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

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

(submitted by the evaluating Competent Authority)



**FANGA B+ BLOC P**

Product type 14

Brodifacoum

Case Number in R4BP: BC-YR018673-07

Evaluating Competent Authority: FR

Date: May 2017

Update: 2020

**Note to the reader**

This consolidated PAR of the product authorisation FANGA B + BLOC P is based on the PAR of the first authorisation for FANGA B + BLOC P, granted by France (FR) on 2017, in which all necessary addenda have been included.

In part 1 and 2 of this consolidated PAR:

* each section contains the initial assessment and the subsequent successive assessments (minor change, major change, 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 it was delivered.
* the assessments related to the renewal of the product are at the end of each section and are highlighted in grey.

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

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-YR018673-07 | 13/06/2017 | National authorisation |
| NA-ADC | *FR* | BC-XY036305-01 | 16/03/2018 | Administrative change for a national authorisation |
| Post-AMM | *FR* | - | XX/XX/2020 | amendment following post-authorisation data assessment |

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# CONCLUSION

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

FANGA B+ BLOC P is a blue wax block (weight of blocks: 4, 20, 25, 30, 40, 50, 100 g) ready-to-use rodenticide.

FANGA B+ BLOC P is not flammable, not autoflammable (self ignition temperature: 253.7°C), has no explosive properties and no oxidizing properties. The product contains more than 10% of H304 compounds. Nevertheless, as the product is a solid, it is not classified for physico-chemical properties.

No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 8 weeks at 40 ± 2°C. No significant change was observed in the content of the active substance after the accelerated storage procedure at 40 °C ± 2 °C for 8 weeks in transparent PE or PP bags, in white opaque PP bucket with bubble wrap and in cardboard box with bubble wrap. The product must be stored at a temperature below 40°C.

A long term storage stability study in commercial packaging is ongoing. Results are required in post authorization in a time limit of 2 years (end expected: November 2018). As the results of the accelerated storage are acceptable, a shelf life of 2 years can be granted. If a shelf life of 4 years is claimed, the applicant should submit a dossier of minor change.

The active substance is sensitive to light. No test has been provided. Therefore, the product must be stored away from light, as it is preconized on the label.

Analytical methods for the determination of brodifacoum in the product FANGA B+ BLOC P has been provided and validated according to SANCO3030/99/rev.4. The applicant has a letter of access of Activa for analytical methods used for the determinaiton of the active substance in food, soil, water and blood.

* **Post authorisation data (2020)**

The shelf life study has been provided by the applicant and results confirm that the product is stable up to 24 months at ambient temperature in commercial packaging.

If the applicant claims a longer shelf life, it will be necessary to apply for minor change. Additionally, attrition resistance after 48 month storage should be provided with the minor change.

**Conclusion on efficacy of the product**

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC Phas shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus* in and around building, in open areas, in waste dumps, landfills and in sewers (only *Rattus norvegicus*) but only on the highest application rates claimed (40 per baiting point for house mice and 200 g per baiting point for rats. Indeed, the efficacy tests presented in the dossier were performed at 40 g per baiting point for house mice and 200 g per baiting point for rats (*Rattus rattus* and *Rattus norvegicus*).

The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product (2 years aged maximum). Then the efficacy is not demonstrated for products aged more than 2 years.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

* **Post authorisation data (2020)**

New efficacy studies were conducted with the product FANGA B+ BLOC P, on *Rattus rattus* with aged bait, to confirm the efficacy of the biocidal product against this species for the shelf life of 24 months required by FR CA.

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus rattus* in and around building, in open areas on the application rate of 120 g per baiting point for a shelf life of 24 months.

**Conclusion for Human Health**

Based on the risk assessment of the active substance, the risk for professional and non-professional users resulting from the intended use is acceptable for FANGA B+ BLOC P for the control of rats and mice.

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

**Conclusion on indirect exposure via residues in food**

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

**Conclusion for environment and ecotoxicolgy**

No studies were conducted with the product FANGA B+ BLOC P 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.

The French Competent Authority in charge of delivring biocidal product authroization also considers that the environmental risk is limited in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning for the following uses:

* around the buidingsby non-professionals ;
* the use in open area by professionals ;
* the use in waste dump by professionals ;
* the use in sewers by professionnals

# ASSESSMENT REPORT

## Summary of the product assessment

In the course of the evaluation of FANGA B+ BLOC P, one manufacturer of the product has been added.

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| FANGA B+ BLOC P | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | TRIPLAN SA |
| **Address** | BP 258 LA POSTE FRANCAISE  AD500  ANDORRA LA VELLA  ANDORRA |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturers of the biocidal 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** | SARL LFT SETA |
| **Address of manufacturer** | CHATEAU DE PUECHASSAU  81140 BROUSSE-LAUTREC  FRANCE |
| **Location of manufacturing sites** | CHATEAU DE PUECHASSAU  81140 BROUSSE-LAUTREC  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | SOFIP |
| **Address of manufacturer** | CHEZ EDIALUX / ZA MACON EST  01750 REPLONGES  FRANCE |
| **Location of manufacturing sites** | ZA MACON EST  01750 REPLONGES  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | INDUSTRIAL CHIMICA SRL |
| **Address of manufacturer** | VIA SORGAGLIA 40  35020 ARRE  ITALY |
| **Location of manufacturing sites** | VIA SORGAGLIA 40  35020 ARRE  ITALY |

