of substance to soil from a campaign | $Elocal_{soil-ID-campaign}$ | 6.33E-02 | g | O | **$Elocal_{soil-ID-campaign}$** = $Q_{prod}$ * $Fc_{prod}$ * $N_{sites}$ * $N_{appl}$ * $F_{released-ID,soil}$ |
| **Concentrations** | | | | | |
| Local concentration in soil resulting from indirect exposure | $Clocal_{soil-ID}$ | 2.07E-04 | $mg.kgwwt^{-1}$ | O | **$Clocal_{soil-ID}$** = $Elocal_{soil-ID-campaign}$ * $10^3$ / ($AREA_{exposed-ID}$ * $DEPTH_{soil}$ * $RHO_{soil}$) |

*1) S: data set; D: default; O: output; P: pick list*

| Summary table on calculated PEC values | | | |
|---|---|---|---|
| **Scenario** | **$PEC_{soil}$** | **$PECIocal_{soil,porew}$** | **$PECIocal_{soil,porew}$** |
| | [$mg/kg_{wwt}$] | [mg/L] | [µg/L] |
| 1.a Rat control: around buildings | 5.64E-03 | 3.49E-05 | 0.03 |
| 1.a Rat control: in buildings | 3.10E-04 | 1.92E-06 | 0.00 |
| 1.b Mouse control: around buildings | 3.76E-03 | 2.33E-05 | 0.02 |
| 1.b Mouse control: in buildings | 2.07E-04 | 1.28E-06 | 0.00 |
| | $PEC_{water}$ | | |
| | [mg/L] | | |
| 3 Rat control: bank slope | 1.29E-04 | | |

**$PEC_{soil\ all}$** the PEC soil are lower than already calculated in the main text of the PAR because the applicant proposes a more frequent refill than the default. Thus no further calculations will be performed.

**$PECIocal_{water}$** : 3 Rat control: bank slope is worked out above in paragraph 2.16.