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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT related to renewal of authorisation**



FANGA B+ RONGEUR

Product type(s) [TP14]

Brodifacoum as included in the Union list of approved active substances

Case Number in R4BP: BC-MG041468-37

Evaluating Competent Authority: FR

Date : 13/02/2019

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Note to the reader:

**Disclaimer regarding general information**

This consolidated PAR for the renewal of the product authorisation FANGA B+ RONGEUR is based on the PAR of the first authorisation FANGA B+ RONGEUR granted by FR on 2016, in which all addenda have been included.

In part 1 and 2 of this consolidated PAR:

⁻ Each section contains the initial assessment and the subsequent successive assessments (major change and post authorisation data) in a chronological order. These assessments are pointed out with specific titles corresponding to the type of application and the year at which they were delivered.

⁻ The assessments related to the renewal of the product are indicated at the end of each section and are highlighted in grey.

In part 3 of the consolidated PAR “proposal for decision”: the summary of product characteristics corresponding to the decision for the renewal.

**Disclaimer regarding user category**

For the risk assessment of PT14, two user categories have been addressed depending on the quantity of manipulated product and the possibility of using PPE: non-professional users and professional users.

In France, any professional user needs a dedicated national certificate, hence it is expected that he/she has the required competence to access to biocidal products that are authorized for professional users they are thus considered as « trained professional users ».

Consequently, in the SPC for minor change in Part 3, uses for “professionals” are mentioned according to the agreed standard SPC, but they are not relevant in France. In case of mutual recognitions, it is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

1. **History of the dossier** (**updated PAR – 2018)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | FR |  | 12/02/2016 | Initial assessment  FANGA B+ RONGEUR |
| NA-ATT | FR |  | 29/01/2018 | Compliance of authorisation |
| NA-ADC | FR | BC-JG036315-50 | 16/03/2018 | Addition, suppression and modification of manufacturers sites of the product |
| NA-MIC | FR | BC-BK037984-32 | 20/08/2018 | Amendment of the authorisation :   * Reduction of use rates against rats. |
| NA-RNL | FR | BC-MG041468-37 | 12/02/2019 | Renewal of authorisation |

**Authorised uses for the minor change 2018 (0.0010% of brodifacoum)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | Rat *(Rattus norvegicus and rattus ratts)* | 100 g / bait point separated by 5-10 meters | In and around buildings  Open areas  Waste dumps and landfills | Individual sachets (PE )  And loose  Minimum pack size: 5 kg |
| Mice (*Mus musculus*) | 30-40 g / bait point separated by 1-2 meters |
| Non professionnals | Rat (*R*attus *norvegicus and rattus rattus*) | 100g / bait point separated by 5-10 meters | In and around buildings | Individual sachets PE  Maximum pack size: 150 g |
| Mice (*Mus musculus*) | 30-40 g / bait point separated by 1-2 meters | Indoor buildings |

**Intended uses for the renewal 2019 (0.0010 % of brodifacoum)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | Rat *(Rattus norvegicus and rattus ratts)* | 100 g / bait point separated by 5-10 meters | In and around buildings  Open areas  Waste dumps and landfills | Individual sachets (PE )  And loose  Minimum pack size: 5 kg |
| Mice (*Mus musculus*) | 30-40 g / bait point separated by 1-2 meters |
| Non professionals | Rat (*R*attus *norvegicus and rattus rattus*) | 100 g / bait point separated by 5-10 meters | In and around buildings | Individual sachets PE  Maximum pack size: 150 g |
| Mice (*Mus musculus*) | 30-40 g / bait point separated by 1-2 meters | Indoor buildings |

# General information about the product application

## Applicant

|  |  |  |
| --- | --- | --- |
| Company Name: | **TRIPLAN** : | **TRIPLAN-** BUREAU DE LIAISON FRANCE |
| Address: | BP258 La Poste Française | 1, place Saint-Silain |
| City: | Andorre la Vieille | Périgueux |
| Postal Code: | AD500 | 24000 |
| Country: | Principauté d’Andorre | FRANCE |
| Telephone: | +376741 454 | +376 741 454 |
| Fax: |  |  |
| E-mail address: | [triplan@andorra.ad](mailto:triplan@andorra.ad) | [triplan@andorra.ad](mailto:triplan@andorra.ad) |

### Person authorised for communication on behalf of the applicant

|  |  |
| --- | --- |
| **Name:** | Fredy Lacroux |
| **Function:** | Managing director |
| **Address:** | BP258 La Poste Française |
| **City:** | Andorre la Vieille |
| **Postal Code:** | AD500 |
| **Country:** | Principauté d’Andorre |
| **Telephone:** | +376741 445 |
| **Fax:** | +376 741 450 |
| **E-mail address:** | [triplan@andorra.ad](mailto:triplan@andorra.ad) |

## Proposed authorisation holder

|  |  |  |
| --- | --- | --- |
| Company Name: | **TRIPLAN** : | **TRIPLAN-** BUREAU DE LIAISON FRANCE |
| Address: | BP258 La Poste Française | 1, place Saint-Silain |
| City: | Andorre la Vieille | Périgueux |
| Postal Code: | AD500 | 24000 |
| Country: | Principauté d’Andorre | FRANCE |
| Telephone: | +376741 454 | +376 741 454 |
| Fax: |  |  |
| E-mail address: | [triplan@andorra.ad](mailto:triplan@andorra.ad) | [triplan@andorra.ad](mailto:triplan@andorra.ad) |
| Letter of appointment for the applicant to represent the authorisation holder provided (yes/no): | NO | |

## Information about the product application

|  |  |
| --- | --- |
| Application received: | 01/07/2014 |
| Application reported complete: | 26/08 2014 |
| Type of application: | National authorisation |
| Further information: | NO |

## Information about the biocidal product

### General information

|  |  |
| --- | --- |
| Trade name: | FANGA B+ RONGEUR |
| Manufacturer’s development code number(s), if appropriate: |  |
| Product type: | TP14, Rodenticide |
| Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex): | Brodifacoum 0.001% w/w |
| Formulation type: | Cereal grains (wheat) |
| Ready to use product (yes/no): | Bait ready for use (RB) |
| Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no);  If yes: authorisation/registration no. and product name:  or  Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no): | YES  FANGA RONGEUR PRO : |

### Information on the intended use(s)

|  |  |
| --- | --- |
| Overall use pattern (manner and area of use): | Rodenticide against wild mice, brown rats and black rats.  In and around buildings and open areas by professional and non-professional users.  In waste dumps and landfills by professional users.  Baits are placed in bait boxes or in secured bait stations. |
| Target organisms: | Scientific name: *Rattus rattus*, common name: roof rat (syn.), development stage: adults/juveniles  Scientific name: *Rattus norvegicus*, common name: brown rat, development stage: adults/juveniles  Scientific name: *Mus musculus*, common name: house mouse, development stage: adults/juveniles |
| Category of users: | Professional and non-professional users |
| Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area: | **Professionals:**   * Rat : 180-200 g of product / bait station; 5 to 10 meters between bait stations. * Mice: 40 g of product / bait station; 1 to 2 meters between bait stations.   **Non professional**   * Rat: 180-200 g per bait station 5 -10m/bait station. 4 bait stations * Mice: 40 g per bait station 1-2m/bait station.4 bait stations   Do not open the sachet. The number of sachets per bait stations must be adapted to the effective dose. Respect the distance between 2 bait stations.  The number of bait stations is function of the area of treatment and the infestation rate.  Distances between bait stations must be respected.  Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.  The biocidal effect appears between 4 and 9 days after ingestion of the baits |
| Potential for release into the environment (yes/no): | Yes |
| Potential for contamination of food/feedingstuff (yes/no) | Yes |
| Proposed Label: | Yes |
| Use Restrictions: |  |

For full details of the intended uses claimed by the applicant, please see Annex 0a.

* **Minor change application – 2018:**

|  |  |
| --- | --- |
| Overall use pattern (manner and area of use): | Rodenticide against wild mice, brown rats and black rats.  In and around buildings and open areas by professional and in buildings for mice and in and around buildings for rats by non-professional users.  In waste dumps and landfills by professional users.  Baits are placed in bait boxes or in secured bait stations. |
| Target organisms: | Scientific name: *Rattus rattus*, common name: roof rat (syn.), development stage: adults/juveniles  Scientific name: *Rattus norvegicus*, common name: brown rat, development stage: adults/juveniles  Scientific name: *Mus musculus*, common name: house mouse, development stage: adults/juveniles |
| Category of users: | Professional and non-professional users |
| Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area: | **Professionals:**   * Rat: 100 g of product / bait station; 5 to 10 meters between bait stations. * Mice: 30 - 40 g of product / bait station; 1 to 2 meters between bait stations.   **Non professional**   * Rat: 100 g per bait station 5 -10m/bait station. * Mice: 30 - 40 g per bait station 1-2m/bait station.   Do not open the sachet. The number of sachets per bait stations must be adapted to the effective dose. Respect the distance between 2 bait stations.  The number of bait stations is function of the area of treatment and the infestation rate.  Distances between bait stations must be respected.  Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.  The biocidal effect appears between 4 and 9 days after ingestion of the baits |
| Potential for release into the environment (yes/no): | Yes |
| Potential for contamination of food/feedingstuff (yes/no) | Yes |
| Proposed Label: | Yes |
| Use Restrictions: |  |

* **Renewal application – 2019:**

|  |  |
| --- | --- |
| Overall use pattern (manner and area of use): | Rodenticide against wild mice, brown rats and black rats.  In and around buildings and open areas by professional for mice and rats, in buildings for mice and in and around buildings for rats by non-professional users.  In waste dumps and landfills by professional users.  Baits are placed in bait boxes or in secured bait stations. |
| Target organisms: | Scientific name: *Rattus rattus*, common name: roof rat (syn.), development stage: adults/juveniles  Scientific name: *Rattus norvegicus*, common name: brown rat, development stage: adults/juveniles  Scientific name: *Mus musculus*, common name: house mouse, development stage: adults/juveniles |
| Category of users: | Professional and non-professional users |
| Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area: | **Professionals:**   * Rat: 100 g of product / bait station; 5 to 10 meters between bait stations. * Mice: 30 - 40 g of product / bait station; 1 to 2 meters between bait stations.   **Non professional**   * Rat: 100 g per bait station 5 -10m/bait station. * Mice: 30 - 40 g per bait station 1-2m/bait station.   Do not open the sachet. The number of sachets per bait stations must be adapted to the effective dose. Respect the distance between 2 bait stations.  The number of bait stations is function of the area of treatment and the infestation rate.  Distances between bait stations must be respected.  Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed.  The biocidal effect appears between 4 and 9 days after ingestion of the baits |
| Potential for release into the environment (yes/no): | Yes |
| Potential for contamination of food/feedingstuff (yes/no) | Yes |
| Proposed Label: | Yes |
| Use Restrictions: |  |

### Information on active substance

|  |  |  |
| --- | --- | --- |
| Active substance chemical name: | Brodifacoum |  |
| CAS No: | 56073-10-0 |  |
| EC No: | 259-980-5 |  |
| Purity (minimum, g/kg or g/l): | 950 g/kg |  |
| Inclusion directive: | 2010/10/UE |  |
| Date of inclusion: | 9 February 2010 |  |
| Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no): | yes |  |
| Manufacturer of active substance(s) used in the biocidal product: |  | |
| Company Name: | PM TEZZA SRL | ACTIVA/PM TEZZA SRL |
| Address: | Via Tre Ponti 22 | Via Feltre 32 |
| City: | S. Maria di Zevio (VR) | Milan |
| Postal Code: | 37050 | 20132 |
| Country: | Italy | Italy |
| Telephone: | +39 02 70 63 73 01 |  |
| Fax: |  | Fax: 0039 02-70637228 |
| E-mail address: | [sara.lodini@activa.it](mailto:sara.lodini@activa.it) | [sara.lodini@activa.it](mailto:sara.lodini@activa.it) |

* **Renewal application – 2019**

**COMPARATIVE ASSESSMENT**

Brodifacoum does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012. Brodifacoum does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for substitution.

A comparative assessment has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council. 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.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

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

There is no substance of concern.

* **Renewal application - 2019**

According to the Guidance on the BPR Volume III Human Health – Part B Risk Assessment[[1]](#footnote-1), FANGA B+ RONGEUR contains two substances of concern. Indeed, the product contains two substances with IOELV: monopropylene glycol (10 mg/m3) and triethanolamine (1 mg/m3). In accordance with the ECHA Vol III Part B + C guidance document, these substances should be considered as substances of concern and risk assessments are required.

### Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products

* **Renewal application - 2019**

According to our assessment, none of the co-formulants contained in the product FANGA B+ RONGEUR are identified as endocrine disruptors.

Please refer to Confidential Annex.

## Documentation

### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product FANGA B+ RONGEUR and FANGA RONGEUR PRO were provided by Triplan. Read across is acceptable (see confidential part).

A letter of access has been provided by Activa to Triplan for physico-chemical properties studies and analytical methods on the active substance.

* **Renewal application - 2019**

Physico-chemical properties studies and analytical methods on the biocidal product FANGA B+ RONGEUR and FANGA RONGEUR PRO were provided by Triplan. Read across is acceptable (See confidential Part).

Some studies (theorical assessment for oxidising and explosive properties) have been provided with formulation FANGA RAT-DICAL TECH. Read across is acceptable (See confidential Part).

For the renewal of the authorization, no additional data was submitted for the physico-chemical properties section.

**Efficacy data**

The following efficacy studies were submitted:

* A free-choice laboratory test was carried out with mice (***Mus musculus*** wild strain), with exposure to 15 months aged **FANGA B+ RONGEUR** (0.001 % brodifacoum) for 4 days.
* A free-choice laboratory test was carried out with rats (***Rattus norvegicus*** wild strain), with exposure to 15 month aged **FANGA B+ RONGEUR** (0.001 % brodifacoum) for 4 days.
* A free-choice laboratory test was carried out with rats (*Rattus rattus* wild strain), with exposure to 3 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum) for 4 days.
* A field test was carried out with mice (*Mus musculus*), with exposure to 2 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).
* A field test was carried out with rats (*Rattus norvegicus*), with exposure to 3 years aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).
* A field test was carried out with rats (*Rattus rattus*), with exposure to 27 months aged **FANGA B+ RONGEUR** (0.001 % brodifacoum).
* **Minor change application – 2018:**
* A field test was carried out with black rats (*Rattus rattus*), with exposure to a 59 months aged formulation of **FANGA B+ RONGEUR** (0.001 % w/w brodifacoum).
* A field test was carried out with brown rats (*Rattus norvegicus*), with exposure to a 58 months aged formulation **FANGA B+ RONGEUR** (0.001 % w/w brodifacoum).
* **Renewal application– 2019:**
* A field test was carried out with mice (*Mus musculus*), with exposure to a 53 months aged formulation of **FANGA B+ RONGEUR** (0.001 % w/w brodifacoum).

**Toxicology data**

The applicant submitted new toxicological data on active substance and studies for the product (see corresponding sections). A new percutaneous absorption study (*in vitro*) has been submitted by TRIPLAN for difenacoum and results were extrapolated to brodifacoum.

**Residue data**

No new study has been submitted for the biocidal product authorisation.

**Ecotoxicology data**

No new study has been submitted for the biocidal product authorisation.

### Access to documentation

As stated in the letter of access granted by Activa to Triplan:

*Activa S.r.l, (via Feltre 32, Milano-ltaly), as Notifier and having rights on all the data included in the Dossier for Brodifacoum (CAS No: 56073-10-0) presented by The Activa/Pelgar Brodifacoum and Difenacoum Task Force (composed by: Activa/Tezza S.r.l and Pelgar International Ltd) for Annex I listing to RMS ltaly* ***authorises*** *the France competent authorities to use these data for authorisation purpose TRIPLAN (BP 258 Poste Francaise - AD500 Andorre la Vieille - PRINCIPAT D'ANDORRA) for the product* ***FANGA B+ RONGEUR*** *(PT14).*

Please refer to the Letter of access for the complete list of studies for which access has been granted.

* **Renewal application - 2019**

For the renewal of the authorization, a LOA (02/2018) has been submitted by Activa to TRIPLAN.

# Summary of the product assessment

The product is to be used in tamper-resistant bait boxes or covered bait stations.

”Tamper-resistant bait boxes” are meant to be tamper-resistant devices, that prevent the access to the baits for children and non-target animals, and that protect the baits from bad weather.

”Covered bait stations” are meant to be devices with the same level of security for the human beings and the environment than the security provided by tamper-resistant bait boxes, fastened to prevent any removal, made in order to avoid direct contact of the bait with the environment. This device must be designed to keep baits out of reach of the general public and non-target animals, and to protect the bait from bad weather.

It is considered that professional users only (on the contrary to the general public) are able to design such covered bait stations.

## Identity related issues

The source of the active substance used in the biocidal product FANGA B+ RONGEUR is ACTIVA, source not used for annex I inclusion. According to the combined CAR (2010),the technical equivalence between Pelgar source and Activa source has been performed and accepted by Italy in August 2013 by IT. Therefore the source ACTIVA used for the biocidal product FANGA B+ RONGEUR is accepted. Refer to the confidential annex for more details.

## Classification, labelling and packaging

### Harmonised classification of the active substance

|  |  |  |
| --- | --- | --- |
| **Classification - Regulation (EC) 1272/2008** | | |
| Hazard statement | Acute Tox. 1 | |
| Acute Tox. 2 | |
| STOT RE 1 | |
| Aquatic Acute 1 | |
| Aquatic Chronic 1 | |
| Precautionary statements | H310 | Fatal in contact with skin. |
| H300 | Fatal if swallowed. |
| H372 | Causes damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |

### Classification of the biocidal product

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | |
| Hazard statement | None |
| Precautionary statements | None |

### Labelling of the biocidal product

|  |  |
| --- | --- |
| **Labelling - Regulation (EC) 1272/2008** | |
| Pictograms: | None |
| Signal words: | None |
| Hazard statements: | None |

* **Renewal application - 2019**

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | |
| Hazard category | - |
| Hazard statements | - |
| Labelling | - |
| Signal words | - |
| Hazard statements | - |
| Precautionnary statements | - |
|  |  |
| Note | - |

### Packaging of the biocidal product

For professional users:

* sachet in PE (20-25-30-40-50-100 g) and packed in bag in paper with or without PE liner ( 5-10-15-20-25 kg) or in PE bucket (5-10-15-18-20 kg) or carton box ( 5-10-12-15-20-50 kg)
* In loose in PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)
* In loose in paper bag with or without PE liner (5-10-15-20-25 kg)
* In loose in PE bucket (5-10-15-18-20-25 kg)
* In loose in carton box with a PE bag inside ( 5-10-12-15-20-25-50 kg)

For non-professional users:

* 20-25-30-40-50-100 g sachets in PE and packed in PE bucket or carton box or metal box without lacquer or HDPE containers (0.1; 0.2; 0.3; 0.4; 0.5; 0.6; 0.7; 0.8; 0.9; 1.0; 1.2; 1.3; 1.4; 1.5 kg) or in bait box in PET/PP/PE/PVC with a capacity of 135cm3 and 235 cm3 .
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For professional users:

FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.

PE/PP sachet (20-25-30-40-50-100 g) are packed in:

- Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg

- Bucket (PE) 5-10-15-18-20kg

- Cardboard box 5-10-12-15-20-50kg

Loose baits are packed in:

- PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)

- bag (paper bags with or without PE film) 5-10-15-20-25kg

- Bucket (PE) 5-10-15-18-20-25kg

- Cardboard box (with a PE film) 5-10-12-15-20-25-50kg

For non-professional users:

FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g).

PE/PP sachet (20-25-30-40-50-100 g) are packed in:

- Bucket (PE)

- Metal box without lacquer

- HDPE container

- Cardboard box

- Bait box (plastic PET/PP/PE/PVC)

## Physico/chemical properties and analytical methods

### Active ingredient

### Identity, origin of active ingredient

The source of the active substance used in the biocidal product FANGA B+ RONGEUR is ACTIVA, source not used for annex I inclusion. According to the combined CAR (2010), the technical equivalence between Pelgar source and Activa source has been performed and accepted by Italy in August 2013 by IT. Therefore the source Activa used for the biocidal product FANGA B+ RONGEUR is accepted. Refer to the confidential annex for more details.

A letter of access to brodifacoum data from Activa has been provided.

#### Physico-chemical properties

Physical and chemical properties of the active substance have already been evaluated at EU level and are presented in the CAR of the active substance brodifacoum (2010). The applicant TRIPLAN has a letter of access to these data.

Source CAR 2010 (Document I):

Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C.

Brodifacoum is non-volatile, with a Henry’s Law Constant value of 2.35E-18 Pa.m3.mol-1. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4-hydroxycoumarin group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log Pow was found to be 4.92 at pH 7 and 20°C. As expected, Log Pow decreased with higher temperature and pH.

Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

#### Analytical method for determination of active ingredient and impurities in the technical active ingredient

Analytical method for the determination of pure active substance brodifacoum in the technical active substance as manufactured has already been performed and validated at EU level in the CAR of brodifacoum (2010). The applicant TRIPLAN has a letter of access to these data.

Summary: (source AR November 2010)

|  |  |
| --- | --- |
|  | **Principle of method** |
| Technical active substance as manufactured: | Brodifacoum is analysed in the technical material by reversed-phased HPLC/UV (254nm)  Purity : 96.2-99.4% w/w (mean: 98.1 % w/w) |

#### Analytical method for determining relevant components and/or residues in different matrices

Analytical methods for the determination of residues of the active substance brodifacoum in the different matrices (plants, soil, drinking, ground and surface water, human and animal body fluids and tissues) have already been performed and validated at EU level in the CAR of brodifacoum (2010). No method in air is required since the active substance is non-volatile.

Analytical methods are presented in Annex of this document.

The applicant TRIPLAN has a letter of access to these data.

### Biocidal product

#### Identity, composition of the biocidal product, packaging

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex 1 of directive 98/8/EC.

|  |  |  |
| --- | --- | --- |
| Trade name | FANGA RONGEUR B+ | |
| Ingredient of preparation | Function | Content |
| brodifacoum (CAS No.56073-10-0) | Active substance | 0.01g/kg (0.001%w/w) |
| Formulants | Details on the composition of the product are included in the Confidential part | |
| Physical state of preparation | solid | |
| Nature of the preparation | Grain bait (wheat) | |

The composition of the product is confidential and is presented in a confidential annex. The product contains 0.001% w/w of pure active substance brodifacoum.

#### Physico-chemical properties

The tested product is FANGA B+ RONGEUR. Some properties have already been described for FANGA RAT-DICAL TECH or for FANGA RONGEUR PRO. Read across of the two compositions allow to accept this justification.