|  |  |
| --- | --- |
| **Name of manufacturer** | RATOUCY SAS |
| **Address of manufacturer** | 29 AVENUE DE LA FORET - LOOZE - BP145  89303 JOIGNY  FRANCE |
| **Location of manufacturing sites** | 29 AVENUE DE LA FORET - LOOZE - BP145  89303 JOIGNY  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | LARC |
| **Address of manufacturer** | ZA DE KERAMPAOU  29140 MELGVEN  FRANCE |
| **Location of manufacturing sites** | ZA DE KERAMPAOU  29140 MELGVEN  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | SALOMEZ |
| **Address of manufacturer** | ZA AV. DU GENERAL DE GAULLE  89130 TOUCY  FRANCE |
| **Location of manufacturing sites** | ZA AV. DU GENERAL DE GAULLE  89130 TOUCY  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | NOXIMA |
| **Address of manufacturer** | CARREFOUR JEAN MONNET - LACROIX SAINT OUEN  60201 COMPIEGNE  FRANCE |
| **Location of manufacturing sites** | CARREFOUR JEAN MONNET - LACROIX SAINT OUEN  60201 COMPIEGNE  FRANCE |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | ACTIVA / TEZZA |
| **Address of manufacturer** | VIA FELTRE 32  20132 MILAN  ITALY |
| **Location of manufacturing sites** | VIA TRE PONTI 22  37050 S. MARIA DI ZEVIO  ITALY |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Brodifacoum |
| **IUPAC or EC name** | 3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin |
| **EC number** | 259-980-5 |
| **CAS number** | 56073-10-0 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 950 g/kg |
| **Structural formula** |  |

#### Candidate(s) for substitution

As agreed in AC meeting, the comparative assessment for AVK rodenticides is performed at the European level.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Brodifacoum | 3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.0012 |
|  |  | Non-active substance[[3]](#footnote-3) |  |  |  |

Co-formulants composition of the product is confidential and is presented in a confidential annex.

#### Information on technical equivalence

No relevant since the origin is already recognized at EU level*.*

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

The biocidal product contains no substances of concern.

#### Type of formulation

|  |
| --- |
| RB - Bait (ready for use) |

### Hazard and precautionary statements[[4]](#footnote-4)

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | - |
| Hazard statement | - |
|  | |
| **Labelling** | |
| Signal words | - |
| Hazard statements | - |
| Precautionary statements | - |
|  | |
| Note | **-** |

There are 2 compounds classified as dangerous for the environment in the products FANGA B+ BLOC P. Nevertheless none of these substances contribute individually to the classification of the biocidal product FANGA B+ BLOC P because their individual concentrations are lower than the limits specified under the Regulation (EC) 1272/2008.

### Authorised use(s)

#### Use description[[5]](#footnote-5)

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  *Mus musculus* (House mouse)  Juveniles  Adults |
| **Field of use** | indoor |
| **Application method(s)** | Bait application - 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 :  - for rats : (200) g of bait per baiting point every 5 to 10 meters depending on the level of infestation.  - for mice : (40) g of bait per baiting point every 1 to 2 meters depending on the level of infestation. - 0 - |
| **Category(ies) of users** | Trained professional |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:  Bag (paper bags several layers with one or without plastic film in lowdensity polyethylene)(5;10;15;20;25kg  High density polyethylene bucket (5;10;15;18;20kg)  - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:  Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg)  Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg)  High density polyethylene bucket (5;10;15;18;20;25kg)  - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[6]](#footnote-6)

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

#### 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. |

#### 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. |

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

|  |
| --- |
|  |

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

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| --- |
|  |

#### Use description[[7]](#footnote-7)

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** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  *Mus musculus* (House mouse)  Juveniles  Adults |
| **Field of use** | outdoor around buildings |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | for rats : (200) g of bait per baiting point every 5 to 10 meters depending on the level of infestation.  for mice : (40) g of bait per baiting point every 1 to 2 meters depending on the level of infestation. |
| **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)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:   * Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20kg)   - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:   * Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) * Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20;25kg) * - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[8]](#footnote-8)

|  |
| --- |
| * 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 [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]. |

#### 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. * [Unless explicitly authorised according to addendum 4]:Do not apply this product directly in the burrows. |

#### 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. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description[[9]](#footnote-9)

Table 3. Use # 3 – Rats – trained professionals – Outdoor open areas & waste dumps

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  Juveniles  Adults |
| **Field of use** | AOutrdeooropenareas&wastedumps |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | for rats : (200) g of bait per baiting point every 5 to 10 meters depending on the level of infestation.  for mice : (40) g of bait per baiting point every 1 to 2 meters depending on the level of infestation. |
| **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)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:   * Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20kg)   - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:   * Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) * Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20;25kg) * - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[10]](#footnote-10)

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| * 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]. |

#### Use-specific risk mitigation measures

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| * 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 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. |

#### 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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| * 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. |

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

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

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#### Use description[[11]](#footnote-11)

Table 4. Use # 4 – Rats – trained professionals – sewers

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  Juveniles  Adults |
| **Field of use** | sewers |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | for rats : (200) g of bait per baiting point every 5 to 10 meters depending on the level of infestation |
| **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)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:   * Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20kg)   - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:   * Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) * Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20;25kg) * - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[12]](#footnote-12)

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| * Baits must be applied in a way so that they do not come into contact with water and are not washed away. * [When available] Follow any additional instructions provided by the relevant code of best practice. |

#### Use-specific risk mitigation measures

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| * [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant. * Do not use this product in pulsed baiting treatments. |

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

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

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#### Use description[[13]](#footnote-13)

Table 5. Use # 5 – House mice – general public – indoor

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Mus musculus* (House mouse)  Juveniles  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | - 40 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 1 to 2 meters. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | The maximum quantity of the packaging is 100 g (mice) and 300 g (mice/rats).  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:  High density polyethylene bucket, carton box, metal box without lacquer and high density container (0.1 ; 0.2 ; 0.3 kg)  bait box already filed or not, in polyethylene terephtaate/polypropylene/high density polyethylyne/polychloride vinyl) with a capacity of 200g |

#### Use-specific instructions for use[[14]](#footnote-14)

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| * 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. |

#### Use-specific risk mitigation measures

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

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

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#### Use description[[15]](#footnote-15)

Table 6. Use # 6 – Rats – general public – indoor

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  Juveniles  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | - 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | The maximum quantity of the packaging is 300 g (mice/rats) and 100 g (mice).  High density polyethylene bucket, carton box, metal box without lacquer and high density container (0.1 ; 0.2 ; 0.3 kg)  bait box already filed or not, in polyethylene terephtaate/polypropylene/high density polyethylyne/polychloride vinyl) with a capacity of 200g |

#### Use-specific instructions for use[[16]](#footnote-16)

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| * 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. |

#### Use-specific risk mitigation measures

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

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

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#### Use description[[17]](#footnote-17)

Table 7. Use # 7 – Rats – general public – outdoor around buildings

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  Juveniles  Adults |
| **Field of use** | Outdoor around buildings |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | - 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | The maximum quantity of the packaging is 300 g.  High density polyethylene bucket, carton box, metal box without lacquer and high density container (0.1 ; 0.2 ; 0.3 kg)  bait box already filed or not, in polyethylene terephtaate/polypropylene/high density polyethylyne/polychloride vinyl) with a capacity of 200g |

#### Use-specific instructions for use[[18]](#footnote-18)

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| * 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. |

#### Use-specific risk mitigation measures

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| * Do not apply this product directly in the burrows |

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

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

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#### Use description[[19]](#footnote-19)

Table 8. Use # 8 – (not relevant in France)– House mice – professionals – indoor

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Mus musculus* (House mouse)  Juveniles  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations  Covered and protected baiting points |
| **Application rate(s) and frequency** | for mice : (40) g of bait per baiting point every 1 to 2 meters depending on the level of infestation. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:   * Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20kg)   - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:   * Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) * Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20;25kg)   - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[20]](#footnote-20)

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| * 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.. |

#### Use-specific risk mitigation measures

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

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

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

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#### Use description[[21]](#footnote-21)

Table 9. Use # 9 – (not relevant in France)– Rats – professionals – indoor

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| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Rattus norvegicus* (Brown rat)  *Rattus rattus* (Roof rat, House rat)  Juveniles  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application –  Bait formulations  Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | for rats : (200) g of bait per baiting point every 5 to 10 meters depending on the level of infestation |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:   * Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20kg)   - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:   * Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg) * Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg) * High density polyethylene bucket (5;10;15;18;20;25kg)   - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[22]](#footnote-22)

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| * 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. |

#### Use-specific risk mitigation measures

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

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

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

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#### Use description[[23]](#footnote-23)

Table 10. Use # 10 – House mice – general public – indoor

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| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Mus musculus* (House mouse)  Juveniles  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Bait application –  Bait formulations:   * Ready-to-use bait to be used in tamper-resistant bait stations * Covered and protected baiting points |
| **Application rate(s) and frequency** | for mice : (40) g of bait per baiting point every 1 to 2 meters depending on the level of infestation. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg)  The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:  Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg)  High density polyethylene bucket (5;10;15;18;20kg)  - Carton box (5;10;12;20;50kg)  The product is also supplied in loose in:  Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg)  Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg)  High density polyethylene bucket (5;10;15;18;20;25kg)  - Carton box (5;10;12;15;20;25;50kg) |

#### Use-specific instructions for use[[24]](#footnote-24)

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| * 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. |

#### Use-specific risk mitigation measures

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

#### 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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| * 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 |

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

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

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### General directions for use

#### Instructions for use[[25]](#footnote-25)

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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 ONLYConsider 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": * Bait in sachets: 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 |

#### 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]. |

#### 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. |

#### 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]. |

#### 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 under 40°C. * Store in places prevented from the access of children, birds, pets and farm animals. * Shelf life: 24 months |

### 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. |

### Packaging of the biocidal product

**Professional**

The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:

* Bag (paper bags several layers with one or without plastic film in low density polyethylene) (5;10;15;20;25kg)
* High density polyethylene bucket (5;10;15;18;20kg)
* Carton box (5;10;12;20;50kg)

The product is also supplied in loose in:

* Low density polyethylene or polypropylene sachet (100;200;300;400;500;600;700;800;900;1000g) and packed in carton box (5;10;12;15;18;20kg)
* Bag (paper bags several layers with one or without plastic film in low density polyethylene (5;10;15;20;25kg)
* High density polyethylene bucket (5;10;15;18;20;25kg)
* Carton box (5;10;12;15;20;25;50kg)

**Non professional**

The product FANGA B+ BLOC P is supplied in 4-20-25-30-40-50-100g sachet in low density polyethylene or polypropylene and packed in:

* High density polyethylene bucket , carton box, metal box without lacquer and high density polyethylene container (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;1.5kg)
* Bait box already filled or not, in polyethylene terephtalate/polypropylene/high density polyethylene/polychloride vinyl) with a capacity of 200g

### Documentation

#### Data submitted in relation to product application

**Identity, physicochemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product FANGA B+ BLOC P were provided by TRIPLAN.