Table 2.3.3.2‑1: Physico-chemical properties of the biocidal product

| **Properties** | **Method** | **Purity/ Specification** | **Results** | **Reference** | | **Acceptable Yes/no** |
| --- | --- | --- | --- | --- | --- | --- |
| **B3 – Physical, chemical and technical properties** | | | | | | |
| **B3.1 Appearance** | | | | | | |
| **B3.1.1 – Physical state and nature**  **B3.1.2 – Colour**  **B3.1.3 – Odour** | Visual examination  Organoleptic determination | FANGA RONGEUR B+  0.00854g/kg brodifacoum  Batch 25/11 | Intact transparent plastic bags containing 50 g of wheat grains, dust free.  Blue/green  Slight odour of grain | CRA-W Study n° 22718[[2]](#footnote-2) | **Acceptable** | |
| **B3.2 Acidity/alkalinity** | | | | | | |
| **pH 1% dilution** | CIPAC MT 75.3 | FANGA RONGEUR PRO  0.049 g/kg  Brodifacoum  Batch 22/11 | The pH mean value of the test item at 1% m/v in standard water D is:  6.46 at 21.4 °C after 1 min.  6.46 at 21.4°C after 2 min.  The pH of the test item being higher than 4 and lower than 10, CIPAC MT 191 the test was not performed. | 11-920010-25[[3]](#footnote-3) | | **Acceptable. Read accross is acceptable.** |
| **B3.3 Relative density and bulk, tap density** | | | | | | |
| **Relative density** | CIPAC MT 186  CIPAC Handbook K (2003) | FANGA RONGEUR PRO  0.049 g/kg  Brodifacoum  Batch 22/11 | The mean pour density of the test item was 0.731 ± 0.002 g/mL.  The mean tap density of the test item was 0.765 ± 0.002g/mL. | 11-920010-024 | | **Acceptable. Read accross is acceptable** |
| **B3.4 Storage stability, stability and shelf-life** | | | | | | |
| **B3.4.1 Storage stability tests** | | | | | | |
| **B3.4.1.1 – Accelerated storage study (2 weeks at 54°C)** | Storage stability of FANGA B+ RONGEUR for 14 days at 54°C ± 2°C  CIPAC MT 46.3 | FANGA RONGEUR B+  0.00854g/kg brodifacoum  Batch 25/11 | **Aspect**  *Before* the accelerated storage procedure for 14 days at 54±2°C:  Blue/green/wheat grains in intact transparent plastic bag (PE) Slight odour of grain.  Polypropylene bucket of 1 kg closed with a green PE lid to clip. Ø :± 22 cm, h : ± 14.5 cm.  Well closed bucket without deterioration or special anomaly.  No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package.  Weight bag: 955.6g  *After* the accelerated storage procedure for 14 days at 54±2°C:  Blue/green wheat grains in intact transparent plastic bag (PE).  Polypropylene bucket of 1 kg closed with a green PE lid to clip. Ø :± 22 cm, h : ± 14.5 cm.  Well closed bucket without deterioration or special anomaly.  No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening of the package.  Weight bag: 948.5g  **DW=-0.7%**  **Conclusion**: No modification of the appearance or no significant pack weight change after an accelerated storage procedure for 14 days at 54 ±2 °C. | 22718-First Interim Report | | **Acceptable. Packaging is stable after accelerated storage in PP packaging.** |
|  | HPLC Defitraces Report n°11-920010-027 AMD | FANGA RONGEUR B+  0.00854g/kg brodifacoum  Batch 25/11 | **Analytical quantification of brodifacoum**  Before the accelerated storage procedure for 14 days at 54±2°C:  The content of brodifacoum was 0.000854 ± 0.000040% w/w. (mean of 3 determinations, RSD (1.88%)< Horwitz value (7.76%))  After the accelerated storage procedure for 14 days at 54±2°C:  The content of brodifacoum was 0.000779 ± 0.000067% w/w. (mean of 3 determinations, RSD (3.48%) < Horwitz value (7.87%))  A significant changewas observed in the content of brodifacoum in FANGA B+ RONGEUR(-8.8% deviation from T = 0 value) after the accelerated storageprocedure for 14 days at 54 ± 2 °C.  The applicant states: FANGA B+ RONGEUR is a grain bait essentialy made of cereal. Content of active substance brodifacoum in the product is very low (0.01g/kg, 10ppm). The product is considered heterogeneous and variations of active substance content (>5%) cannot be explained as a degradation since in the 2 years shelf life study it has been demonstrated that the variation is not linear. | 22718-First Interim Report | | **Acceptable**  **Variation of brodifacoum: -8.8% (limit 5%)**  **Variations can be due to the heterogeneity of the product and to the adsorption of the a.i on the grain.**  **The method used for the determination of brodifacoum is validated.** |
|  | MT 59.4 method (1995) | FANGA RONGEUR PRO  Bodifacoum  0.049 g/kg  Batch 22/11 | Before the accelerated storage procedure (storage 8 weeks at 40°C):   |  |  | | --- | --- | | **Test sieve** | **Mass of residue (g)** | | **250µm** | **100.0** | | **125µm** | **<0.1** | | **Collecting pan** | **<0.1** |   The dust content was lower than 0.1%.   |  |  | | --- | --- | | **Test sieves** | **% or residue** | | **5.6mm** | **<0.1** | | **4.0mm** | **1.4** | | **2.8mm** | **90.2** | | **2.0mm** | **7.8** | | **Collectin pan** | **0.6** |   The majority of the particles (90.2%) of the test item were between 2 mm and 2.8 mm.  After the accelerated storage procedure   |  |  | | --- | --- | | **Test sieve** | **Mass of residue (g)** | | **250µm** | **100.0** | | **125µm** | **<0.1** | | **Collecting pan** | **<0.1** |   The dust content was lower than 0.1%.   |  |  | | --- | --- | | **Test sieves** | **% or residue** | | **5.6mm** | **<0.1** | | **4.0mm** | **0.8** | | **2.8mm** | **89.4** | | **9.5** | **7.8** | | **Collectin pan** | **0.8** |   The majority of the particles (90.2%) of the test item were between 2 mm and 2.8 mm. | 12-920010.008 | | **Read across is acceptable.** |
|  | Method CIPAC MT 78 | BDB10V1 (FANGA B+ RONGEUR), batch 01/15 | Appearance before and after accelerated storage 14 days at 54°C: blue/green grains of wheat, white opaque PP bucket (no significant change)  Attrition beefore and after accelerated storage 14 days at 54°C: 100% | 15-920010-003 | | **Acceptable** |
| **B3.4.1.2 –** **Ambient shelf life study** | CropLife No 17 | FANGA RONGEUR B+  0.00854g/kg brodifacoum  Batch 25/11 | *Before storage:*  Intact transparent PE bags containing 50g of grains, dust free  Colour: blue green  Odour: slight odour of grain  *After* the procedure of storage for:  2 years:  No change in the appearance of the packaging (primary packaging: PE bag containing 50g of grains / secondary packaging: PP bucket of 1kg).  Colour: blue green  Odour: slight odour of grain | 22718-Final Report [[4]](#footnote-4) | | **Acceptable. The product is stable in PE bags.** |
|  | HPLC Defitraces Report n°11-920010-027 AMD | FANGA RONGEUR B+  0.00854g/kg brodifacoum  Batch 25/11 | **Quantitative analysis of Brodifacoum**  Initial active substance content: 8.54± 0.4% w/w.  *After* the procedure of storage for 16 months:  Active substance content: 8.55 ± 0.23 mg/kg  Difference : **+ 0.1%**  After the procedure of storage for 2 years:  Active substance content: 6.16 ± 1.01 mg/kg  Difference : **- 27.8%**  **Conclusion:** No change in the appearance and in the mass oft he packaging after 2 years of stiorage**.**  Significant change in the active ingredient after 2 years of storage  The applicant states: FANGA B+ RONGEUR is a grain bait essentialy made of cereal. Content of active substance brodifacoum in the product is very low (0.01g/kg, 10ppm). The product is considered heterogeneous and variations of active substance content (>5%) cannot be explained as a degradation since variations of active substance brodifacoum with time were not linear. Therefore for this product, it can be assumed that the variations are not related to a degradation of the active substance.   |  |  |  |  | | --- | --- | --- | --- | | Product tested | determination T1 | determination T2 | determination T3 | | FANGA B+ rongeur  (cereal :wheat) | 14 days | 16 months | 24 months | | -8,8% | +0,1% | -27,8% | | 22718-Final Report | | **Acceptable. The variations of active substance content can be due to the heterogeneity of the product and to the adsoprtion of the a.i on the grain.** |
| **B3.4.1.3 – Low temperatures stability test (liquids)** |  |  | Not applicable |  | | **Not applicable** |
| **B3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product** | | | | | | |
| **B3.4.2.1 – Light** | - | - | No data provided. The active substance is sensitive to light (DT50: photolysis in water <1 day). Nevertheless, according to the label it is recommended to store the product away from light. |  | | **The product must be stored away from light.** |
| **B3.4.2.2 – Temperature and humidity** | - | - |  | |
| **B3.4.2.3 – Reactivity towards container material** | - | - |  | |
| **B3.5 Technical characteristics of the biocidal product** | | | | | | |
| **B3.5.1 – Wettability** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.2 – Suspensibility, spontaneity and dispersion stability** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.3 – Wet sieve analysis and dry sieve test** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.4 – Emulsifiability, re-emulsifiability and emulsion stability** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.5 – Disintegration time** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.6 – Particle size distribution, content of dust/ fines attrition, friability** | CIPAC MT 171 (1995) | FANGA RONGEUR PRO  Bodifacoum  0.049 g/kg  Batch 22/11 | **Dustiness**  Mass of the test item: 30.0g  Gravimetric collected dust: 0.5mg (two essays)  The category of the test item was: 1 (nearly dust-free). | 12-920010-008[[5]](#footnote-5) | | **Acceptable. The product is nearly dust free. Read across is acceptable.** |
| CIPAC MT 59.4 (1994) | FANGA RONGEUR PRO  Bodifacoum  0.049 g/kg  Batch 22/11 | **Sieve test**   |  |  | | --- | --- | | **Test sieve** | **Mass of residue (g)** | | **250µm** | **100.0** | | **125µm** | **<0.1** | | **Collecting pan** | **<0.1** |   The dust content was lower than 0.1%.   |  |  | | --- | --- | | **Test sieves** | **% or residue** | | **5.6mm** | **<0.1** | | **4.0mm** | **1.4** | | **2.8mm** | **90.2** | | **2.0mm** | **7.8** | | **Collectin pan** | **0.6** |   The majority of the particles (90.2%) of the test item were between 2 mm and 2.8 mm. | 12-920010-008 | | **Read across is acceptable.** |
| CIPAC MT 59.4(1994) |  | **Dust content**  The dust content of the test item was lower than 0.1% | 11-920010-008 | | **Read across is acceptable.** |
|  | Method CIPAC MT 78 | BDB10V1 (FANGA B+ RONGEUR), batch 01/15 | Attriton  Before and after accelerated storage 14 days at 54°C: 100% | 15-920010-003 | | **Acceptable** |
| **B3.5.7 – Persistent foaming** | - | - | Not applicable |  | | **Not applicable** |
| **B3.5.8 – Flowability/ Pourability/ Dustability** | - | - | Not applicable |  | | **Not required since the product is ready to use and not sold as loose bait** |
| **B3.5.9 – Burning rate – smoke generators** | - | - | Not applicable | - | | **Not applicable** |
| **B3.5.10 – Burning completeness – smoke generators** | - | - | Not applicable | - | | **Not applicable** |
| **B3.5.11 – Composition of smoke – smoke generator** | - | - | Not applicable | - | | **Not applicable** |
| **B3.5.12 –Spraying pattern - aerosols** | - | - | Not applicable | - | | **Not applicable** |
| **B3.5.13 – Other technical characteristics** | - | - | Not applicable | - | | **Not applicable** |
| **B3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised** | | | | | | |
| **B3.6.1 – Physical compatibility** | - | - | The biocidal product is not applied with other products. | - | | **Not applicable** |
| **B3.6.1 –Chemical compatibility** | - | - | The biocidal product is not applied with other products. | - | | **Not applicable** |
| **B3.7 Degree of dissolution and dilution stability** | | | | | | |
| **Dilution stability** | - | - | Not applicable | - | | **Not applicable** |
| **B3.8 Surface tension** | | | | | | |
| **Surface tension** | - | - | Not applicable | - | | **Not applicable** |
| **B3.9 Viscosity** | | | | | | |
| **Viscosity** | - | - | Not applicable | - | | **Not applicable** |
| **B4 – Physical hazards and respective characteristics** | | | | | | |
| **B4.1 – Explosives** | Differential Scanning Calorimetry method (DSC)  Literature survey on explosive and oxidizing properties of the ingredients of the product FANGA RAT-DICAL-TECH | FANGA RONGEUR PRO  0.049 g/kg  Brodifacoum  Batch 22/11  FANGA RAT DICAL TECH | During the first phase, one strong exothermic peak at 249.5 °C with an enthalpy difference of 487.7 J/g which is lower than the limit enthalpy difference of 500 J/g indicated in the Regulation (EC) N°. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.  During the third phase, neither endothermic nor exothermic peak was observed up to 500 °C under the experimental conditions used.  This thermodynamic information allows knowing that a test on explosive properties with EC A14 method should not be required.  Based on most recent approach of structural formulas, no components are classified as explosive or have low explosive limits in air. However due to very low content of these substances in the product FANGA RAT-DICAL TECH (< 2.5% total) these substances are not considered as being able to lead to a classification of the product.  In addition, The DSC graph shows an exothermic effect with decomposition energy lower than 500 J/g which confirms that the product FANGA RONGEUR PRO and consequently FANGA B+ RONGEUR are not likely to be explosive. | 11-920010-024[[6]](#footnote-6) | | **Acceptable. The product is not explosive**. **Read across is acceptable.** |
| **B4.2 – Flammable gases** | - | - | Not applicable | - | | **Not applicable** |
| **B4.3 – Flammable aerosols** | - | - | Not applicable | - | | **Not applicable** |
| **B4.4 – Oxidising gases** | - | - | Not applicable | - | | **Not applicable** |
| **B4.5 – Gases under pressure** | - | - | Not applicable | - | | **Not applicable** |
| **B4.6 – Flammable liquids** | - | - | Not applicable | - | | **Not applicable** |
| **B4.7 – Flammable solids** | EC A10(2008) | FANGA RONGEUR PRO  0.049 g/kg  Brodifacoum  Batch 22/11 | Preliminary test:  Results of assays 1 and 2: The test item ignited and reddened at the contact of the burner’s flame but no propagation of the flame was observed.  Main test: Taking into account the results obtained during the preliminary test, no main test was performed.  The test item was not considered as flammable under the conditions of the test. | 11-920010-024 | | **Acceptable. The product is not highly flammable; Read accross is acceptable.** |
| **B4.8 – Self-reactive substances and mixtures** | - | - | The product does not contain self-reactive substances. | - | | **Not applicable** |
| **B4.9 – Pyrophoric liquids** | - | - | Not applicable | - | | **Not applicable** |
| **B4.10 – Pyrophoric solids** | - | - | Not applicable | - | | **Not applicable** |
| **B4.11 – Self heating substances and mixtures** | EC A16 (2008) | FANGA RONGEUR PRO  0.049 g/kg  Brodifacoum  Batch 22/11 | No self ignition temperature of the test item was observed up to 400 °C (corrected value). | 11-920010-024 | | **Acceptable. The product is not auto-flammable. Read accross is acceptable.** |
| **B4.12 – Substances and mixtures which in contact with water emit flammable** | - | - | Not applicable | - | | **Not applicable** |
| **B4.13 – Oxidising liquids** |  |  | Not applicable | - | | **Not applicable** |
| **B4.14 – Oxidising solids** | Literature survey on explosive and oxidizing properties of the ingredients of the product FANGA RAT-DICAL TECH | FANGA RAT DICAL TECH | Based on most recent approach of structural formulas, the components have no potential for oxidising properties.  Accordingly, the product FANGA B+ RONGEUR is not expected to present a significant hasard and testing is considered as unnecessary. | 11-920010-028 | | **Acceptable**  **Justification for non oxidizing properties have already been provided for the product FANGA RAT-DICAL TECH. Read accross of the two compositions allows to accept this justification.** |
| **B4.15 – Organic peroxides** |  |  | Not applicable | - | | **Not applicable** |
| **B4.16 – Corrosive to metals** |  |  | Not applicable | - | | **Not applicable** |
| **B4.17 Additionnal physical indications of hazard** | | | | | | |

**Conclusion:**

The product

FANGA B+ RONGEUR is a cereal bait ready-to-use rodenticide.

Considering the small changes of composition and the non-physico-chemical classification of formulants, physico-chemical properties of FANGA RONGEUR PRO can be extrapolated to FANGA B+RONGEUR.

FANGA B+ RONGEUR is not flammable, not autoflammable up to 400°C, has no explosive properties and no oxidizing properties. It is not dusty (nearly dust free).

No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 14 days at 54 ±2 °C and 2 years at ambient temperature in PE sachets. A significant change was observed in the content of Brodifacoum in FANGA B+ RONGEUR (-27.8 % deviation from T=0 value) after 2 years of storage. Nevertheless, it has been demonstrated that the variations were not linear during storage stability and cannot be related to a degradation of the active substance. It can be due to the heterogenity of the product. FR considers that the product is stable after accelerated and long term storage. The product is stable in PE sachets and therefore is compatible with all claimed packaging. Technical properties were not changed after storage.

The active subtance is sensitive to light. Therefore, the product must be store away from light.

FANGA B+ RONGEUR is not classified for physico-chemical properties.

**Shelf life: 2 years**

* **Renewal application - 2019**

No additionnal data was submitted in the context of the renewal.

### Analytical methods for detection and identification

#### Analytical method for determining the active substance and relevant component in the biocidal product

Analytical method for the determination of brodifacoum in the product has been provided.

Principle of the method: brodifacoum is analyzed after extraction from the product with methanol, filtered and quantified by reverse phase HPLC-UV.

Chromatographic conditions:

Colum: Zorbax SB Phenyl, length: 25cm, internal diameter: 3.0mm, granulometry: 5.0µm, Agilent.

Detector: UV, 265nm.

Mobile phase: Eluent A acetonitrile, Eluent B water/acetic acid 34/1.

|  |  |  |  |
| --- | --- | --- | --- |
| **Time (min)** | **Eluent% A** | **Eluent %B** | **Rate (mL/min)** |
| 0  15 | 70  70 | 30  30 | 1.0  1.0 |

Rate: 1(mL/min).

Oven temperature: 30°C.

Volume injected: 20µL.

Retention times (min): 4.9 for brodifacoum I and 5.4 for brodifacoum II.

Linearity was performed with 5 calibration standards, prepared in methanol, from 0.51 to 1.50mg/L. The same linearity was used for the determination of active substance in the product FANGA RONGEUR PRO and FANGA BLOC SP PRO.

Precision was performed by analyzing twice five samples of FANGA BLOC SP PRO. The extraction is the same as for FANGA RONGEUR PRO.

Specificity and accuracy were performed with the formulation FANGA RONGEUR PRO:

Test item: FANGA RONGEUR PRO, Batch 22/11.

Blank formulation (FANGA RONGEUR PRO): Batch 27/11.

Reference item: brodifacoum, purity 99.3%, batch SZB8324XV (supplier: SIGMA Aldrich).

Results are summarized in the following table.

Table 2.3.4.1‑1: Analytical method for the determination of brodifacoum (reverse phase HPLC-UV)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range/ number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Repeatability** | **Reference** |
| **range** | **Mean** | **St dev.** |
| FANGA RONGEUR PRO  Batch 22/11  Blank formulation  Batch 27/11 | brodifacoum | reverse phase HPLC-UV | Fortification levels: reconstituted sample at 1 concentration level (0.005%, 1mg/L in solution after dilution).  Two samples prepared and analysed in duplicate. | 0.51-1.50mg/L  Y= 1.4717x -0.09  R2=0.9965 | No interference observed in solvent blank and formulation blank. | 100-101%  2 reconstituted sample at 0.005% of brodifacoum in duplicate (1mg/L). | 100.5% | SD: 0.58  RSD: 0.57% | 5 samples (FANGA BLOC PRO) in duplicate  Mean: 0.0045% (w/w)  SD:0.0001  RSD: 2.90%  Horwitz value: 6.04 | RICAU Hélène, report No. 11-920010-015, May 2012  RICAU Hélène, report No. 11-920010-031, February 2012 |

Chromatograms were provided for the formulation blank, reference item and test item (at 0.005 % w/w of active substance). No interference has been observed at the retention time of brodifacoum. Specificity of the method is acceptable.

Linearity has been demonstrated with 5 calibration standards.

According to Sanco/3030/99 rev.4, recoveries should be between 80-120 % for active substances with nominal content below 0.01%. Accuracy is acceptable.

RSD is below Horwitz value. Repeatability is acceptable.

It is concluded that the provided method is validated and acceptable for the product FANGA RONGEUR PRO.

**Extrapolation to the product FANGA B+ RONGEUR**

Specificity of the method with the formulation FANGA B+ RONGEUR has been demonstrated in the report CRA-W Study n° 22718. Chromatograms of the blank formulation, calibration standard and test item have been provided. No interference at the retention time of brodifacoum was observed. Nevertheless, accuracy must be demonstrated at 0.001%w/w. A complementary analytical method for the determination of brodifacoum in FANGA B+RONGEUR by definition of the accuracy of the method was required during the first evaluation.

**Accuracy of the analytical method: additional data provided in August 2013 (report 11-920010-027, H.RICAU, May 2012)**

Analytical data regarding the accuracy of the method for the determination of brodifacoum in biocidal products of the frame formulation FANGA RONGEUR PRO have been provided. Results are summarized below:

Test item: FANGA RONGEUR PRO, batch 11-203 (formulations tested at 0.001% w/w and 0.005 % w/w)

Blank formulation: batch 11-203BF

Reference item: brodifacoum, batch SZB8324XV, 99.3%, supplier: Sigma Aldrich

**Principle**: extraction with methanol and determination with HPLC-UV

**Accuracy results**: Accuracy was performed with blank formulation fortified with brodifacoum at 0.005 % w/w (0.5g of blank formulation spiked with 0.25mL of a solution of brodicacoum with a concentration of 0.1mg/mL). Two reconstituted samples were prepared and injected twice.

Mean recovery (sample 1): 101 % (two injections)

Mean recovery (sample 2): 100 % (two injections)

Mean recoveries are in acceptable range (80-120 %) for a content of active substance below 0.01% in the formulation.

Nevertheless, accuracy was performed with samples fortified at 0.005 % w/w of brodifacoum. Accuracy must be demonstrated with samples fortified at the lowest content of brodifacoum in FANGA B+ RONGEUR (0.001 % w/w). Additional data were requested and are reported below**.**

Additional validation data on accuracy were provided in report No. R15-920010-002. A blank formulation of FANGA B+ RONGEUR (BDB10V1) was fortified with brodifacoum at a content of 0.001% (10ppm). Two samples were prepared and injected twice. Mean recovery was 98 %. Results are in acceptable range (80-120 %). The method is considered suitable for the determination of brodifacoum in the product FANGA B+ RONGEUR.

#### Analytical methods for determining relevant components and/or residues in different matrices

A letter of access has been provided by Activa to TRIPLAN for analytical methods in the different matrices.

The analytical methods for determination of residues of active substance in different matrices (soil, air, drinking and surface water, body fluids and tissues, in food and feedstuff) provided in the CAR of the active substance are presented in annex 3 of this document.

Since there is no risk of contact with alimentation, no analytical method is required for the determination of brodifacoum residues in food and feedstuff.

* **Renewal application - 2019**

For the renewal, no additional information has been provided.

## Risk assessment for Physico-chemical properties

FANGA B+ RONGEUR is a ready-to-use grain bait. The product is not highly flammable, not auto-flammable (up to 400 °C), not explosive and does not have oxidizing properties.

The variation of the active substance after long term storage in PE bags is above 10 %. Nevertheless, it is not related to a degradation of the active substance and it can be due to the heterogeneity of the product.

The product is compatible with all claimed packaging.

***Risk mitigation measures linked to assessment of physico-chemical properties***

* Store away from light.

***Required information linked to assessment of physico-chemical properties***

None.

* **Renewal application - 2019 - General conclusion on the physical, chemical and technical properties of the product for renewal of national authorisation applications.**

The product FANGA B+ RONGEUR is a ready to use grain formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable.

The appearance of the product is blue/green grain and with a slight odor of grain.

Storage stability study results are acceptable. The biocidal product is stable 2 weeks at 54°C and 2 years at ambient temperature with PP bucket (secondary packaging) containing PE bags (primary packaging) with the product.

Considering that the product is a solid and it is compatible with this type of packaging, compatibility with all claimed packagings is considered acceptable.

eCA recommends to store away from light due to the sensitivity of the active substance to light.

Its technical characteristics are acceptable for a grain ready to use formulation.

Analytical methods are acceptable.

## Effectiveness against target organisms

### Function

MG 03: Pest Control.

Product Type 14: Rodenticide.

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

According to the uses claimed by the applicant, the product FANGA B+ RONGEUR is intended to be used to control rats and mice. The target organisms to be controlled are *Mus musculus, Rattus norvegicus and Rattus rattus.*

FANGA B+ RONGEUR is used in and around buildings, open areas by professional and non-professional users, and in waste dumps by professional users only.

The products, organisms or objects to be protected are public and private buildings, farms, opens areas and waste dump sites.

The application rates recommended by the applicant are the following (see also Annex 0a):

1. Rats: 180-200 g grains/secured bait point separated by 5-10 m.
2. Mice: 30-40 g grains/secured bait point separated by 1-2 m.

* **Minor change application - 2018**

The uses are the same as above, but the application rate is reduced to 100 g against rats instead of 180-200 g.

* **Renewal application - 2019**

The uses are the same as above.

### Effect on target organisms and efficacy

The applicant submitted the following studies, all performed with the product FANGA B+ RONGEUR (0.001 % w/w brodifacoum):

* **First authorisation:**

**Efficacy and palatability laboratory studies**

* Study n° xxx:

For mice (*Mus musculus*), the mean palatability percentage is 79.2 % and the mortality is 100 % (from day 3 to day 9).