* **Post authorisation data (2020)**

The applicant has submitted results of the shelf life study (24, 36 and 48 months at ambient temperature).

**Efficacy data**

The following efficacy studies were submitted:

* A free-choice laboratory test was carried out with house mice (***Mus musculus***), with exposure to a 3 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
* A free-choice laboratory test was carried out with brown rats (***Rattus norvegicus***), with exposure to a 6 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
* A free-choice laboratory test was carried out with black rats (***Rattus rattus***), with exposure to a 6 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) for 4 days.
* A field test was carried out with brown rats (***Rattus norvegicus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
* A field test was carried out with black rats (***Rattus rattus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
* A field test was carried out with house mice (***Mus musculus***), with exposure to a 5 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum).
* A free choice laboratory test was carried out with brown rats (*Rattus norvegicus*), with exposure to a 2 years aged formulation of the product **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum) stored in damp conditions (80 % relative humidity, 30 -35 °C) for 5 days
* A field test was carried out with house mice (***Mus musculus***), with exposure to 21 months aged formulation of **FANGA B+ BLOC P** (0.0012 % w/w brodifacoum)
* **Post authorisation data (2020)**
* A field test ws carried out with black rats (***Rattus rattus***), with exposure to a 4 years aged formulation of **FANGA B+ BLOC P** (0,0012% w/w brodifacoum).

**Toxicology data**

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

**Residues data**

No specific residue data were submitted in the context of this dossier. The product FANGA B+ BLOC P is intended to be used in bait station indoor and outdoor. It will not get in contact with food or feed. Residue in food or feed are not expected. Considering the intended uses no data is required.

**Ecotoxicology data**

None

#### Access to documentation

A letter of access on the annex II data of the active substance has been provided by ACTIVA to TRIPLAN.

## Assessment of the biocidal product

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

Table 3. Intended use # 1 – Professional and non professional users[[26]](#footnote-26)

|  |  |
| --- | --- |
| Product Type(s) | PT14-Rodenticides |
| Where relevant, an exact description of the authorised use | FANGA B + BLOC P is intended to be used as a rodenticide against wild mice, brown rats and black rats in and around buildings, open areas, waste dumps, landfills and sewers by professional users.  It is also intended to be used in and around buildings and open areas by non-professional users.  Baits are placed in bait boxes or in secured bait stations. |
| Target organism (including development stage) | *Rattus rattus*, common name: roof rat (syn.), development stage: adults/juveniles  *Rattus norvegicus*, common name: brown rat, development stage: adults/juveniles  *Mus musculus*, common name: house mouse, development stage: adults/juveniles |
| Field of use | Indoor and outdoor |
| Application method(s) |  |
| Application rate(s) and frequency | Rats :  180-200 g/secured bait point (5-10 meters between 2 bait points)  4 refilling of bait stations over 28 days  Interval between applications (min) : one week  Mice :  30-40 g/secured bait point (1-2 meters between 2 bait points)  4 refilling of bait stations over 28 days  Interval between applications (min) : one week |
| Category(ies) of user(s) | Professional and non professional users |
| Pack sizes and packaging material | PROFESSIONALS  FANGA B+ BLOC P is conditionned in low density polyethylene or polypropylene sachets (4 ; 20 ; 25 ; 30 ; 40 ; 50 ; 100g) and packed in :   * Paper bags with or without a low density polyethylene lining (5 ; 10 ; 15 ; 18 ; 20kg)   The product is also sold in bulk in:   * Low density prolyethylene or polypropylene sachets (100 ; 200 ; 300 ; 400 ; 500 ; 600 ; 700 ; 800 ; 900 ; 1000g) and in carboard boxes (5 ; 10 ; 12 ; 15 ; 18 ; 20kg) * Paper bags with or without low density polyethylene density (5 ; 10 ; 15 ; 20 ; 25kg) * High density polyethylene seals (5 ; 10 ; 15 ; 18 ; 20 ; 25kg) * Cardboard boxes (5 ; 10 ; 12 ; 15 ; 20 ; 25 ; 50kg)   NON PROFESSIONALS  FANGA B+ BLOC P is conditionned in polyethylene or polypropylene sachets (4 ; 20 ; 25 ; 30 ; 40 ; 50 ; 100g) and packed in :   * Low density polyethylene seals, cardboard boxes, metallic boxes without internal varnish, high density polyethylene bottles (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 ; 1.5kg)   Pre-filled or not pre-filled bait stations in terephthalate polyethylene/ polypropylene/ high density polyethylene/ chlorure polyvinyl chloride of 200g |

### Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC.The composition of the product is confidential and is presented in a confidential annex. The product contains 0.0012% of pure brodifacoum (0.001209% technical brodifacoum).