* Study n°xxx:

For brown rats (*Rattus norvegicus*), the mean palatability is 69.3 % and the mortality is 100 % (from day 4 to day 9).

* Study n°xxx:

For black rats (*Rattus rattus*), the mean palatability is 41 % and the mortality is 90 % (from day 5 to day 7).

**Field studies:**

* Study n°xxx :

For mice (*Mus musculus*), the assessment of the bait (2 years aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%. It has to be noted that the quantity of rodent bait is 100 g per bait point.

* Study n°xxx :

For brown rats (*Rattus norvegicus*), the assessment of the bait (3 years aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%.

* Study n°xxx:

For black rats (*Rattus rattus*), the assessment of the bait (27 months aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%.

* **Minor change application - 2018**

* Study n°xxx :

For brown rats (*Rattus norvegicus*), the assessment of the bait (59 months aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%.

* Study n°xxx :

For black rats (*Rattus rattus*), the assessment of the bait (58 months aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%.

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*.

All efficacy studies are presented in annex 9 and 9a.

* **Renewal application - 2019**
* Study xxx

For mice (*Mus musculus*), the assessment of the bait (56 months aged FANGA B+ RONGEUR) has been very well accepted and the estimated efficacy is 100%. It has to be noted that the quantity of rodent bait is 40 g per bait point. Then the efficacy is demonstrated at 40 g per bait point on this target.

French competent authorities (FR CA) consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product against *Rattus norvegicus*, *Rattus rattus* and *Mus musculus*.

### Mode of action including time delay

Brodifacoum acts as a vitamin K antagonist. It interferes with the regeneration of prothrombin disturbing the normal blood clotting mechanisms and increasing tendency to bleed.

The main site of its action is the liver, where several of the blood coagulation precursors under vitamin-K dependent post translation processing take place before they are converted into the respective procoagulant zymogens.

Brodifacoum works by blocking the regeneration of vitamin K 2,3-epoxide to vitamin K hydroquinone. Since, the amount of vitamin K in the body is finite, the progressive block of the regeneration of vitamin K will lead to an increasing probability of a fatal haemorrhage.

Taking into account the results of the submitted laboratory studies, death of target animal occurs 3 to 9 days after ingestion.

### Occurrence of resistance - resistance management / Unacceptable effect

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.

The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.

For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.

For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982[[7]](#footnote-7); Lund, 1984[[8]](#footnote-8); Pelz et al. 1995[[9]](#footnote-9)). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 (Greaves and Cullen-Ayres 1988[[10]](#footnote-10)). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. Greaves et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance (Greaves and Cullen Ayres, 1988; Quy et al. 1992a,b[[11]](#footnote-11)).

Studies carried out in different European countries, in the UK more particularly (Kerins et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication (Baer et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone (Grandemange et al., 2009). The same mutation was also found in UK (Prescott et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone.

So, resistance to second generation anticoagulant rodenticides should not be minimized.

An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).

The document CropLife International (RRAC 2015) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.

The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.

The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.

* **Renewal application - 2019:** A statement has been provided by the applicant indicating that the surveys implemented don’t outline any issues for resistance in the field. Nevertheless, it has to be noticed that rodenticides baits are commonly challenged by the presence of other food.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

### Evaluation of the label claim

* **First authorisation :**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus and Mus musculus*.

Nevertheless for the claim against *Mus musculus*, the application rate used in the field efficacy study is not the one claimed by the applicant. According to the TNSG PT14[[12]](#footnote-12) under revision, in the field efficacy tests, the application rates used should be in accordance with the claims. So, a new field test demonstrating the efficacy of FANGA B+ RONGEUR against house mice at the application rate claimed by the applicant should be submitted no later than 2 years after authorisation.

The application rates validated are the following (see also Annex 0b):

1. Rats (Rattus norvegicus and Rattus rattus): 180-200 g grains/secured bait point separated by 5-10 m.
2. House mice (Mus musculus): 30-40 g grains/secured bait point separated by 1-2 meters.

Bait points should be controlled and resupply as long as the bait is consumed:

- 3 days after the first application then weekly for use in and around building and open areas;

- 1 week after the first application then monthly for use in waste dump.

The product FANGA B+ RONGEUR is supplied in sachets of different amounts. The applicant has to adapt the sachets sizes to the efficient doses. The amount of bait per bait station or bait points must not exceed the recommended application rates.

* **Assessment of minor change (2018)**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*).

The application rates validated are the following:

* Rats: (*Rattus norvegicus* and *Rattus rattus*): 100 g grains/secured bait point separated by 5-10 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

* **Assessment of renewal - 2019**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*) and house mice (*Mus musculus*).

The application rates validated are the following:

* Rats: (*Rattus norvegicus* and *Rattus rattus*): 100 g grains/secured bait point separated by 5-10 m.
* Mice (*Mus musculus*): 40 g grains/secured bait point separated by 1-2 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

### Conclusion of the efficacy assessment

* **First authorisation**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus and Mus musculus* in and around building, in open areas and in waste dump.

Nevertheless for the claim agaisnt *Mus musculus*, the application rate used in the field efficacy study is not the one claimed by the applicant. According to the TNSG PT14 under revision, in the field efficacy tests, the application rates used should be in accordance with the claims. So, a new field test demonstrating the efficacy of FANGA B+ RONGEUR against house mice at the application rate claimed by the applicant should be submitted at the renewal of the authorisation.

***Conditions of use linked to efficacy assessment (professional users)***

* Adapt the number of bait station to the infestation level.
* Products have always to be used in accordance with the label.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
* Inspect and resupply the bait stations as long as the bait is consumed:
  + 3 days after the first application then weekly in and around building and in open areas.
  + 1 week after the first application then monthly for use in waste dump.
* Remove all bait stations after the end of treatment.
* The amount of bait per bait point and distances between bait points must be respected.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
* To avoid resistance:
* The treatment has to be alternated with other kinds of active substances having different modes of action.
* Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures.
* The level of efficacy have to be monitored (periodic check), and the case of reduced efficacy has to be investigated for possible evidence of resistance.
* Do not use the product in areas where resistance is suspected or established.

***Conditions of use linked to efficacy assessment (non-professional users)***

* The amount of bait per bait point and distances between bait points must be respected.
* Products have always to be used in accordance with the label.
* Inspect and resupply the bait stations as long as the bait is consumed, 3 days after the first application then weekly in and around building and in open areas.
* Remove all bait stations after the end of treatment.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

***Recommendations to be taken into account by the applicant***

* Adapt the amount of bait per bait point to the validated effective dose.
* The product label has to contain information on resistance management for rodenticides.

***Required information linked to efficacy assessment***

* The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum, and resistance strategies management must be put in place. Results of the resistance monitoring must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 2 years.
* Field tests against *Mus musculus* must be submitted in order to confirm the efficacy of FANGA B+ RONGEUR in this species at the renewal of the authorisation.
* **Assessment of minor change (2018)**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*).

The application rates validated are the following:

* Rats: (*Rattus norvegicus* and *Rattus rattus*): 100 g grains/secured bait point separated by 5-10 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

* **Assessment of renewal - 2019**

French competent authorities (FR CA) assessed that the product FANGA B+ RONGEUR has shown a sufficient efficacy for the control of rats (*R. norvegicus* and *R. rattus*) and house mice (Mus musculus.

The application rates validated are the following:

* Rats: (*Rattus norvegicus* and *Rattus rattus*): 100 g grains/secured bait point separated by 5-10 m.
* Mice (*Mus musculus*): 40 g grains/secured bait point separated by 1-2 m.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

## Description of the intended use

The product FANGA B+ RONGEUR is intended to be used for the control of rats (*Rattus rattus and Rattus norvegicus*) and mice (*Mus musculus*) in and around buildings, and in open areas by professional and non-professional users; in waste dumps by professional users only.

* Rats (*Rattus norvegicus and Rattus rattus*): 180-200 g grains/secured bait point separated by 5-10 m.
* Mice (*Mus musculus*): 30-40 g grains/secured bait point separated by 1-2 m.

The product is a ready-to-use grain bait with no dilution nor other substances added for application. The mode of application claimed by the applicant is a manual application by professional users in secured bait point (bait stations).

* **Assessment of minor change (2018)**

A new application rate of FANGA B+ RONGEUR against rats is claimed by the applicant : 100 g.

* **Renewal application - 2019**

The product FANGA B+ RONGEUR is intended to be used for the control of rats (*Rattus rattus and Rattus norvegicus*) and mice (*Mus musculus*) in and around buildings, in open areas and waste dumps by professional users ; in building for mice and in and around building for rats by non-professional users.

* Rats (*Rattus norvegicus and Rattus rattus*): 100 g grains/secured bait point separated by 5-10 m.
* Mice (*Mus musculus*): 40 g grains/secured bait point separated by 1-2 m.

The product is a ready-to-use grain bait with no dilution nor other substances added for application. The mode of application claimed by the applicant is a manual application by professional users in secured bait point (bait stations).

## Risk assessment for human health

### Hazard potential - initial PAR 2016

#### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements.

The results of this toxicological assessment can be found in the **combined** AR.

Brodifacoum (CAS no. 56073-10-0) was notified as an existing active substance, by Syngenta Limited and Activa / Pelgar brodifacoum and difenacoum Task Force, hereafter referred to as the applicants, in product-type 14. A combined assessment report was available on December 2010.

The following corresponds to the summary of the effect assessment available in the combined assessment report of brodifacoum.

***A (data from Syngenta) and B (data from Activa/PelGar)***

* **Toxicokinetics**

**A:**

*Brodifacoum* (0.21 mg/kg bw) administered orally to rats was rapidly absorbed (Tmax =8h; Cmax 16.1 ng/ml whole blood). The levels declined slowly and about 10% (1.3 ng/ml) was still present at 10 days after dosing. Almost all (82.5 %) the radioactivity in whole blood was found to be associated with the plasma. Based on the radioactivity still associated to the animal tissues, 10 days after the treatment, the **oral absorptionwas > 75 %.** After a single oral dose of 10 mg/kg of *Brodifacoum* about 64.0% was absorbed and could be accounted for in the liver, carcass and bile 48h after dosing. The rest was recovered in the faeces, as unabsorbed material.

After absorption the product was widely distributed. 10 days after dosing the proportion of the retained dose was highest in the liver (22.8 %), followed by the pancreas (2.3 %), and then the kidney (0.8 %), heart (0.1 %) and spleen (0.2 %). The remainder of the dose (50%) was in the carcass and skin.

*Brodifacoum* was only partially metabolised. 31.3% and 19.6 % of the residues in the carcass and liver, respectively, was unchanged *Brodifacoum*. Two more polar metabolites were detected in the bile, the major one being identified as the glucuronide.

*Brodifacoum* shows a high potential for bioaccumulation: in all studies undertaken and at all dose levels tested, the liver retained the largest % of the dose, even very long time after dosing.

Analyses of the rat livers from the 90 day feeding study, indicate a non-linear accumulation of *Brodifacoum* *vs* dose and time.

A small amount (11 – 14 %) of the radioactivity was slowly eliminated in urine and faeces over 10 days following a single oral dose of 0.25 mg/kg. Biliary and renal routes are of equal significance in the elimination of *Brodifacoum*. The rate of elimination as given by the biological half-life, was calculated to be 150 – 200 days.

The elimination from the liver was biphasic at higher doses. There was a rapid phase (days 1-4) which also corresponded to a reduction in clotting factor synthesis, followed by a slower terminal phase (days 28-84) during which blood clotting function was normal. The half-life of elimination from the liver during the rapid and the slow phase was ≅4 and 128 days, respectively. At low dose levels, clotting factor synthesis was unaffected indicating that probably only the slow elimination phase was present in the liver. The half-life of *Brodifacoum* in the liver was calculated in the range of 282-350 days.

Dermal absorption was assessed by using a formulation (ready-for-use pellet bait) containing 0.0048% *Brodifacoum* w/w tested in vitro test on human skin samples. Over the entire 24 h exposure *Brodifacoum* (determined by LC-MS-MS) was found below the LOQ in the receptor fluid (<3.53 % of the applied dose) and in the epidermis (<1.64 %), after tape stripping. The applied dose was readily removed by mild skin washing and recovered (108 ±6.25%) in the washing fluid. **A ‘surrogate value’ of 5 % dermal absorption was calculated** by summing up the amount in the receptor fluid and in the epidermis after tape stripping, which can be considered as systemically available material. This value has been taken forward to the risk characterization as the worst case, also taking into account that the exposure period exceeds the usual time (*i.e.* 8 hours) of professional handling.

**B:**

Read across to data from some related 2nd generation anticoagulants (*i.e.* *Difenacoum*, *Flocoumafen*) is requested for ADME data, including dermal absorption, and has been applied for other end-points by the RMS.

Beside the similar mode of action, the read across is supported by bridging studies demonstrating the similarity in physico-chemical and toxicological properties of these substances which are presented up-front to Doc. IIA- Section 3.

Anticoagulant rodenticides including *Brodifacoum* are rapidly absorbed via the gastro-intestinal tract and oral absorption is assumed to be 100%, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. The major route of elimination after oral administration is via the faeces, both as polar metabolites and parent compound. *Brodifacoum* is widely distributed and bioaccumulates in the liver with minor concentrations in the kidney.

Elimination processes are very slow with 50-75 % of the administered dose being retained in the liver (t1/2 for hepatic residues more than 200 days).

The metabolism of *Brodifacoum* is limited, although in repeated dose studies evidence of induction of metabolism was reported, with increasing levels of radioactivity associated to polar metabolites recovered in the urine. The toxicologically relevant chemical species is the parent compound.

No study on dermal absorption of *Brodifacoum* has been presented. *Brodifacoum* is expected to be slowly absorbed through the skin, due to the lipophylicity of the molecule, allowing passive transport through the membrane. The read across principle can be applied, based on the close structural relationship, the similar physico-chemical properties and the same mode of action displayed by *Brodifacoum* towards other 2nd generation anticoagulants, such as *Difethialone* and *Difenacoum*. A dermal absorption value =4% has been adopted for *Difethialone*, whereas in the case of *Difenacoum* twodifferent values have been used for risk characterisation depending on the type of formulation, that is 3 % (pellets and grains) or 0.047 % (wax block bait).

In the CAR, by applying the read across from data on a structurally related 2nd generation anticoagulant *Difenacoum*, a 3 % dermal absorption value was adopted for the exposure calculation (below reported under Section 2.2.1.8). This value was calculated from a dermal absorption study testing a pellet formulation containing *Difenacoum* as active substance.

**Conclusion on toxicokinetics:** An almost complete oral absorption can be considered, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. *Brodifacoum* is widely distributed and bioaccumulates mainly in the liver with lower concentrations in the kidney. Hepatic bioaccumulation of *Brodifacoum* is a non-linear *vs* dose and time. The elimination kinetic from the liver was biphasic, with an half-life in the range of 282-350 days. The excretion after oral administration is very slow (11 – 14 % in 10 days), occurring via the urine and the bile, both as polar metabolites (glucuronide) and parent compound. The metabolism of *Brodifacoum* is limited and the toxicologically relevant chemical species is the parent compound.

Concerning the dermal absorption value to be used in the risk characterisation for wax block bait, in the Combined Assessment Report for *Difenacoum* (September 2009) a value of 0.047 % was proposed. Therefore, on the basis of the available study and reading across from data on other 2nd generation anticoagulant rodenticides, two different values should be used for risk characterisation depending on the type of formulation: 5 % (pellets and grains) or 0.047 % (wax block bait).

* **Acute effects**

**A:**

*Brodifacoum* was very toxic to rats and mice with similar oral LD50 of about 0.4 mg/kg bw to the male rat and mouse. *Brodifacoum* is also acutely toxic by the dermal and inhalation routes. Death was the result of internal haemorrhage.

Brodifacoum does not fulfil the EU criteria for classification as a skin or eye irritant, but is able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

***B:***

*Brodifacoum* is very toxic if swallow (oral LD50 <5 mg/kg bw) or in contact with skin (dermal LD50= 7.48 mg/kg bw in rat females; even lower in males).

The waiving for the inhalation toxicity study has been accepted due to low vapour pressure of *Brodifacoum* and data on dustiness and particle size, indicating that the potential for inhalation is limited in addition to ethical and animal welfare reasons. However, based on data with structurally related compounds with the same mechanism of action (*i.e.* 2nd generation anticoagulants), it is expected that the substance is also highly toxic after inhalation.

*Brodifacoum* is not irritant to the skin or eyes of rabbits and showed no sensitizing potential in a LLNA study in mice.

**Conclusion on acute effects:** *Brodifacoum* is very toxic after oral administration and also via the dermal and inhalation routes. Death was the result of internal haemorrhage. Classification with T+; R26/27/28; ‘Very toxic by inhalation, in contact with skin and if swallowed’ is warranted.

*Brodifacoum* does not fulfil the EU criteria for classification as a skin or eye irritant. Although showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

* + - * **Repeated Dose Effects**

**A:**

Repeated dose oral studies show that in the rat and in the dog, the clinical signs, haematological and post mortem data were consistent with the known pharmacological action of *Brodifacoum*: impairment of the clotting cascade and increased prevalence of haemorrhage leading to death. There were no indications of other secondary toxicities: any of the other parameters including histopathological analysis revealed no treatment related alterations.

The subchronic 90-day oral toxicity allowed the derivation of the lowest repeated toxicity NOEL= 0.001 mg/kg bw/day. In this study, no treatment related effects on haematological parameters were evidenced at any dose, after 45 days, but statistically significant increases in both the kaolin-cephalin time (KCT) and the prothrombin time (PT) were measured at the highest dose level, 0.004 mg/kg bw/day after 90 days. Based upon this effect on prothrombin times and based on haemorrhagic changes seen at necropsy, the NOEL was set at the next lowest dose, 0.001 mg/kg bw/day.

Classification with T; R48/23/24/25 “Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed” is warranted based on these data plus extrapolation from the acute data for the dermal and inhalation route of exposure.

**B:**

Repeated oral exposure to *Brodifacoum* resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The overall NOAEL for subchronic oral toxicity is 0.04 mg/kg/day.

No data have been submitted on dermal repeated toxicity. On the basis of both physico-chemical properties and *brodifacoum* mode of action it can be anticipated that subchronic effect due to prolonged skin contact should not be disregarded.

No data on repeated inhalation toxicity have been submitted. As indicated by the low vapour pressure, dustiness and particle size, the potential for inhalation is low and the request for a repeated dose inhalation toxicity study is not considered justified also based on ethical and animal welfare reasons.

However, based on the results of the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum* (being the read across accepted for other end-points), it is justified to assume a similar concern for serious damage to health by prolonged exposure through dermal and inhalation routes also.

* + - * **Genotoxicity**

**A:**

*Brodifacoum* was tested in *Salmonella typhimurium* strains TA 1535, TA 1537,TA 98, TA 100, TA 1538. with and without S9-mix, up to 5000 mg/plate, with negative results. No clastogenic activity was observed in the *in-vitro* cytogenetic assay in human lymphocytes, performed with and without metabolic activation, up to cytotoxic doses. The *in vitro* mammalian cell mutation assay in mouse lymphoma L5178Y cells also resulted negative, with and without S9-mix, while cytotoxic effects was observed at the highest doses. The applicants submitted also an *in vitro* UDS test and in an *in vitro* cell transformation assay, but because of several methodological and reporting shortcomings, they were considered of limited scientific significance. An *in vivo* mouse micronucleus test gave negative results. The studies submitted were rather dated, therefore they were not always compliant with the current guidelines. However a genotoxic potential of the active substance can be reliably ruled out.

**B:**

*Brodifacoum* was tested for genotoxic activity in the bacterial reverse mutation test in *Salmonella thyphimurium* in strains TA 98, TA 100, TA 102, TA 1535 and TA 1537, up to 5000 g/plate, with and without metabolic activation (S9-mix). No genotoxic activity was observed in any bacterial strain. The substance resulted negative up to cytotoxic concentration also in the gene mutations assay in L5178Y mouse lymphoma cells, with and without S9-mix, and in the *in vitro* mammalian chromosome aberration test in human lymphocytes (50% mitotic inhibition at the maximum dosage tested).

* + - * **Carcinogenicity/chronic toxicity**

**A, B:**

Carcinogenicity and long-term toxicity studies were waived as infeasible and unnecessary.

* + - * **Reproductive and developmental toxicity**

**A:**

*Brodifacoum* did not induce developmental effects in two adequate prenatal toxicity studies

in the rat and rabbit, respectively.

In particular, in the rat studies maternal hemorrhages were observed at dose levels > 0.01 mg/kg bw (NOEL 0.001 mg/kg bw) whereas no effects on conceptuses were detected up to the top dose level of 0.02 mg/kg bw. In the rabbit study, the top dose of 0.005 mg/kg b.w caused a high proportion of maternal deaths, whereas no significant effects on litters were observed. In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.

**B:**

There was no evidence of developmental toxicity effects up to the dose levels of 0.04 and 0.004 mg/kg bw in rats and rabbits, respectively. In rabbit dams an increase in kaolin-cephalin and prothrombin time was present at 0.004 mg/kg bw (NOAEL 0.002 mg/kg).

Whereas it is suggested that two-generation studies may not be need for anticoagulant rodenticides, a two-generation study on rat was submitted: findings confirmed those of developmental toxicity, both qualitatively (parental toxicity with haemorrhages, no reproductive or developmentakl effects in the absence of general toxicity) and quantitatively (NOAEL: 0.001 mg/kg bw).

Since the conventional OECD Guideline 414 may have limitations in the detection of possible developmental effects of coumarin related compounds, and in spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin.*

* + - * **Neurotoxicity**

**A:**

None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum*

**B:**

The toxicological studies do not indicate any neurotoxic effects.

**Conclusion on repeated dose effects:** Repeated oral exposure to *Brodifacoum* resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The NOEL for subchronic oral toxicity is in the range 0.04 -0.001 mg/kg/day (the lowest values identified with sensitive end-points, such as increases in both the kaolin-cephalin time and the prothrombin time). Based on results from the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for *Difenacoum*, it is justified to assume serious damages associated to prolonged exposure through dermal and inhalation routes also. Therefore, classification with T; R48/23/24/25 “Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed” is warranted.

**Conclusion on Genotoxicity and Carcinogenicity:** *Brodifacoum* displayed no mutagenic activity in a standard range of genotoxicity tests. No long-term carcinogenicity study was submitted by the two applicants. In fact, chronic toxicity studies were not considered to be technically feasible due to the specific action of the active substance on the test/target species. However, the anticoagulant action is apparently the only pharmacological action of *Brodifacoum*. The active substance has no structural alerts for carcinogenicity and no concern about possible non-genotoxic carcinogenic potential can be derived from the toxicological studies. Therefore the justifications of both the applicants for not-submission of carcinogenicity data was considered acceptable.

**Conclusion on Reproductive toxicity:** Reproductive and developmental toxicity studies on *Brodifacoum* did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw.

In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*.

None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of Brodifacoum.

The harmonised classification of the active substance is the following:

|  |  |
| --- | --- |
| Classification under directive 67/548/EEC | Classification under regulation (EC) 1272/2008 |
| T+ R27/28  T ;R48/24/25  No specific limit concentrations | Acute Tox 1 H310  Acute Tox 2 H300  STOT RE Cat 1 H372  No specific limit concentrations |

The following corresponds to the summary of the derivation of the AELs from the combined Assessment Report of brodifacoum:

**A:** The Acceptable Exposure Level for acute exposure (AELacute) was based on the maternal NOEL from developmental study of 0.001 mg/kg bw/day (rat, maternal effect). A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AELacute results to be of 3.3 x 10-6 mg/kg/day.

The Acceptable Exposure Level for repeated exposure (AELchr) was based on a subchronic NOEL from a 90-day oral rat study of 0.001 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AELchr results to be of 3.3 x 10-6  mg/kg/day.

**B:** The Acceptable Exposure Level for acute exposure (AELacute) was based on NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AELacute results to be of 6.7 x 10-6  mg/kg bw/d.

The Acceptable Exposure Level for repeated exposure (AELchr) was based on NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day. A safety factor of 300 (10 for intra-species variability x 10 for inter-species variability x 3 additional factor for severity of effects). The AELchr results to be of 3.3 x 10-6  mg/kg bw/day.

TMIII09 agreed to derive AELmedium term consistently with what decided for the other AVK rodenticides. Therefore, AELmedium term was calculated from the NOAEL of 0.002 mg/kg bw/day (developmental oral toxicity study in rabbit) divided by an Assessment Factor of 300 (10 for interspecies x 10 for intraspecies x 3 additional factor for severity of effects). The AELmedium term results to be of 6.7 x 10-6 mg/kg bw/day.