The product does not contain PT6 conservative.

Formulation type: ready to use block bait

Hydrocarbon and H304 co-formulant content: ≥10%.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual determination |  | Blocks containing cereal grain | Acceptable. | Demangel B, 2015  Report 15-920010-011 |
| Colour at 20 °C and 101.3 kPa | blue |
| Odour at 20 °C and 101.3 kPa |  |
| Acidity / alkalinity | CIPAC MT 75.3 | DBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | Before the accelerated storage procedure  The mean pH value of the test item at 1% w/v in standard water D was:  6.32 at 19.7 °C after 1 min.  6.32 at 19.8 °C after 2 min. | Acceptable | Demangel B, 2015  Report 15-920010-011 |
| Relative density / bulk density | OECD109, EU method A3 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | The mean relative density of the test item was :  D20/4°C = 1.221 ± 0.002. | Acceptable | Demangel B, 2015  Report 14-920010-006 |
| Storage stability test – **accelerated storage 8 weeks at 40°C** | CIPAC MT 46.3  Analytical method validated (report 14-920010-009)  CIPAC MT 193 | BDBP12V1 (Trade name: FANGA B+ BLOC P)  Batch: LLC 14-28-3 | packaging: transparent PE bag in a cardboard box, transparent PP bags  PRODUCT APPEARANCE : Blue blocks  - Changes in colour: no  - Changes in odour: no  - Changes in clarity: no  - Changes in texture: no  CONTAINER APPEARANCE  -Transparent PE bag in a cardboard box  Description of changes: no change  - Transparent PP bag  Description of changes: no change  MASS CHANGES  - Initial total mass (product + packaging):  Transparent PE bag in a cardboard box (packaging internal number : 3): 471.8 g  Transparent PP bag (packaging internal number: 11) : 20.6 g  Transparent PP bag (packaging internal number: 12) : 20.0 g  - Mass after storage (product + packaging):  Transparent PE bag in a cardboard box (packaging internal number : 3): 452.9 g Difference of weight = -4%  Transparent PP bag (packaging internal number: 11) : 19.6 g Difference of weight = -4.9%  Transparent PP bag (packaging internal number: 12) : 19.1 g Difference of weight = -4.5%  CHANGE IN ACTIVE INGREDIENTS  Results:  - Before the accelerated storage procedure:  Mean: 0.001264% w/w  - After the accelerated storage procedure  \* For the test item in transparent PE bag in a cardboard box:  Mean: 0.001250% w/w  Deviation from T=0 value: -1.1%  \* For the test item in transparent PP bag  Mean: 0.001258% w/w  Deviation from T=0 value: -0.5%  ATTRITION RESISTANCE  Before the accelerated storage procedure  The attrition of tablets was 99.2%.  After the accelerated storage procedure  The attrition of tablets was 99.4%. | Acceptable. The product is stable after 8 weeks at 40°C in PE and PP bags.  The product must be stored at a temperature below 40°C. | Demangel B, 2015  14-920010-007 amended |
|  | CIPAC MT 46.3  Analytical method validated (report 14-920010-009)  CIPAC MT 75.3 | BDBP12V1 (Trade name: FANGA B+ BLOC P)  Batch: LLC 14-28-3 | PRODUCT APPEARANCE  Before storage at 40°C for 8 weeks:  Blue blocks containing cereal grains  After storage at 40°C for 8 weeks:  - Changes in colour: no change  - Changes in odour: no change  - Changes in texture: no change  CONTAINER APPEARANCE  Before storage at 40°C for 8 weeks:  Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap (packaging internal number: 2)  Blue blocks containing cereal grains in cardboard box with bubble wrap (packaging internal number: 3)  - Description of changes: no change.  MASS CHANGES  - Before the accelerated storage procedure  Blue blocks containing cereal grains  White opaque PP bucket with bubble wrap  Weight: 556g  - after the accelerated storage procedure  Blue blocks containing cereal grains  White opaque PP bucket with bubble wrap  Weight: 552.7g (-0.7%)  - Before the accelerated storage procedure  Blue blocks containing cereal grains  Cardboard box with bubble wrap  Weight: 381.7g  - after the accelerated storage procedure  Blue blocks containing cereal grains  Cardboard box with bubble wrap  Weight: 373g (-2.3%)  CHANGE IN ACTIVE INGREDIENTS  Results:  - Before the accelerated storage procedure  Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap  Content of active ingredient: mean 0.0013%  Blue blocks containing cereal grains in cardboard box with bubble wrap  Content of active ingredient: mean 0.0013%  - After the accelerated storage procedure  Blue blocks containing cereal grains in white opaque PP bucket with bubble wrap  Content of active ingredient: mean 0.0013%  - deviation from T0 value: 0.0%  Blue blocks containing cereal grains in cardboard box with bubble wrap  Content of active ingredient: mean 0.0013%  - deviation from T0 value: 0.0%  pH  Before the accelerated storage procedure  The mean pH value of the test item at 1% w/v in standard water D was:  6.32 at 19.7 °C after 1 min.  6.32 at 19.8 °C after 2 min.  After the accelerated storage procedure  The mean pH value of the test item at 1% w/v in standard water D was:  5.24 at 21.2 °C after 1 min.  5.32 at 21.4 °C after 2 min. | Acceptable. The product is stable after 8 weeks at 40°C in PP bucket and cardboard box.  The product must be stored at a temperature below 40°C.  Attrition resistance has been performed in the previous study (Demangel B, 2015  14-920010-007 amended). | Demangel B, 2015  Report 15-920010-011 |
| Storage stability test – **long term storage at ambient temperature** |  |  | Studies on-going since November 2014:  N°14-920010-008: shelf life 2 years at 20°C  N°14-920010-010: 3 years at 20°C  N°14-920010-011: 4 years at 20°C | Results of the shelf life studies are required in post authorization in a time limit of 2 years.  As the results of the accelerated storage are acceptable, a shelf life of 2 years is proposed. If a shelf life of 4 years is claimed, the applicant should submit of dossier of minor change. |  |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not applicable | Not relevant for solid |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | All packaging are opaque. Therefore, the effect of light has not been studied. | Acceptable for cardboard box . However, plastic packaging are not barrier to light. Moreover the active substance is sensitive to light (DT50<1 day; photolysis in water).  Nevertheless, it is mentioned on the label that the product must be store away from light. No further data are required. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | No effect of temperature has been noticed during the accelerated storage stability study. | Acceptable. The product is stable after 8 weeks at 40°C. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | According to the accelerated storage stability studies, the product is compatible with carton and polyethylene/polypropylene packaging. | Acceptable. |  |
| Wettability |  |  | Not applicable | Not relevant |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not relevant |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not relevant |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable | Not relevant |  |