**Conclusions**:

The following AELs should be considered in the risk characterization for *Brodifacoum*:

* AELacute and medium term of 6.7 x 10-6 mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day;

|  |
| --- |
| AELchr of 3.3 x 10-6 mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day |
|  |

#### Toxicology of the substance(s) of concern

The biocidal product FANGA B+ RONGEUR contains no substances of concern.

* **Renewal application - 2019**

According to the Guidance on the BPR Volume III Human Health – Part B Risk Assessment[[13]](#footnote-13), FANGA B+ RONGEUR contains two substances of concern. Indeed, the product contains two substances with IOELV: monopropylene glycol (10 mg/m3) and triethanolamine (1 mg/m3). In accordance with the ECHA Vol III Part B + C guidance document, these substances should be considered as substances of concern and risk assessments are required.

#### Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was / was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been realized with the product FANGA BLOC SP PRO, a block formulation containing 0.005% of brodifacoum. The compositions of FANGA BLOC SP PRO and FANGA B+ RONGEUR are considered similar.

##### Percutaneous absorption

A new study of percutaneous absorption has been submitted by the notifier. A percutaneous absorption value of 0.647% has been set for the difenacoum based on this *in vitro* study realised on human skin with pellets containing 0.005% difenacoum. This dermal absorption value has been considered to be extrapolated to FANGA B+ RONGEUR containing 0.001% of brodifacoum. Indeed, no major increase in the dermal absoprtion value is expected with such very low concentrations of active substance in products and considering that the concentrations are in the same order of magnitude.

* **Renewal application – 2019**

The percutaneous absorption study that has been provided at the time of the initial assessment proposed a percutaneous absorption value of 0.647% (grain form) but, from now on, it presents some methodological limitations. Thus, the difenacoum CAR absorption value of 3% has been used by extrapolation with the reference product in grain form.

##### Acute toxicity

*Oral route*

No mortality occurred during the study (daily examination during 14 days).

No clinical signs related to the administration of the test item were observed.

The body weight evolution of the animals remained normal throughout the study.

The macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.

LD50 of the test item is higher than 2000 mg/kg/bw.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level | LD50 |
| Oral | OECD 423 | Rat 3 males and 3 females | 2000mg/kg bw | >2000 mg/kg bw |

*Dermal route*

No mortality occurred during the study.

The body weight evolution of the animals remained normal throughout the study.

Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.

The macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.

LD50 of the test item is higher than 2000 mg/kg/bw.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level | LD50 |
| Dermal | OCDE 402 | Rat 5 males and 5 females | 2000 mg/kg bw | >2000 mg/kg bw |

Based on the above-mentioned results, no classification is required for FANGA B+ RONGEUR.

##### Irritation and corrosivity

Based on the results of the irritation assays on rabbit’s skin and eye, no classification is required for FANGA B+ RONGEUR.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level |  |
| skin | OECD 404 | Rabbit NZ  3 females | 0.5 g | No irritant |
| eye | OCDE 405 | Rabbit NZ  3 females | 0.1 g | No irritant |

##### Sensitisation

Based on the results of the irritation assays on rabbit’s skin and eye (LLNA), no classification is required for FANGA B+ RONGEUR.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level |  |
| skin | OECD 429 | Mice16 (12 for the treated groups) | Topical way of induction:  5, 10, 25% of the test item | No skin sensitizing |

##### Other studies

No other studies are performed on FANGA B+ RONGEUR.

### Human exposure assessment

*FANGA B+ RONGEUR (PT14) is a ready-to-use rodenticide containing 0.001 % of brodifacoum (pure: 950 g/kg). Baits are packaged in bulk and in sachet for professional users, only in sachet for non professional users.The baits are placed in bait stations (bait boxes or secured bait stations) out of reach of children and domestic animals.*

#### Identification of main paths of human exposure towards active substance from its use in biocidal product

The potential for exposure to brodifacoum grain baits is summarised in the table below:

Table 2.7.2.1‑1: Main paths of human exposure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use** | **Professional use** | **General public** | ***via* the environment** |
| Inhalation | Not relevant | Potentially significant | Negligible | Negligible |
| Dermal | Not relevant | Potentially significant | Potentially significant | Negligible |
| Oral | Not relevant | Negligible | Potentially significan | Negligible |

#### Direct exposure as a result of use of the active substance in biocidal product

**Exposure of professional users**

*In Annex 6„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

FANGA B+ RONGEUR is used for the control of rats and mice in and around buildings, in open areas and waste dumps, by professionals and non professionals with the purpose of protecting human food and animal feedstuffs, and for human hygiene.

The exposure assessment to the product used for the control of rats covers the scenario for the control of mice since lower quantity of product is used for mice.

***Professional - Inhalation exposure***

Exposure by inhalation route is relevant **during the decanting** of the product supplied loose (in bulk). Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the air concentration is 9.62 mg product/m3.

The following parameters were considered:

* duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6kg decanted in 3 kg buckets per day);
* Inhalation rate: 1.25 m3/hour;
* Inhalation absorption: 100 %;
* Active substance in product: 0.001 %;
* Body weight: 60 kg.

Based on these assumptions, the systemic concentration of brodifacoum is 5.01x10-7 mg/kg bw/day for the control of rats covering.

***Professional - Dermal exposure***

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.

The following parameters were taken into account:

* Active substance in product: 0.001 %,
* Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[[14]](#footnote-14)),
* Frequency: one manipulation per day,
* Dermal absorption: 0.647 %,
* Body weight: 60 kg.

The quantities of 200 g for the control of rats correspond to the validated efficient doses.

Therefore, the systemic dose of brodifacoum on fingers/hands during decanting is 3.34x10-8 mg/kg bw/day for the control of rats,

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of brodifacoum on fingers/hands during loading is 1.39x10-7 mg/kg bw/day for the control of rats.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of brodifacoum on fingers/hands during loading is 6.54x10-8 mg/kg bw/day for the control of both rats.

In conclusion, the total systemic dermal exposure is set at 2.37x10-7 mg/kg bw/day without PPE for the control of rats.

***Total exposure***

The total systemic exposure resulting from inhalation and dermal contacts with the product is 7.38x10-7 mg a.s/kg bw/day without gloves for the control of rats.

The estimations above are representative for exposure to FANGA B+ RONGEUR in bulk (supplied loose) but they represent a very worst case when the product is supplied and applied in sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.

Therefore, only exposure during cleaning can be considered: 6.54x10-8 mg a.s/kg bw/day without gloves for the control of rats.

* **Renewal application - 2019**

The exposure assessment to the product used for the control of rats covers the scenario for the control of mice since lower quantity of product is used for mice.

The exposure assessment of the product as grain form constitutes a worst case.

*Professional - Dermal exposure of brodifacoum*

Considering an amount of 100g of grains per bait point (validated efficient dose) and a percutaneous absorption of brodifacoum of 3%:

* the systemic dose of brodifacoum during **decanting** is 5.49x10-7 mg/kg bw/day for the control of rats.
* the systemic dose of brodifacoum duringis **loading** is 6.43x10-7 mg/kg bw/day for the control of rats.
* the systemic dose of brodifacoum duringis **cleaning** is 3.03x10-7 mg/kg bw/day for the control of rats.

In conclusion, the total systemic dermal exposure is set at 1.49x10-6 mg/kg bw/day without PPE for the control of rats.

*Total exposure*

The total systemic exposure resulting from inhalation and dermal contacts with the product is 2x10-6 mg a.s/kg bw/day without gloves for the control of rats.

*Professional – Inhalation exposure of SoCs*

### Exposure by inhalation route of monopropylene glycol and triethanolamine (SoCs) is relevant during the decanting of the product supplied loose. According to the HEEG Opinion 12, the air concentration from decanting is 9.62 mg/m3. Monopropylene glycol and triethanolamine being present in the product at 2.484% and 0.0172%, their air concentration from decanting is respectively 0.24 mg/m3 and 1.65.10-3 mg/m3.

See Excel spreadsheets for more details.

##### Exposure of non-professional users

*In Annex 7 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.*

***Non professional – total exposure***

FANGA B+ RONGEUR is only supplied and applied in sachet for non professional users.

In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered.

Based on the CEFIC study and taking into account the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 5 cleanings in non-professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 5 cleanings per day, the systemic dose of brodifacoum on fingers/hands during loading is 2.44 x10-8 mg/kg bw/day for the control of rats.

* **Renewal application - 2019**

*Non-professional – total exposure (PE sachets)*

Considering a percutaneous absorption of brodifacoum of 3%, the systemic dose of brodifacoum on fingers/hands during loading is 9.48 x 10-8 mg/kg bw/day for the control of rats.

*Non professional – Inhalation exposure of SoCs (PE sachets)*

Exposure by inhalation route of monopropylene glycol and triethanolamine is not expected with PE sachets.See Excel spreadsheets for more details.

#### Indirect exposure as a result of use of the active substance in biocidal product

***Handling of dead rodents (adult, child, infant) – acute scenario***

Exposure can occur during handling of dead rodents by professionnal and general public.

However, this scenario is excluded and considered of low relevance due to unrealistic assumptions (TNsG on human exposure (2007)).

Besides, exposure of non users can occur during ingestion of poison baits.

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the acute AEL of 6.7 x 10-6 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 75 % (as stated in the Assessment report of brodifacoum), ingestion of more than 0.88 mg of product per day by an infant is needed to exceed the AEL.

***Oral exposure by ingesting bait (infant) – acute scenario***

Exposure can occur during handling of dead rodents by professionnal and general public.

However, this scenario is excluded and considered of low relevance due to unrealistic assumptions (TNsG on huma 10-6 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 75 % (as stated in the Assessment report of brodifacoum), ingestion of more than 0.88 mg of product per day by an infant is needed to exceed the AEL n exposure (2007)).

Besides, exposure of non users can occur during ingestion of poison baits.

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the acute AEL of 6.7 x.

* **Renewal application - 2019**

Regarding the exposure of non users occuring during ingestion of poison baits, as stated in the Assessment Report of brodifacoum, a worst case oral absorption of 100% has been retained instead of 75%. Consequently, ingestion of more than 6.7 mg of product/day by an infant is needed to exceed the AEL.

See Excel spreadsheets for more details.

#### Exposure to residues in food

In Annex 8 “Residue behaviour”, the results of the residue assessment are laid out.

The biocidal product will not come into contact with food and it is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore there is no requirement to assess potential residues on foodstuffs. Based on intended uses and proper baiting practices of the biocidal product, contamination of food/feedingstuffs is considered highly unlikely to occur.

Brodifacoum baits should not be placed where food, feedingstuffs or drinking water could be contaminated.

#### Combined exposure

Not relevant.

### Risk assessment for human health

The estimated exposures for the professional users are compared to the systemic AEL of brodifacoum set in the Assessment Report (3.3x10-6 mg/kg bw/day for long-term exposure and 6.7x10-6 mg/kg bw/day for short term exposure).

#### Risk for direct exposure

**Professional users**

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for FANGA B+ RONGEUR, even if gloves are not worn.

Gloves are anyway recommended to help prevent rodent-borne disease. Moreover, the mention “do not open the sachet” has to be added in the label of the product.

Table 4: Summary of risk characterisation for professionals for the control of rats and mice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Loose formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professionnal (without gloves) | 3.3x10-6 | 7.38 x 10-7 | 22% | Acceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professionnal (without gloves) | 3.3x10-6 | 6.5 x 10-8 | 2% | Acceptable |

* **Renewal application - 2019**

Summary of risk characterisation for professionals for the control of rats:

***Brodifacoum***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Loose formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professionnal (without gloves) | 3.3x10-6 | 2 x 10-6 | 60% | Acceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professionnal (without gloves) | 3.3x10-6 | 2.84 x 10-7 | 8.6% | Acceptable |

***Monopropylene glycol (SoC)***

*The only reference value available for monopropylene glycol is an OEL of 10 mg/m3. The risk characterisation for this SoC (professionnals) has been realized with this OEL.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **OEL (mg/m3)** | **Exposure (mg/m3)** | **%OEL** | **Risk** |
| **Loose formulation (inhalation exposure during decanting)** | | | | |
| Professionnal (without gloves) | 10 | 0.24 | 2% | Acceptable |
| **Sachet formulation (no inhalation exposure excepted)** | | | | |
| Professionnal | - | - | - | - |

***Triethanolamine (SoC)***

*The only reference value available for monopropylen glycol is an OEL of 1 mg/m3. The risk characterisation for this SoC (professionnals) has been realized with this OEL.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **OEL (mg/m3)** | **Exposure (mg/m3)** | **%OEL** | **Risk** |
| **Loose formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professionnal (without gloves) | 1 | 1.6 x 10-3 | 0.2% | Acceptable |
| **Sachet formulation (no inhalation exposure excepted)** | | | | |
| Professionnal | - | - | - | - |

##### Non-professional users

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable for FANGA B+ RONGEUR.

Table 5: Summary of risk characterisation for non-professionals for the control of rats

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Non professional | 6.7x10-6 | 2.4 x 10-8 | 0.4% | Acceptable |

* **Renewal application - 2019**

Summary of risk characterisation for non-professionals for the control of rats

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Non professional | 6.7x10-6 | 9.48 x 10-8 | 1.4% | Acceptable |

### Risk for indirect exposure

Based on a reverse scenario, more than 8.9 mg of product per day should be ingested by an infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if FANGA B+ RONGEUR contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

* **Renewal application - 2019**

Considering an oral absorption of brodifacoum of 100%, more than 6.7 mg of product per day should be ingested by an infant to exceed the AEL. Therefore, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants. The specific use restriction must be applied to reduce the risk for secondary poisoning.

### Risk for consumers via residues

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

### Risk for combined exposure

Not relevant.

### Conclusion on human health risk assessment

Based on the risk assessment of this product, the risk for professional and non professional users resulting from the intended use is acceptable for FANGA B+ RONGEUR for the control of rats and mice.

Risk of secondary poisoning to infants and children is considered as relevant. Therefore, even if FANGA B+ RONGEUR contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children.

The intended uses description of the product FANGA B+ RONGEUR indicates that these uses are not relevant in terms of residues in food and feed. However the product does not come in direct or indirect contact with food and feedstuff.

***Risk mitigation measures linked to risk assessment for human health***

* Gloves have to be worn to help prevention against rodent-borne disease.
* Do not open the sachets.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
* Use in tamper-resistant bait boxes or in covered bait stations.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Covered bait stations must be placed only in areas not accessible to the general public and non-target animals.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.

**Non professional**

* Do not open the sachets.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* For non-professional users, use only in tamper-resistant boxes.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.

***Emergency*** *(information provided in the product Safety Data Sheet)*

* If inhaled: breathe fresh air and keep at rest.
* If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners.
* If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water.
* If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. In case of emergency, contact 112.
* Note to doctor: the product FANGA B+ SOURIS RAT contains an anticoagulant-rodenticide, treatment with vitamin K1 could be needed for a long time

***Disposal considerations for professional and non-professional users***

* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.

***Required information linked to risk assessment for human health***

None.

* **Renewal application - 2019**

See Summary of Product Characteristics (SPC) in section 3.

## Risk assessment for the environment

### Fate and distribution in the environment of the active substance Brodifacoum

The summary of information about the active substance brodifacoum is carried out with the data from the combined Assessment Report (AR) of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and difenacoum Task Force[[15]](#footnote-15).

#### Degradation

##### Abiotic degradation

###### Hydrolysis in function of pH

Brodifacoum is considered stable to hydrolysis. It was concluded that the hydrolytic half-life (DT50) was above one year at environmentally relevant pH. The hydrolytic degradation is deemed negligible.

###### Photolysis in water

Brodifacoum photolytically degrades in aqueous solution with a half-life (DT50) < 1 day. Photolysis of brodifacoum was fast with 38 % of removal in the first hour of exposure. Greater than 89 % of photolysis has occurred by around three hours. No degradation products were detected.

###### Photolysis in soil

No data on photolysis of the active substance in soil has been submitted in the combined AR of brodifacoum.

###### Photodegradation in air

The photo-oxidative degradation of brodifacoum in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.90 (AOPWIN). Brodifacoum is predicted to undergo rapid indirect photolysis with OH radicals and ozone (DT50= approximately 2 hours). According to GBPR IV Part B[[16]](#footnote-16), the half-live has been recalculated considering COH = 0.5 \* 106 molec/cm3; corresponding to a DT50 of 0.217 days). There are no predicted effects on the atmosphere.

##### Biotic degradation

###### Aquatic compartment

* Ready biodegradation / inherent biodegradation

Brodifacoum is not readily biodegradable under OECD 301B Test (0% after 28 days). Brodifacoum is not inherently biodegradable under the conditions of the ‘Inherent – Concawe Test’ (OECD 302D) performed (0% after 56 days).

* Degradation in water/sediment system

No study on degradation of the active substance in water/sediment system has been submitted in the combined AR of brodifacoum.

###### Degradation in STP

No study on degradation of the active substance in sewage treatment plant system has been submitted in the combined AR of brodifacoum.

###### Terrestrial compartment

Brodifacoum is persistent in soil with a DT50 value of 157 days at 20°C, corresponding to a DT50 value of 298 days à 12°C.

#### Distribution

Based on literature data, the Koc value (50 000 L/kg) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater. A laboratory study carried out by another applicant shows that with Koc values which ranged from 17.8 (pH 8.46) to 426 579 (pH 3.29), with a Koc value of 9155 L/kg at pH7.1-7.6, brodifacoum can be considered immobile in soil. Under basic conditions (high pH), brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Brodifacoum is not expected to move from soil into water.

#### Accumulation

Brodifacoum has a log Kow > 6 (6.12) and is highly adsorptive; consequently these properties indicate that brodifacoum is likely to bioaccumulate in aquatic or terrestrial species.

The aquatic BCF has been estimated with calculation method for substances with a Kow > 6:

**BCFfish = 35 645 L/kg**(according to Equation 75; GBPR IV Part B).

The terrestrial BCF has been estimated with calculation method:

**BCFearthworm = 15 820 L/kg**(according to Equation 82d; GBPR IV Part B).

These BCF values confirm the high bioaccumulation potential of brodifacoum in aquatic and terrestrial species.

#### Behaviour in air

The vapour pressure of brodifacoum has been determined to be << 1 x 10-6 Pa (OECD 104, EC methods A.4). Furthermore, Henry’s law constant has been calculated to be << 2.18 x 10-3 Pa.m3.mol-1 at pH 7 (based on a water solubility of 0.24 mg/L). Based on these data brodifacoum is not expected to partition into atmosphere to a relevant extent.

In addition, brodifacoum is predicted to undergo rapid indirect photolysis with OH radicals and ozone (DT50= approximately 2 hours) and undergoes rapid direct photodegradation (DT50 = 0.217 days).

### Effects on environmental organisms for active substance Brodifacoum

The summary of information about the active substance brodifacoum is carried out with the data from the combined AR of brodifacoum owned by Syngenta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force[[17]](#footnote-17).

#### Aquatic compartment (including water, sediment and STP)

##### Aquatic organisms

Based on the results of acute toxicity studies submitted in the combined AR by Activa / PelGar brodifacoum and difenacoum Task Force, brodifacoum is toxic to aquatic organisms at low concentrations. No long-term tests have been performed. Studies are available for the three trophic levels (fish, daphnia and algae). *Selenastrum capricornutum* is the most sensitive species with a 72h ErC50 of 0.04 mg a.s./L.

Table 2.8.2‑1 Toxicity to freshwater aquatic organisms (measured concentrations)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint** | **Results(mg a.s./L)** | **Reference** |
| OECD 203 | *Oncorhynchus mykiss -* fish | LC50 – 96h | 0.042 | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc III‑A 7.4.1.1 |
| OECD 202 | *Daphnia magna -* invertebrate | EC50 – 48h | 0.25 | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc III‑A 7.4.1.2 |
| OECD 201 | *Selenastrum capricornutum* - algae | EbC50 – 72h  ErC50 – 72h | 0.016  0.04 | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc III‑A 7.4.1.3 |

Justification of PNECwater

According to the GBPR, the PNECwater is derived from the 72h ErC50 value (0.04 mg a.s./L) for *Selenastrum capricornutum* divided by an assessment factor of 1000. Therefore,

**PNECwater = 0.04 µg a.s./L.**

##### Sediment dwelling organisms

No experimental data are available for sediment dwelling organisms. A PNECsediment (0.043 mg/kgwwt) is derived through the Equilibrium Partitioning Method. However, due to the absence of measured data for the determination of a PECsediment and according to the GBPR a quantitative risk characterization cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

According to the GBPR and considering the log Kow > 5, the PEC/PNEC ratio for the aquatic compartment is increased by a factor of 10 to take into account the possible additional uptake via sediment ingestion.

##### STP micro-organisms

The toxicity to microorganisms in a sewage treatment plant (STP) was estimated by a respiration inhibition test (OECD 209) submitted by Activa / PelGar brodifacoum and difenacoum Task Force. No effect of brodifacoum on aerobic biological sewage treatment processes was expected. Due to the lack of measured values of test substance concentration, the EC10 was conservatively set greater than brodifacoum water solubility (0.058 mg a.s/L).

Table 2.8.2‑2 Toxicity to STP microorganisms

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline/Test method** | **Species / Inoculums** | **Endpoint / Type of test** | **Duration** | **Results [mg a.s/L]** | | | | **Reference** |
| **EC10** | **EC20** | **EC50** | **EC80** |
| OECD 209 | Activated sludge | Respiration Inhibition | 3h | > 0.058\* | | | | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc III‑A 7.1.4 |

\* corresponding to the water solubility at pH=7 and T=20°C

Justification of PNECmicororganisms

According to GBPR when an EC10 from a respiration inhibition test is used, an assessment factor of 10 must be applied.

**PNEC STP microorganisms > 0.0058 mg a.s/L**

Additional endpoints:

According to the combined AR of brodifacoum, a lower PNEC value for sewage treatment microorganisms is provided by Syngeta Limited:

**PNEC STP microorganisms > 0.0038 mg a.s/L**.

Therefore, as the data set are considered equivalent, the worst case PNEC from the combined AR must be used in the risk assessment.

#### Atmosphere

Brodifacoum has a low volatility and is not intended to be sprayed or fumigated. It is formulated into a non-volatile solid consequently its occurrence in air is highly unlikely. Moreover, significant phototransformation in air due to hydroxyl radicals would be expected. brodifacoum is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

#### Terrestrial compartment

No effect of brodifacoum, in soil concentration ranging up to 994 mg/kg dry weight, were found on earthworms in a test conducted according to the guideline OECD 207. LC50 was determined to be > 994 mg/kg dry weight, corresponding to a LC50 >879.6 mg/kg in wet weight.

Table 2.8.2‑3 Toxicity to soil organisms

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint / Type of test** | **Exposure** | | **Results (mg a.s/kg wwt soil)** | | **Reference** |
| **design** | **duration** | **NOEC** | **LC50** |
| OECD 207 | *Eisenia foetida* | LC50 | soil exposure | 14days | 879.6 | >879.6 | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc IIIA 7.5.1.2 |

Justification of PNECsoil

Since LC50 was determined to be >879 mg/kg wet weight, when corrected for soil humidity, an assessment factor of 1000 was used in accordance with GBPR (2003).

**PNECsoil > 0.88 mg/kg wet weight**

#### Non compartment specific effect relevant to the food chain

The exposure of brodifacoum directly to non-target birds and mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered in the risk assessment.

Table 2.8.2‑4 Toxicity to birds and mammals (key studies)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint / Type of test / Duration** | **Results** | | **Reference** |
| **NOEC/NO(A)EL** | **LD50** |
| OPPTS 850.2100 | Japanese quail | LD50/ acute oral  Single dose followed by 14 days oservation | - | LD50 = 19 mg a.s/kg bw | Activa / PelGar Brodifacoum and Difenacoum Task Force  CAR a.s.  Doc IIIA 7.5.3.1.1 |
| OECD 416 | Rat Wistar | High dose F1: haemorrhagic diathesies  2-generation | NO(A)EL  Parental (females) = 0.001 mg/kg bw/day) | - | Morris, 1995 |

##### Primary poisoning & Secondary poisoning

Acute/short-term qualitative assessment

Acute primary toxicity for birds and mammals is assessed only qualitatively in accordance with the decision from TMIII-06.

**For mammals** the acute toxicity to rat: a LD50 value =< 5 mg a.s. /kg bwis provided.

Additional endpoints:

According to the combined AR of brodifacoum, a lower **LD50** value of **0.4** **mg a.s. /kg bw (**recalculated into **LC50 = 8 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the GBPR II is the lowest value for the acute toxicity.**)** is provided by another notifier. Therefore, as the data set are considered equivalent, the worst case LD50 value from the combined AR is used in the qualitative assessment for comparisons with estimated daily uptakes of brodifacoum (ETE, mg a.s. /kg bw).

**For birds** the acute toxicity to Japanese quail: **LD50 = 19 mg a.s. /kg bw** is provided.

Additional endpoints:

According to the combined AR of brodifacoum, a lower LD50 value of **0.31** **mg a.s. /kg bw** is provided by another notifier. Therefore, as the data set are considered equivalent, the worst case LD50 value from the combined AR is used in the qualitative assessment for comparisons with estimated daily uptakes of brodifacoum (ETE, mg a.s. /kg bw).

Studies on dietary toxicity were submitted by another notifier in the combined AR and provided a **LC50 = 0.72 mg/kg food**. No data about the dietary toxicity to birds was submitted by Activa / PelGar Brodifacoum and Difenacoum Task Force in the combined AR.

Long-term quantitative assessment

For **mammals**, in a two-generation fertility study with rats, a NOAEL of 0.001 mg/kg bw/day was estimated. According to the GBPR, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the AForal of 90 is applied to this NOEC, which results in a

**PNECoral (mammal) = 0.001/90 = 1.1E-05 mg/kg bw/day**

**equivalent to**

**PNECoral (mammal) = 0.001\*20/90 = 2.22E-04 mg/kg food**

For **birds** the NOEC for brodifacoum is based on the results of the chronic toxicity study with difenacoum (on Japanese Quail), chosen as reference chemical for second generation anticoagulants (NOEC > 0.1 mg difenacoum /kg diet). An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for difenacoum (LD50 = 66 mg/kg, male and females) and brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. Brodifacoum results show high toxicity to birds, with NOEC = 0.012 mg brodifacoum/kg diet (obtained as NOEC > 0.1 mg difenacoum /kg diet / 8.05) and NOEL = 0.0012 mg brodifacoum/kg bw/d.

According to GBPR, an assessment factor of 30 is applied to derive the PNEC:

**PNECoral for birds (dose) = 0.0012/30 = 4E-05 mg/ kg bw/ day**

**equivalent to**

**PNECoral for birds (conc. In food) = 0.012/30 = 43E-04 mg/kg food**

Additional endpoints: according to the combined AR of brodifacoum, a lower **PNECoral for birds** is provided by another notifier. The long-term toxicity was extrapolated by read across to reproduction toxicity of difenacoum to Japanese Quail (NOEC > 0.1 mg Difenacoum /kg diet), selected as representative compound of the second generation anticoagulants. A factor of 26 was applied to take into account differences in toxicity between the two compounds. A NOEC = 0.0038 mg brodifacoum /kg diet and a NOEL = 3.85E-04 mg Brodifacoum/kg bw/d are derived.

According to GBPR, an assessment factor of 30 is applied to derive the PNEC:

**PNECoral for birds (dose) = 1.3E-05 mg/ kg bw/ day**

**equivalent to**

**PNECoral for birds (conc. In food) = 1.3E-04 mg/kg food**

Therefore, as the data set are considered equivalent, the worst case PNEC from the combined AR is used in the risk assessment.

#### Summary of PNECs of the active substance Brodifacoum

Table 2.8.2‑5 Summary of the brodifacoum (a.s.) PNECs used for risk assessment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Compartment** | | **Test Value** | **AF** | **PNEC** | **Source** |
| Aquatic | PNECwater | 72h ErC50 = 0.04 mg a.s./L | 1000 | 0.04 µg a.s./L | Combined AR |
| PNECSTP | EC10 > 0.0038 mg a.s. /L | 100 | > 0.0038 mg a.s/L | combined AR |
| Terrestrial | PNECsoil | 14-d LC50 > 879.6 mg a.s. /kg ww soil | 1000 | > 0.88 mg/kg wet weight | Combined AR |
| Primary and secondary poisoning | PNECoral for birds | NOEC = 0.0038 mg/kg food  NOEL = 3.85E-04 mg/kg bw/day | 30 | 1.3E-04 mg/kg food  1.3E-05 mg/ kg bw/ day | Combined AR |
| PNECoral for mammals | NO(A)EL=0.001mg a.s/kg bw/day  NOEC= (0.001\*20)=0.02 mg a.s/kg food | 90 | 1.1E-05 mg/kg bw/day  2.22E-04 mg/kg food | Combined AR |

According to the combined AR, the lowest PNEC values (from Syngenta limited or Activa / PelGar brodifacoum and difenacoum Task Force) are used in the risk assessment.

#### PBT and ED Assessment

Persistence

According to results given in the combined AR, brodifacoum is not readily, inherently or anaerobically biodegradable. In addition, brodifacoum is hydrolytically stable, but undergoes rapid photolysis in water. These results indicate, according to screening criteria, that brodifacoum can be considered as potentially persistent (P) and very persistent (vP).

Bioaccumulation

Based on log Kow = 6.12 and BCFfish = 35 645 L.Kg-1 (according to Equation 75; GBPR), brodifacoum potentially fulfils the B criterion and vB criterion.

Toxicity

Brodifacoum is proposed to be classified as Repr. Cat 1 or 2, R61. brodifacoum is also proposed to be classified as T+;R26/27/28, R43, R48/23/24/25, R61, N;R50/53. According to the GBPR, brodifacoum fulfils the T criterion.

**Brodifacoum is considered as a potential PBT, according to the GBPR on Risk Assessment (2003)**.

### Effects on environmental organisms for biocidal product

It is important to note that the applicant did not provide ecotoxicological data about the biocidal product FANGA B+ RONGEUR. So the whole effect assessment for the product is based on the data obtained from the active substance brodifacoum (Combined Assessment Report According to Directive 98/8EC, Active substance in Biocidal Products, Brodifacoum CAS 56073-10-0, Product Type 14 (Rodenticides), RMS Italy, Revision 2: November 2010).

Denatonium benzoate is used in the biocidal product as bittering agent. This substance is classified as “Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment” in the frame of the Directive 91/414/EEC. Nevertheless at the concentration used in FANGA B+ RONGEUR, the substance does not contribute to the classification of the biocidal product.

The 2,6−di−tert.−butyl−p−crésol as ”BHT” is used in the biocidal product as antioxydant. This substance is classified as Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment” according to the product Data Sheet. Nevertheless in the concentration used in the product FANGA B+, the substance does not contribute to the classification of the biocidal product.

No other substance used in the biocidal product is classified for the environment.

#### Aquatic compartment (including water, sediment and STP)

##### Aquatic organisms

Refers to section Aquatic compartment (including water, sediment and STP)

##### Sediment dwelling organisms

Refers to section Aquatic compartment (including water, sediment and STP)

##### STP micro-organisms

Refers to section Aquatic compartment (including water, sediment and STP)

#### Atmosphere

Refers to section Atmosphere

#### Terrestrial compartment

Refers to section Terrestrial compartment

#### Non compartment specific effect relevant to the food chain

Refers to section **Erreur ! Source du renvoi introuvable.**

#### Summary of PNECs

Refers to section Summary of PNECs of the active substance Brodifacoum

### Environmental exposure assessment

As the product contains no substances of concern except brodifacoum, it is considered that risks posed to environment following the use of FANGA B+ RONGEUR can adequately be assessed based on the evaluation conducted for the active substance. Therefore the exposure assessment is carried out with the data obtained from the active substance brodifacoum only.

The product FANGA B+ RONGEUR is a rodenticide bait containing 0.001% brodifacoum (0.01 g/kg). The product is in the form of a paste (individually packaged in sachet). Baits are placed in secured bait box for professional and non-professional users. The product is used as 40 g for mouse and 200 g for rat / bait point. The secured bait points are refilled 4 times over 28 days. Dead rodents and unconsumed baits are removed each week.

FANGA B+ RONGEUR is used in the following areas:

* In and around buildings (professional and non-professional use);
* Open areas (professional and non-professional use);
* Waste dumps area (professional use only).

For the intended uses, the terrestrial (including groundwater) compartment is the only relevant compartment of release. The risks are also calculated for primary and secondary poisoning.

#### Aquatic compartment (surface water, sediment, STP)

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for sewers. Contamination of surface water, STP or sediment with brodifacoum from the placing of bait in and around buildings, in open areas or in waste dumps is considered negligible according to the ESD PT14.

#### Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 2.6 x 10-22 Pa at 20°C and low Henry’s law constant of 2.35 x 10-18 Pa.m3.mol-1), brodifacoum is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FANGA B+ RONGEUR biocidal product.

#### Terrestrial compartment (soil and groundwater)

##### In and around buildings

The exposure assessment has been carried out according to the ESD (Larsen, 2003) for rodenticides (ESD PT14)[[18]](#footnote-18) and the GBPR IV Part B[[19]](#footnote-19). The ESD PT14 indicates that the only primary compartment to be exposed during a use in and around buildings is the terrestrial compartment. Emission calculations to soil and groundwater were conducted with the default parameters of the ESD PT14 as well as the specific information on the product provided by the applicant:

* A brodifacoum concentration of 0.001% (w/w),
* The protection of baits in bait stations,
* Maximal dose rates: 200 g for rats and 40 g for mice,
* Minimal distance between two bait points: 4 m for rats and 1 m for mice (default value) / 5 m for rats and 1 m for mice (specific parameter),
* Number of refilling times: 5 (default value) / 4 (specific parameter).

Exposure of the terrestrial compartment (soil) will occur when brodifacoum bait is deployed outdoors. ESD (Larsen, 2003) considers a scenario that entails outdoor baiting with bait blocks around a farm building. In this situation, exposure is assumed to arise through a combination of transfer (direct release) and deposition *via* urine and faeces (disperse release) onto soil. The active substance metabolism is taken into account; ESD (Larsen, 2003) considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces.

In both scenarios, the direct and disperse brodifacoum releases (Elocalsoil, mg) to the relevant soil surfaces may be calculated according to the input values presented in the table below. The different PEC values are calculated using the GBPR equations. The degradation in soil was not considered in the calculations.

Table 2.8.4‑6 PEC brodifacoum in soil and groundwater for uses in and around buildings

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | **ESD Default parameters: realistic worst-case** | | **Refined and specific parameters: typical scenario** | |  |
| **Symbol** | | **Variable/parameters** | **Rat** | **Mouse** | **Rat** | **Mouse** | **Unit** | |
| **INPUTS** |
| Q*prod:* | | Amount of product used in control operation for each bait box | 200 | 40 | 200 | 40 | [g] | |
| Fc*product*: | | Concentration of active substance in product | 0.01 | 0.01 | 0.01 | 0.01 | [g.kg-1] | |
| Nsites: | | Number of application sites | 10 | 10 | 10 | 10 | [-] | |
| N*refil*: | | Number of refilling times | 5 | 5 | 4 | 4 | [-] | |
| F*release-D, soil*: | | Fraction of product released directly to soil | 0.01 | 0.01 | 0.01 | 0.01 | [-] | |
| F*release-ID, soil*: | | Fraction released indirectly to soil | 0.9 | 0.9 | 0.9 | 0.9 | [-] | |
| Koc | | Organic carbon adorption coefficient | 9 155 | 9 155 | 9 155 | 9 155 | [L.kg-1] | |
| Distance | | Distance between 2 bait points | 4 | 1 | 5 | 1 | [m] | |
| AREA*exposed-D*: | | Area directly exposed to rodenticide originating from one bait box | 0.09 | 0.09 | 0.09 | 0.09 | [m2] | |
| AREA*exposed-ID*: | | Area indirectly exposed to rodenticide | 440 | 110 | 510 | 110 | [m2] | |
| DEPTH*soil*: | | Depth of exposed soil | 0.1 | 0.1 | 0.1 | 0.1 | [m] | |
| RHO*soil*: | | Density of exposed soil | 1700 | 1700 | 1700 | 1700 | [kg.m-3] | |
| **OUTPUTS** |
| Elocal*soil-campaign, direct*: | | *Direct emission to soil from a campaign* | 1.00E-03 | 2.00E-04 | 8.00E-04 | 1.60E-04 | [g.camp-1] | |
| Elocal*soil-campaign, indirect*: | | *Indirect emission to soil from a campaign* | 8.91E-02 | 1.78E-02 | 7.13E-02 | 1.43E-02 | [g.camp-1] | |
| Elocal*soil-campaign*: | | *Total emission to soil from a campaign* | 9.01E-02 | 1.80E-02 | 7.21E-02 | 1.44E-02 | [g.camp-1] | |
| Clocal*soil-D* | | *Local concentration in soil due to direct release (AREAexposed-D) after a campaign:* | 6.54E-03 | 1.31E-03 | 5.23E-03 | 1.05E-03 | [mg.kg-1wwt] | |
| Clocal*soil-ID* | | *Concentration in soil due to indirect (disperse=* *AREAexposed-ID ) release after a campaign:* | 1.19E-03 | 9.53E-04 | 7.62E-04 | 7.62E-04 | [mg.kg-1wwt] | |
| **Clocal*soil*** | | ***Worst case total concentration in soil =* Clocal*soil-D +* Clocal*soil-ID*** = ***PECsoil*** | **7.73E-03** | **2.26E-03** | **5.99E-03** | **1.81E-03** | **[mg.kg-1wwt]** | |
| **Clocalsoil mean concentration** | | ***Mean concentration in soil. The total amount of product release (=Elocalsoil-campaign) is divided by the whole area exposed(=AREAexposed-ID)*** | **1.20E-03** | **9.64E-04** | **7.71E-04** | **7.71E-04** | **[mg.kg-1wwt]** | |
| Kpsoil | | *Partition coefficient solid-water in soil* | 1.83E+02 | 1.83E+02 | 1.83E+02 | 1.83E+02 | [L.kg-1] | |
| Ksoil water | | *Soil-water partitioning coefficient* | 2.75E+02 | 2.75E+02 | 2.75E+02 | 2.75E+02 | [m3.m-3] | |
| **PEClocal soil, porew** | | ***Worst case concentration in groundwater (based on the total concentration in soil)*** | **4.78E-05** | **1.40E-05** | **3.71E-05** | **1.12E-05** | **[mg.L-1]** | |
| **PEClocal soil, porew** | | ***Mean concentration in groundwater (based on mean concentration in soil)*** | **7.45E-06** | **5.96E-06** | **4.77E-06** | **4.77E-06** | **[mg.L-1]** | |

***High-tier assessment for groundwater***

For the scenario “in and around buildings”, the calculated values for the groundwater compartment indicated a potential risk to groundwater. A higher-tier assessment of the potential for groundwater contamination has also been carried out using the simulation model FOCUS-PEARL 4.4.4. Simulations were performed for all nine FOCUS scenarios.

It is necessary to calculate an effective brodifacoum application rate on a per-hectare basis.

The corresponding application rate of brodifacoum to land can be calculated using the following equation:

Where:

|  |  |  |  |
| --- | --- | --- | --- |
| Symbol | Value | Unit | Source |
| *Q prod* | 0.2\* | [kg] | Input |
| *Fc product* | 1E-05 | [kg.kg-1] | Input |
| N sites | 10\*\* | [-] | Input |
| N *refil*: | 5 | [-] | Input |
| AREA *exposed* | 440 | [m2] | Input |
| AREA *total* | 10 000 | [m2] | Input |
| *Appl rate* | 2.27E-03 | [kg.ha-1.yr-1] | Output |

.\* Amount of product used in control operation for each bait box

.\*\* ESD Default parameters: realistic worst-case

One application of brodifacoum were modelled each year during the simulation period (20 years), each at a rate of 2.27 g a.s.ha-1. In accordance with FOCUS guidelines, applications were simulated to the soil surface. Canopy interception was set to 0% in the simulations.

**Relevant input variables in PEARL**

| **Parameter** | **Unit** | **Value** |
| --- | --- | --- |
| ***Substance parameters*** | | |
| Molecular weight | g.mol-1 | 523.42 |
| Water solubility (20 °C) | mg.L-1 | 0.058 |
| Molar enthalpy of dissolution | kJ.mol-1 | 27 |
| Saturated vapour pressure (20 °C) | Pa | 2.6E-22 |
| Molar enthalpy of vaporisation | kJ.mol-1 | 95 |
| Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 |
| Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 |
| Half-life (20°C, pF2) | d | 157 |
| Arrhenius activation energy | kJ.mol-1 | 65.4 |
| Kom\*\* value | mL.g-1 | 5310.32 |
| Freundlich exponent 1/n | - | 0.951 |
| Method of subroutine description | - | pH independent |
| ***Tab Scenario*** | | |
| Location | | All 9 EU scenarios |
| Crop Calendar | | GRASS |
| Irrigation | | FOCUS standard irrigation scheme |
| Tillage | | No tillage |
| Repeat interval for application events (years) | | 1 |
| Deposition | | No deposition |
| **Absolute Application** | | |
| Application type | | To the soil surface |
| Date | | 01-May |
| Dosage (kg/ha) | | 2.27E-03 |

**Overview of results of FOCUS runs**

|  |  |  |
| --- | --- | --- |
| RESULT\_TEXT | Brodifacoum | LOCATION |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | CHATEAUDUN |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | HAMBURG |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | JOKIOINEN |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | KREMSMUENSTER |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | OKEHAMPTON |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | PIACENZA |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | PORTO |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | SEVILLA |
| Concentration closest to the 80th percentile (ug/L) | 0.000000 | THIVA |

Calculated PECGW for brodifacoum, represented by the 80th percentile annual average leachate concentration at a soil depth of 1 m, were <0.0001 μg.L-1 for all scenarios. All PECGW values for brodifacoum and its metabolites were therefore several orders of magnitude below the trigger value of 0.03 μg.L-1, indicating safe use for brodifacoum.

##### Open areas

FANGA B+ RONGEUR is applied in open areas inside or near the openings of the tunnels of the target rodents. According to the ESD (Larsen, 2003), the use near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. Thus this section “Open areas” only assesses the use inside the tunnels during which, according to the scenario presented in ESD (Larsen, 2003), two treatments would typically be applied in the interval of six days. Bait deployment comprises 200 g of product against rats and 40 g against mice per application and per tunnel entrance. Based on a tunnel of 8 cm diameter, worst-case soil exposure is assumed to occur to a depth of 10 cm from the contact half (*i.e*. the burrow floor) of a 30 cm tunnel section in which the bait is placed. This section of tunnel floor is assumed to receive an input corresponding to 5% of the product during application and a further 20% as the bait is consumed. This scenario is worst case as the product FANGA B+ RONGEUR is intended to be applied in secured bait boxes only.

Considering the localized treated area, the risk for groundwater from this use was not considered relevant.

Table 2.8.4‑7 PEC of brodifacoum in soil and groundwater for uses in open area

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | Rat treatment | Mice treatment | unit |
| INPUTS | Qprod: | | Amount of product used in control operation | 200 | 40 | [g.burrow-1] | |
| Fc*product*: | | Fraction of active substance in product | 0.01 | 0.01 | [g a.i. kg-1] | |
| N*app*: | | Number of application sites | 1 | 1 | [-] | |
| N*refil*: | | Number of refilling times | 2 | 2 | [-] | |
| F*release, soil, appl*: | | Fraction of product released to soil during application | 0.05 | 0.05 | [-] | |
| F*release, soil, use*: | | Fraction of product released to soil during use | 0.2 | 0.2 | [-] | |
| Vsoil*exposed*: | | Soil volume exposed to rodenticide | 0.0085 | 0.0085 | [m3] | |
| RHO*soil*: | | Density of wet exposed soil | 1700 | 1700 | [kg.m-3] | |
| Koc | | Organic carbon adorption coefficient | 9155 | 9155 | [L.kg-1] | |
|  | |
| OUTPUTS | Elocal*soil-campaign* | | *Local emission of active substance to soil during a campaign* | 1.00E-03 | 2.00E-04 | [g.camp] | |
| Clocal*soil* | | *Local concentration in soil after a campaign* | 6.92E-02 | 1.38E-02 | [mg.kg-1wwt] | |

##### Waste dumps

The default exposure scenario suggests in the event of an infestation outbreak a treatment with 40 kg of baits distributed over an area of 1 ha, with a total of seven applications per year. In this situation, soil exposure is assumed to arise through a combination of deposition via urine and faeces combined with rodenticide contained in the carcasses of poisoned target rodents. In general, ninety percent of the total amount of rodenticide consumed by the target rodents over the duration of each baiting campaign is assumed to enter soil over the 1 ha surface.

FANGA B+ RONGEUR is intended to be used in bait boxes containing 200 g of biocidal product (0.001%) with 5 m spacing. So to predict the concentration of bromadiolone in soil and groundwater for the uses in waste dump, the intended doses are calculated for the 1 ha surface as below:

Q*prod* = (length of the waste dump of 1ha/distance between bait) + 1) x (length of the waste dump of 1ha/distance between bait) x (amount of product per bait point)

Q*prod* = ((100 m /5 m) + 1) x (100 m / 5 m) x 0.2 kgproduct

Q*prod* = 84 kg/ha

The ESD (Larsen, 2003) considers that, in general, 90% of the total amount of rodenticide consumed by the target rodents over the duration of the outdoor baiting campaign enters soil via urine and faeces.

Table 2.8.4‑8 PEC of brodifacoum in soil and groundwater for uses in waste dump

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | **Anticoagulant-Rat- ESD default values** | **Dose for rat intended by the applicant** | **Unit** | |
| INPUT | **Q*prod*** | Amount of product used in control operation / ha | 40 | 84 | [kg.ha-1] |
| **Fc*product*** | Fraction of active substance in product | 0.01 | 0.01 | [g a.i.kg-1] |
| **N*app*** | Number of applications | 7 | 7 | [-] |
| **F*release, soil*** | Fraction of product released to soil | 0.9 | 0.9 | [-] |
| **AREA*exposed*** | Area exposed to rodenticide | 10 000 | 10 000 | [m2] |
| **DEPTH*soil*** | Depth of exposed soil | 0.1 | 0.1 | [m] |
| **RHO*soil*** | Density of wet exposed soil | 1700 | 1700 | [kg.m-3] |
| **Koc** | Organic carbon adsorption coefficient | 9 155 | 9 155 | [L.kg-1] |
| OUTPUT | **Elocal*soil-campaign*** | *Local emission of active substance to soil from a campaign* | 2.5 | 5.3 | [g.camp-1] |
| **Clocal*soil*** | *Local concentration in soil after a campaign* | 1.48E-03 | 3.11E-03 | [mg.kg-1wwt] |
| **Kpsoil** | *Partition coefficient solid-water in soil* | 1.83E+02 | 1.83E+02 | [L.kg-1] |
| **Ksoil water** | *Soil-water partitioning coefficient* | 2.75E+02 | 2.75E+02 | [m3.m-3] |
| **PEClocal soil, porew** | *Concentration in groundwater* | 9.17E-06 | 1.93E-05 | [mg.L-1] |

#### Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

##### Primary poisoning

Non-target birds and mammals may encounter bait containing brodifacoum if they are small enough to be able to reach the bait, or because the bait is inadequately safeguarded or a secured bait point has become damaged, or by finding pieces of bait which have been removed by target rodents. The quantities of brodifacoum potentially accessible to non-target mammals can be calculated based on the size and number of bait at each secured bait point and an estimate of the amount of bait removed from them. The primary poisoning risk assessment is presented in this dossier according to the scenario “in and around building” covering the other uses.

Primary poisoning - Tier 1 assessment

The Tier 1 assessment assumes that the whole day’s food requirement is satisfied by consumption of bait and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 10 mg.kg-1 (0.001 % w/w of brodifacoum in FANGA B+ RONGEUR). Hence, **the worst case Tier 1 PEC oral is 10 mg.kg-1**.

**For birds**, a separate, graded assessment of long-term risks of primary poisoning by bait has been done. It is based on different intakes of brodifacoum-treated bait in relation to untreated food, depending on to which extent brodifacoum bait is accessible to birds.