| Disintegration time |  |  | Not applicable | Not relevant |  |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 193 | BDBP12V1 (Trade name: FANGA B+ BLOC P)  Batch: LLC 14-28-3 | Before the accelerated storage procedure  The attrition of tablets was 0.8%.  After the accelerated storage procedure  The attrition of tablets was 0.6%. | Acceptable.  Dust content has not been studied. Nevertheless, according to the composition and the type of product (block bait), this test is not relevant. | Demangel B, 2015  14-920010-007 amended |
| Persistent foaming |  |  | Not applicable | Not relevant |  |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not relevant |  |
| Burning rate — smoke generators |  |  | Not applicable | Not relevant |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not relevant |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not relevant |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not relevant |  |
| Physical compatibility |  |  | Not applicable. The product is not intended to be mixed with others products. | Not relevant |  |
| Chemical compatibility |  |  | Not applicable. The product is not intended to be mixed with others products. | Not relevant |  |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not relevant |  |
| Surface tension |  |  | Not applicable | Not relevant |  |
| Viscosity |  |  | Not applicable | Not relevant |  |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | DSC | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | A test was performed to determine if the product presents exothermic reaction during DSC analysis.  During the first phase, one exothermic peak was observed at 244.2 °C. The exothermic reaction energy is less than 500 J/g (256.8J/g) and the onset of exothermic decomposition is below 500°C. The test item is not expected to get explosive properties. | Acceptable. The product is not explosive. | Demangel B, 2015  Report 14-920010-006 |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids |  |  | Not applicable | Not applicable |  |
| Flammable solids | United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2010) Test N.1 (Part III, Section 33.2.1.4) | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | Type of test item Block (The test item was grated)  Application of the flame 43 s for the assay No. 1 and 35 s for the assay No. 2 4.1.2.  Assay No. 1  From 43 s to 1 min 42 s, the test item ignited and a propagation of the combustion was observed over about 1 cm. Neither ignition, nor propagation was observed after 1 min 42 s.  Assay No. 2  From 35 s to 1 min 29 s, the test item ignited and a propagation of the combustion was observed over about 1.5 cm. Neither ignition, nor propagation was observed after 1 min 29 s.  Main test  Taking into account the results obtained during the preliminary test, no main test was performed.  Since the burn rate is below 2.2mm/s, the test item was not classified as a flammable solid of Division 4.1 and thus was not assigned to any packing group, under the experimental conditions used. | Acceptable. The product is not highly flammable. | Demangel B, 2015  Report 14-920010-006 |
| Self-reactive substances and mixtures |  |  | According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances  should be considered for classification in this hazard class unless their exothermic decomposition energy is  less than 300 J/g. As the exothermic decomposition is below this limit, the product is not a self reactive mixture. | Acceptable. |  |
| Pyrophoric liquids |  |  | Not applicable | Not applicable |  |
| Pyrophoric solids |  |  | Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable. |  |
| Self-heating substances and mixtures | EEC A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | No test was provided. Nevertheless, regarding the composition, the product is not expected to heat with air without additional energy. | Acceptable The product is not a self heating mixture. | Demangel B, 2015  Report 14-920010-006 |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The product does not contain compounds which are suspected to emit gases in contact with water. | Acceptable |  |
| Oxidising liquids |  |  | Not applicable | Not applicable |  |
| Oxidising solids | United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2009) Test O.1 (Part III, Section 34.4.1) | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | Preparation of the mixtures  30.0 g ± 0.1 g mixtures were prepared with the following proportions:  Test item : mixture item/cellulose (4:1, 1:1)  reference: potassium bromate/cellulose (3:7, 2:3, 3:2)  Five assays were performed with each mixture, and the mean time of the main reaction was calculated.  The mean time of reaction with the test item / cellulose mixture in proportions 4:1 was higher than the mean time of reaction with the reference item / cellulose mixture in proportions 3:7. Therefore, the test item was not considered as an oxidising solid of Division 5.1 and thus was not assigned to any packing group. | Acceptable. The product has no oxidizing properties. | Demangel B, 2015  Report 14-920010-006 |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  |  |  |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | The self-ignition temperature of the test item was 253.7°C. | Acceptable. The product is not auto-flammable up to 253.7°C. | Demangel B, 2015  Report 14-920010-006 |
| Relative self-ignition temperature for solids | EU A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | The self-ignition temperature of the test item was 253.7 °C | Acceptable. The product is not auto-flammable up to 253.7°C. | Demangel B, 2015  Report 14-920010-006 |
| Dust explosion hazard |  |  | Not applicable | Not relevant |  |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| FANGA B+ BLOC P is a blue wax block (weight of blocks: 4, 20, 25, 30, 40, 50, 100 g) ready-to-use rodenticide.  FANGA B+ BLOC P is not flammable, not autoflammable (self ignition temperature: 253.7°C), has no explosive properties and no oxidizing properties. The product contains more than 10% of H304 compounds. Nevertheless, as the product is a solid, it is not classified for physico-chemical properties.  No change appeared in the appearance of the biocidal product or the packaging after storage procedures for 8 weeks at 40 ± 2°C. No significant change was observed in the content of the active substance after the accelerated storage procedure at 40 °C ± 2 °C for 8 weeks in transparent PE or PP bags, in white opaque PP bucket with bubble wrap and in cardboard box with bubble wrap. The product must be stored at a temperature below 40°C.  A long term storage stability study in commercial packaging is ongoing. Results are required in post authorization in a time limit of 2 years (end expected: November 2018). As results of the accelerated storage are acceptable, a shelf life of 2 years can be granted. The active substance is sensitive to light. No test has been provided. Therefore, the product must be stored away from light, as it is preconized on the label.  **Labelling mention:**shelf life: 2 years. store away from light. The product must be stored below 40°C. |