**Table 2.8.4‑**9 **PECoral for non-target, birds exposed to brodifacoum in bait removed from secured bait points in and around buildings**

|  |  |
| --- | --- |
| **Proportion of bait point contents accessible, expressed as fraction of ingested food (%)** | **Bromadiolone conc. potentially ingested by non-target vertebrates (mg/kg)  PECoral** |
| 100 | 10 |
| 50 | 5 |
| 40 | 4 |
| 30 | 3 |
| 20 | 2 |
| 10 | 1 |
| 5 | 0.5 |
| 2 | 0.2 |
| 1 | 0.1 |

Primary poisoning - Tier 2 assessment, acute exposure

According to ESD (Larsen, 2003), a Tier 2 assessment can be done estimating a daily uptake of a compound (ETE, mg.kg-1bw.d-1) by non-target animals according to the equation 19 of ESD:

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

With:

ETE is the estimated daily uptake of the active substance (mg.kg-1bw.d-1),

FIR: food intake rate of the indicator species (g.d-1),

BW: indicator species body weight (g),

C: concentration of the active substance in fresh diet (mg.kg-1),

AV: avoidance factor (-),

PT: fraction of diet obtained in treated area (-),

PD: the fraction of the food type in the diet (-).

In Tier 2 step 1 (worst case) AV, PT and PD are all set at 1; in Step 2 (realistic worst case) AV and PT are refined to 0.9 and 0.8, respectively.

Table 2.8.4‑10 Expected concentrations of brodifacoum in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target mammal** | **BW (g)a** | **FIR**  **(g dry weight.day-1)** | **C (mg.kg-1)** | **ETE = concentration of brodifacoum after one meal**  **(mg.kg-1 bw.d-1)** | |
| **Step 1** | **Step 2** | |
| **Dog** | 10 000 | 456b | 10 | 0.46 | 0.33 | |
| **Pig** | 80 000 | 600a | 10 | 0.08 | 0.05 | |
| **Pig, young** | 25 000 | 600a | 10 | 0.24 | 0.17 | |
| **Tree sparrow** | 22 | 7.6a | 10 | 3.45 | 2.49 | |
| **Chaffinch** | 21.4 | 6.42a | 10 | 3.00 | 2.16 | |
| **Wood pigeon** | 490 | 53.1a | 10 | 1.08 | 0.78 | |
| **Pheasant** | 953 | 102.7a | 10 | 1.08 | 0.78 | |

a From EUBEES 2, Table 3.1, Section 3.2.1.

b From EUBEES 2, using the equation log FIR = 0.822 log BW – 0.629 (for mammals)

Primary poisoning – Tier 2 assessment, long-term exposure

The long-term risks of brodifacoum are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC are calculated by using the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (Step 2), calculated above. When calculating the long-term risks, elimination and metabolism of the substance (El) have to be considered. Calculations are performed according to the equation 20 of the ESD (Larsen, 2003).

**EC = ETE\*(1-El)**

According to the ESD (Larsen, 2003), a default value of 0.3 for daily uptake eliminated (El) can be used if no studies are submitted. The EC values are the expected concentration of active substance brodifacoum in non-target animals in primary poisoning scenarios after one meal followed by 24 hour elimination period.

**Table 2.8.4‑**11 **Expected concentrations of brodifacoum in non-target animals in realistic worst case (Step 2) for long-term situation.**

|  |  |
| --- | --- |
| **Non-target animal** | **PEC: EC, concentration of brodifacoum after one day elimination (mg/kg)** |
| Dog | 0.23 |
| Pig | 0.04 |
| Pig, young | 0.12 |
| Tree sparrow | 1.74 |
| Chaffinch | 1.51 |
| Wood pigeon | 0.55 |
| Pheasant | 0.54 |

##### Secondary poisoning

###### ***Secondary poisoning via the aquatic food chain***

As no exposure of the aquatic compartment is foreseen with the use of FANGA B+ RONGEUR for the uses in and around buildings, in open areas and in waste dumps, no risk assessment for secondary poisoning through the aquatic food chain is required.

###### ***Secondary poisoning via the terrestrial food chain***

According to the GBPR secondary poisoning through the terrestrial route is soil → terrestrial organisms (earthworm) → earthworm-eating mammal or bird. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in the soil. The risk assessment for secondary poisoning for earthworm-eating mammals and birds has been carried out for the in and around use and for the waste dump application. As the use in open area is quite localised, the exposure of earthworm was deemed negligible in this case.

The calculation is done according to equation 80 and 82 (GBPR, 2015):

**PEC oral, predator = C earthworm**

**C earthworm = (BCF earthworm \* C porewater) + C local soil mean concentration \* F gut \* CONV soil) / (1+Fgut \* CONV soil)**

With (example for rat treatment application for the in and around - typical scenario):

BCF earthworm = 15 820 L.kg wet earthworm-1,

C porewater = 4.77 E-06 mg.L-1 (based on mean concentration in soil – typical case)

C local soil mean concentration = 7.71 E-04 mg.kg-1wwt,

F gut = 0.1 Kg dwt.kg wwt-1,

CONV soil = 1.13 Kg wwt.kg dwt-1,

According to the GBPR, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, thus when the PEC local, soil is used in calculation, the PEC oral, predator to be used in risk assessment is C earthworm x 0.5.

**Table 2.8.4‑**12 **Expected concentrations of brodifacoum in predator**

|  |  |  |
| --- | --- | --- |
|  | **PEC oral, predator mg/kg wet earthworm-1** | |
| **ESD Default parameters: realistic worst-case** | **Refined and specific parameters: typical scenario** |
| ***TIER I: Worst case (based on the total concentration in soil)*** | | |
| *Rat treatment* | 3.40E-01 | 2.64E-01 |
| *Mice treatment* | 9.94E-02 | 7.96E-02 |
| ***TIER I: Mean (based on the mean concentration in soil)*** | | |
| *Rat treatment* | 5.30E-02 | 3.39E-02 |
| *Mice treatment* | 4.24E-02 | 3.39E-02 |
| ***TIER II: Mean (based on the mean concentration in soil) + considering degradation in soil*** | | |
| *Rat treatment* | 5.12E-02 | 3.28E-02 |
| *Mice treatment* | 4.10E-02 | 3.28E-02 |

###### ***Secondary poisoning for the rodent-eating mammal or the rodent-eating bird***

According to the ESD (Larsen, 2003) document, for uses ‘in and around buildings’, ‘open areas’ and ‘waste dumps’, it is assumed that predators among mammals and birds may occur inside buildings or they may hunt rats in the immediate vicinity of buildings (parks and gardens or further away). Scavengers may also search for food close to buildings. Therefore secondary poisoning through poisoned rats exists, even in case of an indoor use. Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access.

###### Secondary poisoning - Tier 1 assessment, acute

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of brodifacoum in their food, i.e. the poisoned rodents. This PECoral is then compared to the LC50 values for a qualitative risk assessment in accordance with the decision from TM III-06. According to the ESD section 3.3.1, the consumption of rodenticides makes up at least 20 % of total consumptions in a choice test and could in a worst case be up to 100 %, whilst 50 % would be considered as the normal situation. Therefore, in the calculations the fractions of the food type in the diet (PD) are set to 0.2, 0.5 and 1.0. The FIR/BW quotient (food intake rate of the indicator species/indicator species body weight) is a default value set to 0.1, i.e. it is assumed that the rats eat 10 % of their bodyweight each day. The avoidance factor (AV) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PT) obtained in the area is set to 1.

The calculation is done according to equation 19 in the ESD:

**ETE = (FIR/BW) \* C \* AV \* PT \* PD (mg brodifacoum.kg bw-1.day-1)**

This equation gives the concentration of brodifacoum in the rat (PECoral) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by the equation 21 in the ESD:

n

For the active substance brodifacoum, the default value of 0.3 is used for elimination (El).

Table 2.8.4‑13 Residues of brodifacoum in target animals at specific point in times and varying bait consumption

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Residues in target animal (mg.kg-1 bw)** | | |
| **20%** | **50%** | **100%** | |
| Day 1 after the first meal | 0.20 | 0.50 | 1.00 | |
| Day 2 before new meal | 0.14 | 0.35 | 0.70 | |
| **Day 5 after the last meal** | 0.55 | 1.39 | 2.77 | |
| Day 7 mean time to death | 0.27 | 0.68 | 1.36 | |

According to the ESD, the concentrations of brodifacoum in rats are at peak after consuming bait for 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide. The values from day 5 are used as PECoral.

###### Secondary poisoning - Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days are used considering that the consumption of rodenticides makes up 100% of total consumptions (refer to Table above).

**Table 2.8.4‑**14 **Residues of brodifacoum in target animals at specific point in times and varying bait consumption used in the long term assessment**

|  |  |
| --- | --- |
| **Birds / Mammals** | **PECoral**  **Brodifacoum conc. in target rodent (mg.kg-1 bw),**  **ESD default values** |
| **Day 5 after the last meal** | 2.77 |

###### Secondary poisoning - Tier 2 assessment, long-term

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, according to the Table 3.5 in the ESD. The calculations are based on the expected values for uptake of active substance by a mammal predator after a single day of exposure presented as an illustrative example in the ESD.

The amount of a.i. consumed by the non-target animal is 2.77 mg.kg-1 bw for rodents caught on day 5 and 3.31 mg.kg-1 bw for rodents caught on day 14, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal, the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in Table below.

**Table 2.8.4‑**15 **Expected concentrations of brodifacoum in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of brodifacoum in rodenticide bait 0.001%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | **Normal susceptible rodents caught on day 5** | | **Resistant rodents caught on day 14** | | |
| **Species** | **Body weight**  **(g)** | **Daily mean food intake**  **(g.d-1)** | **Amount a.i. (mg)1** | **Conc. (mg.kg-1)2** | **Amount a.i. (mg)1** | **Conc. (mg.kg-1)2** |
| Barn owl  *(Tyto alba)* | 295 | 72.9 | 0.10 | 0.34 | 0.12 | 0.41 |
| Kestrel  *(Falco tinnunculus)* | 209 | 78.7 | 0.11 | 0.52 | 0.13 | 0.62 |
| Little owl  *(Athene noctua)* | 164 | 46.4 | 0.06 | 0.39 | 0.08 | 0.47 |
| Tawny owl  *(Strix aluco)* | 426 | 97.1 | 0.13 | 0.32 | 0.16 | 0.38 |
| Fox  *(Vulpes vulpes)* | 5700 | 520.2 | 0.72 | 0.13 | 0.86 | 0.15 |
| Polecat  *(Mustela putorius)* | 689 | 130.9 | 0.18 | 0.26 | 0.22 | 0.31 |
| Stoat  *(Mustela erminea)* | 205 | 55.7 | 0.08 | 0.38 | 0.09 | 0.45 |
| Weasel  *(Mustela nivlis)* | 63 | 24.7 | 0.03 | 0.54 | 0.04 | 0.65 |

1Amount a.i. consumed by non-target animal

2 Conc. in non-target animal

### Risk characterisation for the environment

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD50) according to the guidance in Technical guidance document (GBPR, 2003) and “Emission Scenario document for biocides used as rodenticides” (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

#### Aquatic compartment (including water, sediment and STP)

##### In and around building

Exposure scenario is not considered relevant in the ESD for rodenticides. brodifacoum is not expected to occur to any significant extent following the use of FANGA B+ RONGEUR in and around buildings. Therefore, PEC values for brodifacoum in surface water and sediment are assumed to be negligible and have not been further considered.

##### Open areas

Exposure of surface water arising from the use of FANGA B+ RONGEUR bait in open areas is not expected to be significant or widespread for open area uses. Therefore, estimates of brodifacoum concentrations in surface water have not been calculated and aquatic PEC/PNEC ratios are not presented. Since the scope for exposure is negligible, the risks presented to aquatic biota by brodifacoum are expected to be very low. No further assessment of risk is necessary.

##### Waste dumps

Exposure of surface water arising from the use of FANGA B+ RONGEUR bait is not expected to be significant or widespread for waste dump uses. Therefore, estimates of brodifacoum concentrations in surface water have not been calculated and aquatic PEC/PNEC ratios are not presented. Since the scope for exposure is negligible, the risks presented to aquatic biota by brodifacoum deployed in waste dumps are expected to be very low. No further assessment of risk is necessary.

#### Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 2.6 x 10-22 Pa at 20°C and low Henry’s law constant of 2.35 x 10-18 Pa.m3.mol-1), brodifacoum is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FANGA B+ RONGEUR biocidal product.

#### Terrestrial compartment (including soil and groundwater)

Soil exposure occurs both through a combination of direct and indirect releases from the use of FANGA B+ RONGEUR bait in the scenario ‘in and around buildings’, ‘open areas’ and ‘waste dump’.

##### In and around building

Exposure of the terrestrial compartment (soil) will occur when FANGA B+ RONGEUR is deployed outdoors.

Realistic worst case and typical case predicted soil concentrations (PECs) have been calculated for the use scenario in and around buildings, for application in control campaign. The resulting PEC/PNEC ratios for the worst case scenario (addition of direct and indirect exposure) for the soil are summarized in the table below:

Table 2.8.5‑16 PECsoil/PNECsoil for soil organisms exposed to brodifacoum following outdoor use of bait around buildings

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Baiting scenario**  **(ESD PT14)** | **PECsoil**  **(mg brodifacoum.kg wwt soil-1)** | | **PNECsoil (mg brodifacoum.kg wwt soil-1)** | **PEC/PNEC ratio** |
| **Realistic worst case** | |
| Rat treatment | 7.73E-03 | | 0.88 | 8.78E-03 |
| Mice treatment: | 2.26E-03 | | 2.57E-03 |
| **Typical scenario** | |
| Rat treatment | 5.99E-03 | | 0.88 | 6.81E-03 |
| Mice treatment | 1.81E-03 | | 2.05E-03 |

The PEC/PNEC ratios are below 1 indicating no unacceptable risks to the terrestrial compartment when the product FANGA B+ RONGEUR is used in and around building.

The risk is acceptable in groundwater for the use of FANGA B+ RONGEUR in and around building as presented below:

Table 2.8.5‑17 PEC groundwater due to use of FANGA B+ RONGEUR in and around building

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Baiting scenario**  **(ESD PT14)** | **PEC groundwater (µg brodifacoum.L-1)** | | **Threshold value in groundwater (µg.L-1)** | **Risk characterization** |
| **Realistic worst case** | |
| Rat treatment | <0.0001 | | 0.03\* | Acceptable |
| Mice treatment | <0.0001 | |
| **Typical scenario** | |
| Rat treatment | <0.0001 | | 0.03\* | Acceptable |
| Mice treatment | <0.0001 | |

‘1 After refinement by Focus model

\*0.03µg/L corresponds on the threshold value for the toxicity in drinking water.

##### Open areas

Exposure of the terrestrial compartment (soil) will occur when FANGA B+ RONGEUR bait is applied in open areas by inserting inside the openings of the tunnels of the target rodents.

Predicted soil concentrations (PECs) have been calculated for the use scenario in open areas, for application in rats/rodents control campaign according to the doses claimed by the applicant. The resulting PEC/PNEC ratios for the soil are summarized in the table below:

Table 2.8.5‑18 PECsoil/PNECsoil for soil organisms exposed to brodifacoum following use of bait in open area

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario (EUBEES 2)** | **PECsoil**  (mg /kg wwt) | **PNECsoil**  (mg /kg wwt) | **PEC/PNEC** |
| **Typical use (rat treatment)** | 6.92E-02 | 0.88 | 0.079 |
| **Typical use (mice treatment)** | 1.38E-02 | 0.016 |

The PEC/PNEC ratios are below 1.0 and indicate that there are no unacceptable risks to the terrestrial compartment when the product FANGA B+ RONGEUR is used in the tunnels of open areas. According to the EUBEES 2 scenario, the use near the openings of the tunnels is covered by the assessment of the scenario “in and around buildings” with bait box. As argued above (section above), there is no unacceptable risk for the terrestrial compartment (including groundwater) when the FANGA B+ RONGEUR is used near the openings of the tunnels of the target rodents.

Considering the localized treated area in the tunnels, the risk for groundwater was not considered relevant.

##### Waste dump

Predicted soil concentrations (PECs) have been calculated for the use scenario in waste dump. The resulting PEC/PNEC ratios for the soil are summarized in the Table below:

Table 2.8.5‑19 PECsoil/PNECsoil for soil organisms exposed to brodifacoum following use of bait at waste dumps

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario**  **(ESD PT14)** | **PECsoil**  **(mg brodifacoum.kg wwt soil-1)** | **PNECsoil (mg brodifacoum.kg wwt soil-1)** | **PEC/PNEC ratio** |
| **Rat treatment**  **(40 kg.ha-1)** | 1.48E-03 | 0.88 | 0.002 |
| **Rat treatment**  **(84 kg.ha-1)** | 3.11E-03 | 0.88 | 0.004 |

The PEC/PNEC ratios are below 1 indicating that there no unacceptable risks to the terrestrial compartment when the product FANGA B+ RONGEUR is used in waste dump.

Table 2.8.5‑20 PEC groundwater due to use of FANGA B+ RONGEUR in waste dump

|  |  |  |  |
| --- | --- | --- | --- |
| **Baiting scenario**  **(ESD PT14)** | **PEC groundwater (µg brodifacoum.L-1)** | **Threshold value in groundwater (µg.L-1)** | **Risk characterization** |
| **Rat treatment**  **(40 kg.ha-1)** | 9.17E-03 | 0.03 | Acceptable |
| **Rat treatment**  **(84 kg.ha-1)** | 1.93E-02 | Acceptable |

The risk for groundwater is acceptable.

#### Non-compartmental specific effects relevant to the food chain

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD50) according to the guidance in Technical guidance document (GBPR, 2003) and “Emission Scenario document for biocides used as rodenticides” (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

Bait containing brodifacoum contains also 50 mg denatonium benzoate per kg, a powerful bittering agent that is intended to deter accidental ingestion of blocks or gains by humans. It may also deter some non-target mammals.

###### Primary poisoning

Tier 1 assessment

The PEC value for Tier 1 assessment is compared to the long-term PNEC for mammals and for birds.

**Table 2.8.6.1‑6 Tier 1 risk characterization of primary poisoning – Long-Term**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PEC1**  mg.kg food-1 | **PNEC1**  mg.kg food-1 | **PEC/PNEC** |
| **Mammals** | 10 | 2.22E-04 | **45 000** |
| **Birds** | 10 | 1.30E-04 | **77 000** |

1 Concentration of brodifacoum in food.

The resulting PEC/PNEC ratio reveals a high risk of long-term primary poisoning for mammals.

For birds, a separate, graded assessment of long-term risks of primary poisoning by bait has been done. It is based on different intakes of brodifacoum-treated bait in relation to untreated food, depending on to which extent brodifacoum bait is accessible to birds. The PNEC for birds has been used as a worst case in the calculations.

Table 2.8.6.1‑7 PEC oral/ PNEC oral for non-target, birds exposed to brodifacoum in bait removed from secured bait points in and around buildings

|  |  |  |  |
| --- | --- | --- | --- |
| **Fraction of ingested food (%)** | **PECoral**  mg.kg food-1 | **PNEC**  mg.kg food-1 | **PEC/PNEC** |
| 100 | 10 | 1.30E-04 | **76 923** |
| 50 | 5 | **38 462** |
| 40 | 4 | **30 769** |
| 30 | 3 | **23 077** |
| 20 | 2 | **15 385** |
| 10 | 1 | **7 692** |
| 5 | 0.5 | **3 846** |
| 2 | 0.2 | **1 538** |
| 1 | 0.1 | **769** |

The long-term assessment indicates clearly unacceptable risks even if only 1% of the food is constituted of bait. The risk is, however, mitigated by the prerequisite that good practice requires that secured bait points, containing bait in a chamber not directly accessible from the access hole, be used in locations where a potential for avian exposure exists.

**Tier 2 assessment – acute**For the acute situation of primary poisoning only a qualitative risk assessment is carried out in accordance with the decision from TM III-06. In this Tier 2 acute qualitative assessment, the PEC values are compared to the LD50 value.

Table 2.8.6.1‑8: Tier 2 acute qualitative risk assessment of primary poisoning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **PECoral1**  mg.kg-1 bw | | **LD50 dose**  mg.kg-1 bw d-1 | **PECoral > LD50**  **(y/n)** | |
| Step 1 | Step 2 | Step 1 | Step 2 |
| **Tree sparrow** | 3.45 | 2.49 | 0.31 | y | y |
| **Chaffinch** | 3.00 | 2.16 | y | y |
| **Wood pigeon** | 1.08 | 0.78 | y | y |
| **Pheasant** | 1.08 | 0.78 | y | y |
| **Dog** | 0.46 | 0.33 | 0.4 | y | n |
| **Pig** | 0.08 | 0.05 | n | n |
| **Pig young** | 0.24 | 0.17 | n | n |

1 PECoral = ETE, concentration of brodifacoum after one meal

The qualitative approach for the acute situation confirms the potential risk of primary poisoning to dogs. The level of the risk is not clarified for all other species with this approach, as A PEC below the LD50 does not indicate the absence of unacceptable risk if the required margin of safety is not established

**Tier 2 assessment – long-term**

The PEC values are compared to the PNEC values.

Table 2.8.6.1‑9: Tier 2 long-term risk assessment of primary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECoral1**  **mg.kg-1 bw** | **PNEC**  **mg.kg-1 bw d-1** | **PEC /PNEC** |
| **Step 2** | | |
| **Dog** | 0.57 | 1.1E-05 | **51 818** |
| **Pig** | 0.09 | **8 182** |
| **Pig young** | 0.30 | **27 273** |
| **Tree sparrow** | 4.35 | 1.3E-05 | **334 615** |
| **Chaffinch** | 3.78 | **290 769** |
| **Wood pigeon** | 1.37 | **105 385** |
| **Pheasant** | 1.36 | **104 615** |

1 PECoral = EC, concentration of brodifacoum after one day of elimination

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Non-target animal** | | **PECoral**1  mg.kg-1 bw | **PNEC**  mg.kg-1 bw d-1 | | **PEC/PNEC** | |
| Dog | 0.23 | | | 1.10E-05 | | **20 909** |
| Pig | 0.04 | | | **3 636** |
| Pig, young | 0.12 | | | **10 909** |
| Tree sparrow | 1.74 | | | 1.30E-05 | | **133 846** |
| Chaffinch | 1.51 | | | **116 154** |
| Wood pigeon | 0.55 | | | **42 308** |
| Pheasant | 0.54 | | | **41 538** |

1 PECoral = EC, concentration of brodifacoum after one day of elimination

This assessment provides indication of very high risks to both mammals and birds, but, it should be noted that consumption of these quantities of brodifacoum bait is generally not realistic and should be regarded strictly as worst case.

#### Secondary poisoning

###### ***Secondary poisoning via the aquatic food chain***

As no exposure of the aquatic compartment is foreseen with the use of FANGA B+ RONGEUR for the uses in and around buildings, in open areas and in waste dumps, no risk assessment for secondary poisoning through the aquatic food chain is required.

###### ***Secondary poisoning via the terrestrial food chain***

**The PEC oral predator values are compared to the long-term PNEC for mammals and for birds.**

Table 2.8.6.2‑1. risk characterization of secondary poisoning via the terrestrial food chain

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PEC oral, predator**  mg/kg wet earthworm-1 | | **PNEC oral**  mg.kg food-1 | | **PEC/PNEC** | | | | |
| **ESD Default parameters** | **Typical scenario** | **Mammals** | **Birds** | **ESD Default parameters** | | **Typical scenario** | | |
| **Mammals** | **Birds** | **Mammals** | **Birds** | |
| ***TIER I: Worst case (based on the total concentration in soil)*** | | | | | | | | | |
| *Rat treatment* | 3.40E-01 | 2.64E-01 | 2.22E-04 | 1.30E-04 | **1 532** | **2 615** | **1 189** | | **2 031** |
| *Mice treatment* | 9.94E-02 | 7.96E-02 | **448** | **765** | **359** | | **612** |
| ***TIER I: Mean (based on the mean concentration in soil)*** | | | | | | | | | |
| *Rat treatment* | 5.30E-02 | 3.39E-02 | 2.22E-04 | 1.30E-04 | **239** | **408** | **153** | | **261** |
| *Mice treatment* | 4.24E-02 | 3.39E-02 | **191** | **326** | **153** | | **261** |
| ***TIER II (based on time-weight average concentration (180d) in soil)*** | | | | | | | | | |
| *Rat treatment* | 5.12E-02 | 3.28E-02 | 2.22E-04 | 1.30E-04 | **231** | **394** | **148** | | **252** |
| *Mice treatment* | 4.10E-02 | 3.28E-02 | **185** | **315** | **148** | | **252** |

Whatever the scenario, the PEC/PNEC ratio exceeds 1 for both earthworm eating birds and mammals.

***Secondary poisoning for the rodent-eating mammal or the rodent-eating bird***

##### Tier 1 assessment, acute

The PECoral are compared to the LC50 value presented in the section above for qualitative risk assessment in accordance with the decisions taken at the TMII-06.

Table 2.8.6.2‑2: Tier 1 long-term risk assessment of secondary poisoning

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  mg.kg-1 bw | | | **LC50 dose**  mg.kg-1 food | **PECoral > LC50**  **(y/n)** | | | |
| PD=0.2 | PD=0.5 | PD=1 |  | PD=0.2 | PD=0.5 | PD=1 |
| Birds | 0.55 | 1.39 | 2.77 | 8 | n | n | n |
| Mammals | 2.8 | 6.9 | 13.9 | 0.72 | **y** | **y** | **y** |

1 PECoral = Expected concentration in rodent caught on day 5 after meal

PD = fraction of the food type in the diet

This qualitative risk assessment indicates no risk for birds and indicates risk for mammals at all fractions of food type in the diet and with a PEC in rodent caught on day 5 after meal

Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 5 days is used and compared to the long-term PNECoral for birds and mammals.

Table 2.8.6.2‑3 Tier 1 long-term risk assessment of secondary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  mg.kg-1 bw | **PNEC**  mg.kg-1 food | **PEC /PNEC** |
| Birds | 2.77 | 1.30E-04 | **21 308** |
| Mammals | 2.77 | 2.22E-04 | **12 477** |

PECoral = Expected concentration in rodent caught on day 5 after meal

The tier 1 long-term assessment indicates very high risks of long-term secondary poisoning for birds and mammals.

##### Tier 2 assessment, long-term

**Table 2.8.6.2‑4: Tier 2 long-term risk assessment of secondary poisoning**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species** | **PEC (mg/kg bw)** | | **PNEC (mg/kg bw)** | **PEC/PNEC** | | |
| **day 5** | **day 14** |  | **day 5** | **day 14** |
| Barn owl  *(Tyto alba)* | 0.34 | 0.41 | 1.30E-05 | **26 154** | **31 538** |
| Kestrel  *(Falco tinnunculus)* | 0.52 | 0.62 | **40 000** | **47 692** |
| Little owl  *(Athene noctua)* | 0.39 | 0.47 | **30 000** | **36 154** |
| Tawny owl  *(Strix aluco)* | 0.32 | 0.38 | **24 615** | **29 231** |
| Fox  *(Vulpes vulpes)* | 0.13 | 0.15 | 1.10E-05 | **11 818** | **13 636** |
| Polecat  *(Mustela putorius)* | 0.26 | 0.31 | **23 636** | **28 182** |
| Stoat  *(Mustela erminea)* | 0.38 | 0.45 | **34 545** | **40 909** |
| Weasel  *(Mustela nivlis)* | 0.54 | 0.65 | **49 091** | **59 091** |

The tier 2 risk characterisation shows very high risks for secondary poisoning at long-term for birds and mammals. Nevertheless, in order to reduce the risk of secondary poisoning, it is very important to follow the use instructions of the rodenticide baits. The risk reduction measures are considered in the section 2.9.

### Conclusion of the risk assessment for the environment

No studies were conducted with the product FANGA B+ RONGEUR for the environment part; therefore the environmental risk assessment has been carried out with data from the Combined AR of brodifacoum. The environmental risk is considered as limited for the indoor use by non-professionals and for the use in and around building by professionals, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

Nevertheless, the Authority in charge of the efficacy and risk assessment is not able to assess the applicability of the specific use instructions and restrictions for

* the outdoor applications by non-professionals ;
* the use in open area by professionals ;
* the use in waste dump by profession

***Risk mitigation measures linked to risk assessment for environment***

***professionals***

* Use in tamper-resistant bait boxes or in covered bait stations. The bait stations must be placed only in areas not accessible to the general public and non-target animals.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Never wash the tamper-resistant bait boxes and covered bait stations with water.
* Place the tamper-resistant bait boxes and covered bait stations in areas non-liable to floodings.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment[[20]](#footnote-20).
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Dispose of the tamper-resistant bait boxes and covered bait stations, packaging, uneaten baits and dead rodents in accordance with local requirements.
* Remove all bait points after the end of treatment.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

Non-professional uses

* Use only in tamper-resistant bait boxes.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Never wash the tamper-resistant bait boxes with water.
* Place the tamper-resistant bait boxes in areas non-liable to floodings
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Dispose of the tamper-resistant bait boxes, packaging, uneaten baits and dead rodents in accordance with local requirements.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Remove all bait points after the end of treatment.

***Disposal considerations for professional et non-professional users***

* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Dispose of the tamper-resistant bait boxes and covered bait stations, packaging, uneaten baits and dead rodents in accordance with local requirements.
* Never wash the tamper-resistant bait boxes and covered bait stations with water.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Remove all bait points after the end of treatment.

***Required information linked to risk assessment for environment***

None.

|  |
| --- |
| * **Renewal application - 2019**   No new ecotoxicological information has been submitted at the renewal of the approval of the active substance brodifacoum and in the product dossier. No studies were conducted with the product FANGA B+ RONGEUR for the environment part; therefore the environmental risk assessment has been carried out with data from the combined CAR of brodifacoum. The environmental risk is considered as acceptable for the intended uses except for the primary and secondary poisoning. The specific use restriction must be applied to reduce the risk for primary and secondary poisoning.  The conclusions remains unchanged. |

## Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC).*

# Proposal for decision – Renewal 2019

**1. Administrative information**

**1.1. Trade name(s) of the product**

| **Trade name(s)** | FANGA B+ RONGEUR |
| --- | --- |
|  |  |

**1.2. Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | TRIPLAN |
| **Address** | BP 258 LA POSTE FRANCAISE  AD500  ANDORRA LA VELLA  ANDORRE |
| **Authorisation number** | FR-2016-0006 | |
| *Suffixes to the authorisation number linked to trade names* |  | |
| *R4BP asset reference number* |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

**1.3. Manufacturer(s) of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | HDA |
| **Address of manufacturer** | ZA LA CHARME MENETROL  63200 RIOM  FRANCE |
| **Location of manufacturing sites** | ZA LA CHARME MENETROL  63200 RIOM  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | AEDES PROTECTA |
| **Address of manufacturer** | 75 rue d'Orgemont  95210 SAINT-GRATIEN  FRANCE |
| **Location of manufacturing sites** | LIEU DIT DOUILLAC  81310 PARISOT  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | RATOUCY SAS |
| **Address of manufacturer** | 29 rue de la Forêt LOOZE - BP145  89303 JOIGNY  FRANCE |
| **Location of manufacturing sites** | 29 rue de la Forêt LOOZE - BP145  89303 JOIGNY  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | SOFAR FRANCE |
| **Address of manufacturer** | ZA DU DREVERS BP 02  29190 PLEYBEN  FRANCE |
| **Location of manufacturing sites** | ZA DU DREVERS BP 02  29190 PLEYBEN  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | EKO-DEZ d.o.o |
| **Address of manufacturer** | VUKASOVICEVA 55/9  11090 BELGRADE  SERBIA |
| **Location of manufacturing sites** | VUKASOVICEVA 55/9  11090 BELGRADE  SERBIA |

|  |  |
| --- | --- |
| **Name of manufacturer** | INDUSTRIAL CHIMICA SRL |
| **Address of manufacturer** | VIA SORGAGLIA 40  35020 ARRE (PD)  ITALIA |
| **Location of manufacturing sites** | VIA SORGAGLIA 40  35020 ARRE (PD)  ITALIA |

|  |  |
| --- | --- |
| **Name of manufacturer** | FARMAVIT OOD |
| **Address of manufacturer** | Bul Tsar Boris III, n°63, Office n°1  1612 SOFIA  BULGARIA |
| **Location of manufacturing sites** | Industrialna Str 2. - Pleven District  5960 GULIANTSI  BULGARIA |

|  |  |
| --- | --- |
| **Name of manufacturer** | IRIS |
| **Address of manufacturer** | 1126A, Avenue du Moulinas, Route de Saint-Privat  30340 SALINDRES  FRANCE |
| **Location of manufacturing sites** | 1126A, Avenue du Moulinas, Route de Saint-Privat  30340 SALINDRES  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | SALOMEZ |
| **Address of manufacturer** | ZI Av. du Général de GAULLE  89130 TOUCY  FRANCE |
| **Location of manufacturing sites** | ZI Av. du Général de GAULLE  89130 TOUCY  FRANCE |

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

|  |  |
| --- | --- |
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | ACTIVA / TEZZA |
| **Address of manufacturer** | VIA FELTRE 32  20132 MILAN  ITALIE |
| **Location of manufacturing sites** | VIA FELTRE 32  20132 MILAN  ITALIA |

**2. Product composition and formulation**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Brodifacoum | 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.0010 % m/m |
| Monopropylene glycol | propane-1,2-diol | Co-formulant | 57-55-6 | 200-338-0 | 2.4836 |
| Triethanolamine | 2,2',2’’-nitrilotriéthanol | Co-formulant | 102-71-6 | 203-049-8 | 0.0172 |

**2.2. Type of formulation**

|  |
| --- |
| Ready-to-use bait: (grain) |

**3. Hazard and precautionary statements**

| Hazard statements |  |
| --- | --- |
| Precautionary statements | P statements in this section should only be those resulting from classification according to the CLP Regulation and not statements that correlate to risk mitigation. Such statements should be included in sections 4 or 5. |

**4. Authorised use(s)**

**4.1. Use description**

**Table 1. Use # 1 – House mice and/or rats – trained professionals – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | Mus musculus (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations[[21]](#footnote-21)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats: 100 g of bait per baiting point every 5 to 10 meters.  - Mice: 40 g of bait per baiting point every 1 to 2 meters. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| - Remove the remaining product at the end of treatment period.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.1.2. 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 (e.g. 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. |

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

|  |
| --- |
| - When placing bait points close to water drainage systems, ensure that bait contact with water is avoided. |

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

|  |
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|  |

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

|  |
| --- |
|  |

**4.2. Use description**

**Table 2. Use # 2 Mice and/or rats – trained professionals – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations.  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats: 100 g of bait per baiting point every 5 to 10 meters.  - Mice: 40 g of bait per baiting point every 1 to 2 meters. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.2.1.* *Use-specific instructions for use***

|  |
| --- |
| - 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*.*  - *[When available]* Follow any additional instructions provided by the relevant code of best practice.  *- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].* |

***4.2.2. 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 this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use this product in pulsed baiting treatments.  - Do not apply this product directly in the burrows. |

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

|  |
| --- |
| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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

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|  |

**4.3. Use description**

**Table 3. Use # 3 – Mice and/or rats – trained professionals – Outdoor open areas & waste dumps**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor open areas □  Outdoor waste dumps □ |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations.  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  - Rats: 100 g of bait per baiting point every 5 to 10 meters.  - Mice: 40 g of bait per baiting point every 1 to 2 meters. |
| **Category(ies) of users** | Trained professionals only |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.3.1.* *Use-specific instructions for use***

|  |
| --- |
| - Protect bait from the atmospheric conditions. Place the bait stations 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 *[Not applicable where explicitly authorised according to addenda 4]*.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice.  *- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].* |

***4.3.2. 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]*.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatmentat frequent intervals*,* in line with the recommendations provided by the relevant code of best practice.  - Do not use this product in pulsed baiting treatments  - Do not apply this product directly in the burrows. |

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

|  |
| --- |
| - When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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

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**4.4. Use description**

**Table 4. Use # 4 *(not relevant in France)*– House mice – professionals – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations[[22]](#footnote-22) |
| **Application rate(s) and frequency** | 40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 1 to 2 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40 g) or in bulk.  PE/PP sachet (20-25-30-40 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.4.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited at least every 2 to 3 days 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. |

***4.4.2. Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.5. Use description**

**Table 5. Use # 5 *(not relevant in France)*– Rats – professionals – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - 100 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.5.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited only 5 to 7 days 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.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

***4.5.2. Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
| - When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided. |

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

|  |
| --- |
|  |

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

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|  |

**4.6. Use description**

**Table 6. Use # 6 *(not relevant in France)*– House mice and/or rats – professionals – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - Rats: 100 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 5 to 10 meters.  - Mice: 40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 1 to 2 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only****: minimum pack size of 5 kg)*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g) or in bulk.  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bag (paper bags with or without plastic film PE) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20kg  - Cardboard box 5-10-12-15-20-50kg  Loose baits are packed in:  - PE or PP sachets (100-200-300-400-500-600-700-800-900-1000g) and packed in carton box (5-10-12-15-18-20 kg)  - Bag (paper bags with or without PE film) 5-10-15-20-25kg  - Bucket (PE) 5-10-15-18-20-25kg  - Cardboard box (with a PE film) 5-10-12-15-20-25-50kg |

***4.6.1.* *Use-specific instructions for use***

|  |
| --- |
| - 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 *[for mice -* at least every 2 to 3 days at*]* *[for rats -* only 5 to 7 days 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. |

***4.6.2. Use-specific risk mitigation measures***

|  |
| --- |
| - Do not apply this product directly in the burrows. |

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

|  |
| --- |
| - When placing bait stations close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided. |

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

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|  |

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

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|  |

**4.7. Use description**

**Table 7. Use # 7 – House mice – general public – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations[[23]](#footnote-23). |
| **Application rate(s) and frequency** | Bait products:  - 40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 1 to 2 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 50 g for mice and 150 g for mice and rats*.*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g).  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bucket (PE)  - Metal box without lacquer  - HDPE container  - Cardboard box  - Bait box (plastic PET/PP/PE/PVC) |

***4.7.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited at least every 2 to 3 days 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. |

***4.7.2. Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

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

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|  |

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

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|  |

**4.8. Use description**

**Table 8. Use # 8 – Rats – general public – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor. |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  - Rats: 100 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 150 g*.*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g).  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bucket (PE)  - Metal box without lacquer  - HDPE container  - Cardboard box  - Bait box (plastic PET/PP/PE/PVC) |

***4.8.1.* *Use-specific instructions for use***

|  |
| --- |
| - The bait stations should be visited only 5 to 7 days 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. |

***4.8.2. Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.8. Use description**

**Table 8. Use # 8 – Rats – general public – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  - Rats: 100 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 150 g*.*  FANGA B+ RONGEUR is supplied in PE/PP sachet (20-25-30-40-50-100 g).  PE/PP sachet (20-25-30-40-50-100 g) are packed in:  - Bucket (PE)  - Metal box without lacquer  - HDPE container  - Cardboard box  - Bait box (plastic PET/PP/PE/PVC) |

***4.8.1.* *Use-specific instructions for use***

|  |
| --- |
| - Place the bait stations in areas not liable to flooding.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - The bait stations should be visited only 5 to 7 days 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. |

***4.8.2. Use-specific risk mitigation measures***

|  |
| --- |
| - Do not apply this product directly in the burrows. |

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

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|  |

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

|  |
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***4.8.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage***

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**5. General directions for use**

**5.1. Instructions for use**

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - 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.  - The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - 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 *(see section 5.3 for the information to be shown on the label)*.  - *[If national policy or legislation requires 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.  ***FOR TRAINED PROFESSIONAL ONLY****- 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.  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.  ***FOR PROFESSIONNALS ONLY*** 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.  ***FOR PROFESSIONNALS ONLY*** Remove the remaining bait or the bait stations at the end of the treatment period.  *- Instructions for use that are "bait-specific":*   * *Do not open the sachets containing the bait*.   **FOR NON PROFESSIONAL USERS**  - 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 *- where relevant for the bait formulation in the product].*  - 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. |

**5.2. Risk mitigation measures**

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| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - 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".  - ***FOR TRAINED PROFESSIONAL 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.  - ***FOR TRAINED PROFESSIONAL ONLY*** 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]*.  - ***FOR PROFESSIONAL ONLY*** 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].*  - ***FOR PROFESSIONAL ONLY*** Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - ***FOR PROFESSIONAL ONLY.*** 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").   - ***FOR PROFESSIONAL ONLY*** 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.  **FOR NON PROFESSIONAL USERS**  - 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.  - Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).  - 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]*. |

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

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| - 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.  - Antidote: Vitamin K1 administered by medical/veterinary personnel only.  - In case of:  - Dermal exposure, wash skin with water and then with water and soap.  - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.  - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*  - 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]*"  - Hazardous to wildlife. |

**5.4. Instructions for safe disposal of the product and its packaging**

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| - At the end of the treatment, dispose the uneaten bait and the packaging in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

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| - Store in a dry, cool and well ventilated place. 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: 24 months |

**6. Other information**

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| - (**in France only** : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum. Results of the resistance monitoring must be submitted at the renewal of the product.)  - Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.  - 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. |

# Appendices

Annex 0a: Practical use claimed by the applicant – updated 2018

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the product and type of formulation (grains, powder, paste, block…)** | **Target organism (rat, mice…)\*** | **User category (professional/non professional)\*** | **Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,…)\*** | **Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)** | **Time delay of the action of the product** | **Frequency and method of controls** | **Size(s) of the bait (g/bloc, g/grain, g/sachet, g/paste  …)** | **Distance between 2 bait points, for high and low infestation (if appropriate)** | **Methods of application of the bait (ex: pre-filled secured bait box)** | **Package details : Individual packaging (yes/no)\*\*** | **Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes** | **Secondary packaging** | **Accepted and authorised by the RMS (yes/no)** |
| **FANGA B+ RONGEUR**  Formulation: grains | Brown rat*: Rattus norvegicus* | Professional | In and around buildings, open areas, waste dumps | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | yes | sachet | Bag (paper bags several layers with one or without plastic film in PE) 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20 kg  Carton box (carton) - 5-10-12-15-20-50 kg |  |
| Brown rat*: Rattus norvegicus* | Professional | In and around buildings, open areas, waste dumps | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | bulk | 5-10 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | no | bulk | Sachet PE or PP 100g -200-300-400-500-600-700-800-900- 1000g packed in carton box 5-10-12-15-18- 20 kg  Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20-25 kg  Carton box (cardboard with a plastic bag inside) - 5-10-12-15-20 -25-50kg |  |
| Brown rat*: Rattus norvegicus* | Non professional | In and around buildings, open areas | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Pre-filled secured boxes  Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | yes | sachet | Bucket (PE) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Carton box (carton) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Metal box (without lacquer) - 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm  Flacon (PEHD) 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg |  |
| Black rat: *Rattus rattus* | Professional | In and around buildings, open areas, waste dumps | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | yes | sachet | Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20 kg  Carton box (cardboard)- 5-10-12-15-20-50 kg |  |
| Black rat: *Rattus rattus* | Professional | In and around buildings, open areas, waste dumps | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | bulk | 5-10 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | no | bulk | Sachets PE or PP100g -200-300-400-500-600-700-800-900- 1000g packed in carton box from 5-10-12-15-18- 20 kg  Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20-25 kg  Carton box (cardboard with a plastic bag inside) - 5-10-12-15-20 -25-50kg |  |
| Black rat: *Rattus rattus* | Non professional | In and around buildings, open areas | 100 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Pre-filled secured boxes  Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm | yes | sachet | Bucket (PE) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Carton box (carton) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Metal box (without lacquer) - 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Bait box (plastic PET/PP/PE/PVC ) dimensions 230 mm x 135 mm x 85 mm  Flacon (PEHD) 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg |  |
| Mice: *Mus musculus* | Professional | In and around buildings, open areas, waste dumps | 30-40 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20- 30- 40g sachet | 1-2 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 127 mm x 95 mm x35 mm | yes | sachet | Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20 kg  Carton box (carton) - 5-10-12-15-20-50 kg |  |
| Mice: *Mus musculus* | Professional | In and around buildings, open areas, waste dumps | 30-40 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | bulk | 1-2 meters | Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 127 mm x 95 mm x35 mm | no | bulk | Sachets PE or PP100g -200-300-400-500-600-700-800-900- 1000g packed in carton box from 5-10-12-15-18- 20 kg  Bag (paper bags several layers with one or without plastic film in PE) – 5-10-15-20-25 kg  Bucket (PE) - 5-10-15-18-20-25 kg  Carton box (cardboard with a plastic bag inside) - 5-10-12-15-20 -25-50kg |  |
| Mice: *Mus musculus* | Non professional | In and around buildings, open areas | 30-40 g/secured bait point | 3 to 10 days | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 20 - 30 - 40g sachet | 1-2 meters | Pre-filled secured boxes  Manual application of baits in secured  bait box (plastic PET/PP/PE/PVC ) dimensions 127 mm x 95 mm x35 mm | yes | sachet | Bucket (PE) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Carton box (carton) – 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Metal box (without lacquer) - 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg  Bait box (plastic PET/PP/PE/PVC ) dimensions 127 mm x 95 mm x 35 mm  Flacon (PEHD) 0,1-0,2 -0,3-0,4 -0,5 – 0,6-0,7- 0,8- 0,9- 1- 1,2- 1,3-1,4-- 1,5 kg |  |

Annex 0b: Proposed uses for authorisation in the frame of the Minor Change 2018

*This table reflects the results of the risk assessment. In case of differences between the uses suggested by Anses to be authorised and the uses contained in the decision taken by the French ministry, only the original and signed decision has a legal value.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the product and type of formulation (grains, powder, paste, block…)** | **Target organism (rat, mice…)** | **User category (professional/non professional)** | **Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps…)** | **Dosage validated expressed in g/bait point, for high and low infestation (if appropriate)** | **Methods of application of the bait (ex: pre-filled secured bait box)** | **Primary packaging: type : bulk, individual wrapping…** | **Authori-zation** |
| **FANGAB+ RONGEUR**  Formulation: grain bait | Mice: *Mus musculus* | Professional | In and around buildings | 30 - 40 g grains/secured bait station separated by 1-2 meters. | Manual application of baits in tamper-resistant bait boxes or in covered bait stations  Bait points should be controlled and resupply as long as the bait is consumed:   * 3 days after the first application then weekly for use in and around building | Sachet (polyethylene) and bulk in bucket, carton, paper bag  Sachet (polyethylene) and bulk in bucket, carton, paper bag | yes |
| Black and Brown *rats (Rattus rattus and attus Norvegicus)* | Professional | In and around buildings | 100 g grains/secured bait station separated  5-10 meters |
| Mice: *Mus musculus* | Non-Professional | Indoor only | 30 - 40 g grains/secured bait boxes separated by 1-2 meters. | Manual application of baits in tamper-resistant bait boxes or in covered bait stations  Bait points should be controlled and resupply as long as the bait is consumed:   * 3days after the first application then weekly for use in the building | Sachet (polyethylene) |
| Black and Brown *rats (Rattus rattus and attus Norvegicus)* | Non-Professional | Indoor only | 100 g grains/secured bait boxes separated by 5-10 meters. |

Annex 0c: Proposed uses for authorisation in the frame of the renewal 2019

*This table reflects the results of the risk assessment. In case of differences between the uses suggested by Anses to be authorised and the uses contained in the decision taken by the French ministry, only the original and signed decision has a legal value.*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the product and type of formulation (grains, powder, paste, block…)** | **Target organism (rat, mice…)** | **User category (professional/non professional)** | **Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps…)** | **Dosage validated expressed in g/bait point, for high and low infestation (if appropriate)** | **Methods of application of the bait (ex: pre-filled secured bait box)** | **Primary packaging: type : bulk, individual wrapping…** | **Authori-zation** |
| **FANGAB+ RONGEUR**  Formulation: grain bait | Mice: *Mus musculus* | Professional | In and around buildings | 40 g grains/secured bait station separated by 1-2 meters. | Manual application of baits in tamper-resistant bait boxes or in covered bait stations  Bait points should be controlled and resupply as long as the bait is consumed:   * 3 days after the first application then weekly for use in and around building | Sachet (polyethylene) and bulk in bucket, carton, paper bag  Sachet (polyethylene) and bulk in bucket, carton, paper bag | yes |
| Black and Brown *rats (Rattus rattus and attus Norvegicus)* | Professional | In and around buildings | 100 g grains/secured bait station separated  5-10 meters |
| Mice: *Mus musculus* | Non-Professional | Indoor only | 40 g grains/secured bait boxes separated by 1-2 meters. | Manual application of baits in tamper-resistant bait boxes or in covered bait stations  Bait points should be controlled and resupply as long as the bait is consumed:   * 3days after the first application then weekly for use in the building | Sachet (polyethylene) |
| Black and Brown *rats (Rattus rattus and attus Norvegicus)* | Non-Professional | Indoor only | 100 g grains/secured bait boxes separated by 5-10 meters. |