* **Post authorisation data (2020)**

The applicant has submitted results of the final shelf life study following storage up to 24, 36 and 48 months at ambient temperature.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Storage stability test – **24, 36 and 48 months at ambient temperature** | Gifap monograph 17  Analytical method validated (report 14-920010-009,identical to method validated in report 14-920010-008 below)  CIPAC MT 193 | BDBP12V1 (Trade name: FANGA B+ BLOC P)  Batch: LLC 14-28-3 | packaging: cardboard box with PE bag inside or PP bags  PRODUCT APPEARANCE :  Before storage blue blocks  After storage 24, 36 and 48 months: blue blocks  CONTAINER APPEARANCE  Before storage:  cardboard box with PE bag inside and PP bags  After storage 24, 36 and 48 months:  cardboard box with PE bag inside and PP bags  (no sign of degradation or leak was observed)  MASS CHANGES (packaging)  Before storage: /  After storage 24 months:  -1.6% for cardboard box with PE bag inside  -1.8% for PP bags  After 36 months:  -1.5% for cardboard box with PE bag inside  -1.5% for PP bags  After 48 months:  -1.2% for cardboard box with PE bag inside  -1.5% for PP bags  CHANGE IN ACTIVE INGREDIENTS  Before storage: 0.001264% w/w  After 6 months in PE bags: 0.001280% w/w (+1.3%)  After 12 months in PE bags: 0.001277% w/w (+1.0%)  After storage 24 months in PP bags: 0.001257% w/w (-0.6%)  After storage 24 months in PE bags: 0.001280 % w/w (+1.3%)  After storage 30 months in PE bags: 0.001252 % w/w (-0.9%)  After storage 36 months in PP bags: 0.001198 % w/w (-5.2%)  After storage 36 months in PE bags: 0.001227 % w/w (-2.9%)  After storage 42 months in PE bags: 0.001252 % w/w (-0.95%)  After storage 48 months in PP bags: 0.001187 % w/w (-6.1%)  After storage 48 months in PE bags: 0.001230 % w/w (-2.7%)  ATTRITION OF TABLETS  Before storage: 0.8%  After storage 24 months: 1.6% | Acceptable. The product is stable up to 24 months at ambient temperature in commercial packaging.  The results in method CIPAC MT 193 are expressed as follow:  Attrition = (E – R) x 100 /E  E= mass of sample at t0 in g  R = mass of residue on the sieve in g after attrition test  In CIPAC MT 178 (attrition of granules), results are expressed as follow:  Attrition = R / E x 100  The expression of the results in each method is different but the calculation provides the same information. In CIPAC MT 193, the result is related to the loss of material after the attrition test, while in CIPAC MT 178 the results is the comparison between the initial and final mass after the attrition test. To make a parallel with CIPAC MT 178, this means that the blocks have an attrition of 99.2% before storage and 98.4% after storage, which is acceptable.  The product is also stable up to 36 and 48 months at ambient temperature. However attrition is missing.  If the applicant claims a shelf life longer than 24 months, a dossier for minor change should be submitted.  Additionally, attrition according to CIPAC MT 193 should be provided after storage 48 months at ambient temperature | THEBAULT Aloïs, 2017  Report No. 14-920010-008  CLAUDON Cécile, 2018, report No. 14-920010-010  TORRANO AGABAS Darryl, 2019, report No. 14-920010-011 |