Annex 1: Summary of product characteristics

*See separated file.*

* **Minor change application - 2018**

*See section 3 : ”Proposal for decision – Minor change 2018”.*

Annex 2: List of studies reviewed

##### List of new data[[24]](#footnote-24) submitted in support of the evaluation of the active substance

**None**

##### List of new data submitted in support of the evaluation of the biocidal product

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section n°/**  **Reference n°** | **Author** | **Year** | **Title** | **Data protectionY/N** | **Owner** | **Letter of Acces**  **Y/N** | **Essential for the evaluation**  **Y/N** |
| B3.1,3.4 | De Ryckel B | 2012 | Physical and chemical properties and storage stability of FANGA B+ RONGEUR- FIRST INTERIM REPORT Analysis on the test item as received and after 14 days at 54°C ± 2°C. Centre wallon de Recherches agronomiques, Report n°22718 of 6 September 2012, GLP. | Y | Triplan | N | Y |
| B3.2 | Ferron N | 2012 | Physico-chemical tests and analyses before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FANGA RONGEUR PRO in compliance with CIPAC MT 46.3. DEFITRACES, Report n° 11-920010-025 of 16 May 2012, GLP. | Y | Triplan | N | Y |
| B3.2-3.3 | Colombies N | 2012 | Physico chemical tests on FANGA RAT-DICAL TECH. DEFITRACES, report n° 11-920010-028 of 22 February 2012, GLP, unpublished | Y | Triplan | N | Y |
| B3.3, 4.1, 4.2, 4.4, 4.17.1 | Demangel B | 2012 | Physico chemical tests on FANGA RONGEUR PRO. DEFITRACES, Report n°11-920010-024 of 23 January 2012, GLP. | Y | Triplan | N | Y |
| B3.4 | De Ryckel B | 2014 | Physical and chemical properties and storage stability of FANGA B+ RONGEUR FINAL REPORT Analysis on the test item as received after 14 days at 54°C ± 2°C and after 16 months and 2 years at 20°C ± 2°C. Centre wallon de Recherches agronomiques, Report n° 22718 of 29 April 2014, GLP. | Y | Triplan | N | Y |
| B3.4, B3.5 | Demangel B | 2015 | Attrition resistance of granules after an accelerated storage procedure at 54°C for 14 days on BDB10V1, Report n° 15-920010-003 of 15 April 2015, GLP, unpublished. | Y | Triplan | N | Y |
| B3.5 | Grevin P | 2012 | Sieve test and dustiness for granular products test before and after an accelerated storage procedure for 8 weeks at 40 ± 2 °C on FANGA RONGEUR PRO In compliance with CIPAC MT46.3 - Handbook J (2000). DEFITRACES, Report n° 12-920010-008 of 28 September 2012, GLP. | Y | Triplan | N | Y |
| B5 | Ricau H | 2012 | Ricau H. 2012. Analytical method validation for the determination of Brodifacoum in the FANGA BLOC SP PRO in compliance with SANCO/3030/99 rev.4 from 11/07/00. DEFITRACES, Amended report n° 11-920010-015 of 04 May 2012, GLP. | Y | Ricau H | Y | Y |
| B5 | Ricau H | 2012 | Analytical method validation for the determination of brodifacoum in the FANGA RONGEUR PRO In compliance with SANCO/3030/99 rev. 4 from 11/07/00. DEFITRACES, Amended report n°11-920010-027 of 18 May 2012, GLP | Y | Triplan | N | Y |
| B5 | Ricau H | 2015 | Validation of the analytical method for the determination of brodifacoum in BDB10V1, Report n° 15-920010-002 of 14 April 2015, GLP, unpublished. | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Palatability of « FANGA B+ RONGEUR» ready-to-use bait (10 ppm Brodifacoum) targeting brown rat (*Rattus norvegicus*) and house mouse (*Mus musculus*). XXX. | Y | Triplan | N | N |
| B6.7 | XXX | XXX | Study on the palatability and the efficacy of a 0.001% Brodifacoum wheat bait in house mouse (*Mus musculus*). XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Study on the palatability and the efficacy of a wheat bait containing 0.001% Brodifacoum in brown rat (*Rattus norvegicus*). XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation of FANGA B+ RONGEUR (brodifacoum 0.001% w/w a.i., wheat bait) against Roof rat (*Rattus rattus* L.) in Italy. XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Study on the palatability and efficacy of a 0.001% w/w brodifacoum oat bait in black rat (Rattus rattus) XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation of BDB10V1 (brodifacoum 0.001% w/w a.i, oat bait) against Norway rats (Rattus norvegicus Berk.) in Italy, XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation of BDB10V1 (brodifacoum 0.001% w/w a.i, oat bait) against House mouse (Mus musculus L.) in Italy, XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation on BDB10V1 (brodifacoum 0.001% w/w a.i., blue wheat bait) against black rats (*Rattus rattus L.*) in Italy, XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation on BDB10V1 (brodifacoum 0.001% w/w a.i., blue wheat bait) against brown rats (*Rattus norvegicus* Berk*.*) in Italy, XXX | Y | Triplan | N | Y |
| B6.7 | XXX | XXX | Efficacy evaluation of BDB10V1 (brodifacoum 0.0010% w/w a.i;, wheat bait) against House mouse (*Mus musculus L.*) in Italy | Y | Triplan | N | Y |
| B8.1 | XXX | XXX | FANGA BLOC SP PRO assessment of acute dermal irritation. XXX | Y | Triplan | N | Y |
| B8.2 | XXX | XXX | FANGA BLOC SP PRO assessment of acute eye irritation. XXX | Y | Triplan | N | Y |
| B8.3 | XXX | XXX | FANGA BLOC SP PRO assessment of the skin sensitization potential in the mouse using the local lymph node assay (LLNA). XXX | Y | Triplan | N | Y |
| B8.5.1 | XXX | XXX | FANGA BLOC SP PRO evaluation of acute oral toxicity in rats – acute toxic class method. XXX | Y | Triplan | N | Y |
| B8.5.3 | XXX | XXX | FANGA BLOC SP PRO evaluation of acute dermal toxicity in rats. XXX | Y | Triplan | N | Y |
| B8.6 | XXX | XXX | ACTIPELLET-DIFE In vitro dermal delivery with human skin. XXX | Y | ACTIVA | N | Y |

Annex 3: Analytical methods residues – active substance

Brodifacoum

Date: 25.09.2015

Methods suitable for the determination of residues (monitoring methods)

Extract from document IIA of final CAR of brodifacoum.

Table 2.8.6.2‑1: Analytical methods for the determination of brodifacoum residue

| Sample | **Test substance** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of determination** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Range | Mean | RSD |
| Soil | *Brodifacoum* | RP-HPLC/DAD (detection at 264 nm) | 0.016÷-0.16 mg/kg in soil, with 4 replicates per level | 0.256÷-12.8 μg/ml (0.006÷-0.32 mg/kg in soil), single determinations at 8 concentrations levels. r2 = 0.9999  No matrix-matched calibration | Not highly specific  LC/MS method for confirmation (only experimental conditions  provided) | 88.5÷-95.4 (overall) | 92.9 (overall) | 2.2 (overall) | LOQ = 0.016 mg/kg in soil  (lowest validated concentration level) | **IIIA4.2 (a)** |
| Drinking water *(natural mineral water Fiuggi)* | *Brodifacoum* | RP-HPLC with MS/MS detection.  Molecular ion (SIM): 521 (m/z), daughter ion (SRM): 187 (m/z)  Quantification by calibration curve, except for spiking level 0.05 μg/l (quantification with the lowest standard calibration level) | 0.05 μg/l (n=5)  0.5 μg/l (n=5)  5.0 μg/l (n=5)  50 μg/l (n=5) | 0.1÷-0.5 μg/ml  (0.05÷-0.25 μg/l in water),  4 determinations at 5 concentration levels  r = 0.995 (SIM mode)  r = 0.997 (SRM mode) | Highly specific | 83.5*÷-*92.0  77.7*÷-*94.1  72.3*÷-*94.6  83.2*÷-*107.7 | 87.8  82.5  81.7  97.8 | 3.8  7.2  9.8  10.6 | LOQ = 0.05 05 μg/l in drinking and ground water;  0.5 μg/l in surface water  (lowest validated concentration level)  LOD = 0.025 μg/l in water | **IIIA4.2 (c)** |
| Ground water  *(Well SB1 I.Pi.Ci)* | 0.05 μg/l (n=5)  0.5 μg/l (n=5)  5.0 μg/l (n=5)  50 μg/l (n=5) | 80.4*÷-*100.6  82.6*÷-*94.4  80.1*÷-*94.6  81.3*÷-*101.2 | 90.5  98.7  87.3  92.5 | 9.3  5.6  7.3  7.0 |
| Surface water *(sampled at Desenzano, Garda lake)* | 0.05 μg/l (n=5)  0.5 μg/l (n=5)  5.0 μg/l (n=5)  50 μg/l (n=5) | 116*÷-*124.3  79.5*÷-*88.0  78.7*÷-*98.6  104.6*÷-*117 | 120.6  84.5  87.3  110.8 | 2.9  4.5  7.8  3.6 |
| Blood serum  (*from Rabbit, lyophilized powder from clotted whole blood)* | *Brodifacoum* | RP-HPLC with MS/MS detection.  Molecular ion (SIM): 523 (m/z), daughter ion (SRM): 187 (m/z)  Quantification by calibration curve at 0.06 mg/l , quantification with the lowest standard calibration level at 0.3 mg/l | 0.06 mg/l (n=5)  0.3 mg/l (n=6) | 0.05-0.40 μg/ml  (0.05-0.40 mg/l in blood serum), 4 determinations at 5 concentration levels  r = 0.99679 (SIM mode)  r = 0.99623 (SRM mode | Highly specific | 80.8-96.6  86.2-109.1 | 92.1  101.7 | 6.5  8.6 | LOQ = 0.06 mg/l (lowest validated concentration level) | **IIIA4.2 (d)(2)** |
| Cucumber | *Brodifacoum* | LC/MS/MS.  Internal standard: Difenacoum  Linear calibration curve for all determinations, except for both spiking levels in lemon and for the validation in meat at 0.1 mg/kg (multi-level calibration standards used)  Brodifacoum  precursor ion 1: 521; product ion 1: 79;  precursor ion 2: 523; product ion 2: 81  *Coumatetralyl*  precursor ion 1: 291; product ion 1: 143; precursor ion 2: 291; product ion 2: 141  Product ion 1 used for measurements | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 0.03-1.2 μg/ml,  2 determinations at 4 concentration levels. Matrix-matched calibration solutions used  r2: 0.9095÷-0.9963 | Highly specific | 82-103  86-106 | 91  94 | 9  9 | LOQ = 0.01 mg/kg in all 5 matrices (lowest validated concentration level) | **IIIA4.3**  **[also IIIA4.2(d)(1) for Meat only]** |
| Wheat | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 88-126  71-90 | 107  84 | 13  9 |
| Meat | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 62-86  45-87 | 73  61 | 13  29 |
| Oil-seed rape | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 75-99  110-134 | 86  119 | 10  8 |
| Lemon | 0.01 mg/kg (n=5)  0.1 mg/kg (n=5) | 74-93  62-89 | 84  76 | 10  13 |

**Annex 4 : Toxicology and metabolism –active substance**

**<BRODIFACOUM>**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 19/11/2014

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 3.3 x 10-6 mg/kg bw/d | Reproductive 2-generation study in rats | 300 |
| AEL medium-term | 6.67 x 10-6 mg/kg bw/d | Maternal toxicity from developmental study in rabbits | 300 |
| AEL acute  ADI  ARfD | 6.67 x 10-6 mg/kg bw/d 3.3 x 10-6 mg/kg bw/d  Not applicable | Maternal toxicity from developmental study in rabbits Reproductive 2-generation study in rats | 300 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 75% |
| Dermal absorption | 0.647% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | T+ R27/28  T ;R48/24/25  No specific limit concentrations |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 1 H310  Acute Tox 2 H300  STOT RE Cat 1 H372  No specific limit concentrations |

**Annex 5 : Toxicology – biocidal product**

**<FANGA B+ RONGEUR>**

Date: 19/11/2014

|  |  |
| --- | --- |
| **General information** | |
| Formulation Type | Cereal grain bait (wheat) |
| Active substance(s) (incl. content) | Brodifacoum (0.001% m/m) |
|  |  |

| **Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)** | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 420) | > 2 000 mg/kg bw |  |  |  |
| Rat LD50 dermal (OECD 402) | > 2 000 mg/kg bw |  |  |  |
| Rat LC50 inhalation (OECD 403) | No data submitted |  |  |  |
| Skin irritation (OECD 404) | Non irritant |  |  |  |
| Eye irritation (OECD 405) | Non irritant |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | Non sensitizing |  |  |  |

| **Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)** | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies | None |  |  |  |
| Toxicological data on active substance(s) (not tested with the preparation) | None |  |  |  |
|  | None |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | None |  |  |  |
|  | None |  |  |  |
| Further toxicological information | None | | | |

|  |  |
| --- | --- |
| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
| Directive 1999/45/EC | None |
| Regulation 1272/2008/EC | None |

**Annex 6 : Safety for professional operators**

**< FANGA B+ RONGEUR >**

Date: 19/11/2014

**Exposure assessment**

| **Exposure scenarios for intended uses (Annex IIIB, point 6.6 )** |
| --- |

Primary exposure of professionals – FANGA B+ RONGEUR – Control of rats

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| **Loose formulation** | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 2.37x10-7 | 5.01x10-7 | CEFIC  study |
| **Sachet formulation** | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 6.54 x10-8 | Not applicable | CEFIC  study |

Risk assessment – Professional

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| **Loose formulation** | | | | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 3.3x10-6 | 100 | 0.647 | 7.38x10-7 | 22 | Acceptable |
| **Sachet formulation** | | | | | | | | |
| Professionnal rat  (without gloves) | Brodifacoum | 56073-10-0 | 3.3x10-6 | 100 | 0.647 | 6.54x10-8 | 2 | Acceptable |

* **Renewal application - 2019**



**Annex 7 : Safety for non-professional operators and the general public**

**<FANGA B+ RONGEUR>**

Date:19/11/2014

| **General information** | |
| --- | --- |
| Formulation Type | Cereal grain bait (wheat) |
| Active substance(s) (incl. content) | Brodifacoum (0.001% m/m) |

| **<Active Substance>** |
| --- |

| **Data base for exposure estimation** | |
| --- | --- |
| according to | Appendix: Toxicology and metabolism – active substance/CAR |

| **Exposure scenarios for intended uses (Annex IIIB, point 6.6 )** | |
| --- | --- |
| Primary exposure | CEFIC Study and HEEG opinion n°12 |
| Secondary exposure, acute | Reverse scenario |
| Secondary exposure, chronic | na |

Conclusion:

Exposure of non-professionals and the general public to the biocidal product containing 0.001% brodifacoum as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Primary exposure of non professionals – FANGA B+ RONGEUR – Control of rats

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| **Sachet formulation** | | | | | |
| Non Professionnal | Brodifacoum | 56073-10-0 | 2.44x10-8 | Not applicable | CEFIC  study |

Risk assessment – Non -professional

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| **Sachet formulation** | | | | | | | | |
| Non Professionnal | Brodifacoum | 56073-10-0 | 6.7x10-6 | 100 | 0.647 | 2.44x10-8 | 0.4 | Acceptable |

* **Renewal application - 2019**



Annex 8: Residue behaviour

Brodifacoum

Date: 20.08.2015

**Intended Use:** TP14 - Rodenticide against wild mice, brown rats and black rats.

**Active substance:** brodifacoum

**Formulation of biocidal product:** bait

**Place of treatment:** In and around buildings and open areas by professional and non-professional users. In waste dumps and landfills by professional users.

The intended use descriptions of the brodifacoum-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as bait stations in and around buildings and open areas. No further data are required concerning the residue behaviour.

The intended uses are not relevant in terms of consumer health protection.

Annex 9a: Efficacy of the active substance from its use in the biocidal product

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Test substance*** | ***Test organism(s)*** | ***Test method*** | ***Test conditions*** | ***Test results: effects, mode of action, resistance*** | ***Reference\**** | ***RI*** |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *House mice*  *Mus musculus*  *Brown rat*  *Rattus norvegicus* | *Laboratory test*  *House mice: 10 animals (4 males and 6 females).*  *Brown rat: 10 animals (6 males and 4 females).*  *Intoxication duration: 20 days with daily measurement of mortality and food consumption.* | *Acclimation: 5 days in individual cage.*  *D0-D5: routine food has been given:*  *40.0 g for rats, 10.0 g for mice.*  *D6-D20: routine food and tested baits have been given in different feeding dishes.*  *40.0 g of routine food and 40.0 g of tested baits for rats*  *10.0 g of routine food and 10.0 g of tested baits for mice.*  *Food and bait consumption were measured and mortality was observed during 20 days after the first day of intoxication.* | *For brown rats: Only one rat did not eat tested bait all along the test.*  *Mean palatability percentage = 9.8 %*  *Mortality percentage = 70 %*  *For house mice: one which has eaten 1.3 g of bait did not die.*  *Mean palatability percentage = 50.7 %*  *Mortality percentage on house mouse = 80 %.* | XXX | *3* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *Brown rats*  *(Rattus norvegicus)* | *Laboratory test*  *Brown rats:*  *5 males and 5 females.*  *Intoxication duration: 4 days with daily measurement of mortality and consumption.* | *Acclimatization: 4 days in individual cage at room temperature.*  *Day 0: reference food and bait biocidal product have been given:*  *- 50 g per animal of reference food for the assessment of palatability,*  *- 50 g per animal of paste bait for the assessment of efficacy during 4 consecutive days with daily consumption measurements.*  *Mortality was observed during 21 days every 24 hours.* | *A palatability equivalent to 69.3 %*  *A mortality of 100 % in a period from day 4 to day 9* | XXX | *1* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *Brown rats*  *Rattus norvegicus* | *Field test*  *The rodenticide was evaluated using the census baiting technique, which involved the following phases:*  *Pre-treatment census*  *Pre-treatment lag phase*  *Treatment census*  *Post-treatment lag phase*  *Post-treatment census*  *During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.* | *Acclimatization: 17 days (200 g of wheat per station per day)*  *Treatment : 200 g of bait per day in each lockable bait station –total 8 bait stations) during 20 days*  *Post-baiting: 6 days*  *(200 g of wheat per station per day)* | *The efficacy was of 100 %.*   * *Pre-baiting plateau = 1298 g/day* * *Post-baiting = 0 g* * *Assessed efficacy = 100 %*   *The assessed bait has been very well accepted by brown rats and effective and the results are consistent with laboratory ones (100 %).* | XXX | *1* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *House mice (Mus musculus)* | *Laboratory test*  *House mice:*  *10 males and 10 females.*  *Intoxication duration: 4 days with daily measurement of mortality and consumption.* | *Acclimatization: 4 days in individual cage at room temperature.*  *Day 0: reference food and bait biocidal product have been given:*  *- 50 g per animal of reference food for the assessment of palatability,*  *- 50 g per animal of paste bait for the assessment of efficacy during 4 consecutive days with daily consumption measurements.*  *Mortality was observed during 21 days every 24 hours.* | *A palatability equivalent to 79.2 %*  *A mortality of 100 % in a period from day 3 to day 9* | XXX | *1* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *House mice (Mus musculus)* | *Field test*  *The rodenticide was evaluated using the census baiting technique, which involved the following phases:*  *Pre-treatment census*  *Pre-treatment lag phase*  *Treatment census*  *Post-treatment lag phase*  *Post-treatment census*  *During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.* | *Acclimatization: 17 days (100 g of wheat per station per day)*  *Treatment : 100 g of bait per day in each lockable bait station –total 8 bait stations) during 20 days*  *Post-baiting: 6 days*  *(100 g of wheat per station per day)* | *The efficacy was of 100 %.*   * *Pre-baiting plateau = 454 g/day* * *Post-baiting = 0 g* * *Assessed efficacy = 100 %*   *The assessed bait has been very well accepted by brown rats and effective and the results are consistent with laboratory ones (100 %).* | XXX | *1* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *Black rats*  *(Rattus rattus)* | *Laboratory test*  *Black rats:*  *5 males and 5 females.*  *Intoxication duration: 4 days with daily measurement of mortality and consumption.* | *Acclimatization: 4 days in individual cage at room temperature.*  *Day 0: reference food and bait biocidal product have been given:*  *- 50 g per animal of reference food for the assessment of palatability,*  *- 50 g per animal of paste bait for the assessment of efficacy during 4 consecutive days with daily consumption measurements.*  *Mortality was observed during 21 days every 24 hours.* | *A palatability equivalent to 69.3 %*  *A mortality of 90 % in a period from day 5 to day 7* | XXX | *1* |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *Black rats*  *(Rattus rattus)* | *Field test*  *The rodenticide was evaluated using the census baiting technique, which involved the following phases:*  *Pre-treatment census*  *Pre-treatment lag phase*  *Treatment census*  *Post-treatment lag phase*  *Post-treatment census*  *During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites.* | *Acclimatization: 17 days (100 g of wheat per station per day)*  *Treatment : 100 g of bait per day in each lockable bait station –total 8 bait stations) during 20 days*  *Post-baiting: 6 days*  *(100 g of wheat per station per day)* | *The efficacy was of 100 %.*   * *Pre-baiting plateau = 1022 g/day* * *Post-baiting = 0 g* * *Assessed efficacy = 100 %*   *The assessed bait has been very well accepted by black rats and effective and the results are consistent with laboratory ones (90 %).* | *XXX* | *1* |

Annex 9a: Efficacy of the active substance from its use in the biocidal product (minor change – 2018)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Test substance*** | ***Test organism(s)*** | ***Test method*** | ***Test conditions*** | ***Test results: effects, mode of action, resistance*** | ***Reference\**** | ***RI*** |
| FANGA B +RONGEUR (BDB10V1)  0.001% w/w  Brodifacoum | Brown rats  *Rattus norvegicus* | Field study  EPPO PP 1/114(2)  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 15 days (100 g mixture of maize grain and poultry/pig feed)  Treatment: 100 g of bait per day in each lockable bait station –total 8 bait stations) during 17 days  Post-baiting: 6 days  (100 g mixture of maize grain and poultry/pig feed per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 757 g/day  Post-baiting = 0 g | XXX[[25]](#footnote-25) | *1* |
| FANGA B +RONGEUR (BDB10V1)  0.001% w/w  Brodifacoum | Black rats  *Rattus rattus* | Field study  EPPO PP 1/114(2)  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 14 days (100 g mixture of maize grain and poultry/pig feed)  Treatment: 100 g of bait per day in each lockable bait station –total 8 bait stations) during 17 days  Post-baiting: 5 days  (100 g mixture of maize grain and poultry/pig feed per station per day) | Estimated efficacy = 100 %  Pre-baiting plateau = 800 g/day  Post-baiting = 0 g  R.I. =1 | XXX[[26]](#footnote-26) | *1* |

Annex 9b: Efficacy of the active substance from its use in the biocidal product (minor change – 2018)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Test substance*** | ***Test organism(s)*** | ***Test method*** | ***Test conditions*** | ***Test results: effects, mode of action, resistance*** | ***Reference\**** | ***RI*** |
| *FANGA B+ RONGEUR*  *0.001% brodifacoum* | *House mice (Mus musculus)* | *Field test*  *The rodenticide was evaluated using the census baiting technique, which involved the following phases:*  *Pre-treatment census*  *Pre-treatment lag phase*  *Treatment census*  *Post-treatment lag phase*  *Post-treatment census*  *During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites.* | *Acclimatization: 14 days (40 g of maize grain and poultry/pig feed per station per day)*  *Treatment : 40 g of bait per day in each lockable bait station –total 8 bait stations) during 15 days*  *Post-baiting: 6 days*  *(40 g of maize grain and poultry/pig feed per station per day)* | *The efficacy was of 100 %.*   * *Pre-baiting plateau = 179.8 g/day* * *Post-baiting = 0 g* * *Assessed efficacy = 100 %*   *The assessed bait has been very well accepted by house mice and effective and the results are consistent with laboratory ones (100 %).* | *XXX* | *1* |

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20. If the dead rodents, uneaten bait and bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations are not entirely collected, primary and secondary poisoning risks remain unacceptable. [↑](#footnote-ref-20)
21. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-21)
22. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-22)
23. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-23)
24. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-24)
25. XXX. Efficacy evaluation of BDB10V1 (brodifacoum 0.001% w/w a.i., blue wheat bait – aged formulation) against Roof rat (*Rattus rattus* L.) in Italy, XXX [↑](#footnote-ref-25)
26. XXX. Efficacy evaluation of BDB10V1 (brodifacoum 0.001% w/w a.i., blue wheat bait, aged formulation) against Norway rat (*Rattus norvegicus* Berk.) in Italy, XXX [↑](#footnote-ref-26)