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| --- |
| **Conclusion on post authorisation data** |
| The product is stable up to 24 months at ambient temperature in commercial packaging. If the applicant claims a longer shelf life, it will be necessary to apply for minor change and attrition of tables according to CIPAC MT 193 should be provided after end of storage. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | DSC | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | A test was performed to determine if the product presents exothermic reaction during DSC analysis.  During the first phase, one exothermic peak was observed at 244.2 °C. The exothermic reaction energy is less than 500 J/g (256.8J/g) and the onset of exothermic decomposition is below 500°C. The test item is not expected to get explosive properties. | Acceptable. The product is not explosive. | Demangel B, 2015  Report 14-920010-006 |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids |  |  | Not applicable | Not applicable |  |
| Flammable solids | United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2010) Test N.1 (Part III, Section 33.2.1.4) | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | Type of test item Block (The test item was grated)  Application of the flame 43 s for the assay No. 1 and 35 s for the assay No. 2 4.1.2.  Assay No. 1  From 43 s to 1 min 42 s, the test item ignited and a propagation of the combustion was observed over about 1 cm. Neither ignition, nor propagation was observed after 1 min 42 s.  Assay No. 2  From 35 s to 1 min 29 s, the test item ignited and a propagation of the combustion was observed over about 1.5 cm. Neither ignition, nor propagation was observed after 1 min 29 s.  Main test  Taking into account the results obtained during the preliminary test, no main test was performed.  Since the burn rate is below 2.2mm/s, the test item was not classified as a flammable solid of Division 4.1 and thus was not assigned to any packing group, under the experimental conditions used. | Acceptable. The product is not highly flammable. | Demangel B, 2015  Report 14-920010-006 |
| Self-reactive substances and mixtures |  |  | According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances  should be considered for classification in this hazard class unless their exothermic decomposition energy is  less than 300 J/g. As the exothermic decomposition is below this limit, the product is not a self reactive mixture. | Acceptable. |  |
| Pyrophoric liquids |  |  | Not applicable | Not applicable |  |
| Pyrophoric solids |  |  | Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable. |  |
| Self-heating substances and mixtures | EEC A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | No test was provided. Nevertheless, regarding the composition, the product is not expected to heat with air without additional energy. | Acceptable The product is not a self heating mixture. | Demangel B, 2015  Report 14-920010-006 |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The product does not contain compounds which are suspected to emit gases in contact with water. | Acceptable |  |
| Oxidising liquids |  |  | Not applicable | Not applicable |  |
| Oxidising solids | United Nations Recommendations on the Transport of Dangerous Goods Manual of tests and Criteria Fifth revised edition (2009) Test O.1 (Part III, Section 34.4.1) | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | Preparation of the mixtures  30.0 g ± 0.1 g mixtures were prepared with the following proportions:  Test item : mixture item/cellulose (4:1, 1:1)  reference: potassium bromate/cellulose (3:7, 2:3, 3:2)  Five assays were performed with each mixture, and the mean time of the main reaction was calculated.  The mean time of reaction with the test item / cellulose mixture in proportions 4:1 was higher than the mean time of reaction with the reference item / cellulose mixture in proportions 3:7. Therefore, the test item was not considered as an oxidising solid of Division 5.1 and thus was not assigned to any packing group. | Acceptable. The product has no oxidizing properties. | Demangel B, 2015  Report 14-920010-006 |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  |  |  |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | The self-ignition temperature of the test item was 253.7°C. | Acceptable. The product is not auto-flammable up to 253.7°C. | Demangel B, 2015  Report 14-920010-006 |
| Relative self-ignition temperature for solids | EU A16 | BDBP12V1  Trade name: FANGA B+ BLOC P  Batch: LLC 14-28-3 | The self-ignition temperature of the test item was 253.7 °C | Acceptable. The product is not auto-flammable up to 253.7°C. | Demangel B, 2015  Report 14-920010-006 |
| Dust explosion hazard |  |  | Not applicable | Not relevant |  |

### Methods for detection and identification

**Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient**

Physical and chemical properties of the active substance and analytical methods for determination of active ingredients in the technical active ingredient have already been evaluated at EU level and are presented in the CAR of the active substance. The notifier TRIPLAN of the product FANGA B+ BLOC P is not the applicant that supported the annex I inclusion dossier of the active substance but it has a letter of access to these data.

**Summary for Brodifacoum:**

|  |  |
| --- | --- |
|  | Principle of method |
| Technical active substance as manufactured: | A. HPLC with UV detection at 254 nm using an internal standard B. Dissolution in methanol/dichloromethane (3:2,v/v). Determination by RP-HPLC/UV. LOQ = 0.79 µg/ml RP-HPLC/UV method for the isomeric content determination also available |
| Impurities in technical active substance: | A HPLC with UV detection using either an internal or an external standard, or with fluorescence detection using an external standard B. RP-HPLC/UV |

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | RP-HPLC/DAD (detection at 264 nm) – not validated  A new LC-MS/MS method has been provided as post inclusion data and is validated. |
| Air (principle of method and LOQ) | Not relevant, since Brodifacoum is a non-volatile substance intended to be used only in solid formulations |
| Water (principle of method and LOQ) | Extraction from spiked samples (drinking, ground, and surface water) with dichloromethane. Extract evaporation by rotary evaporator. Residue re-dissolution in 0.5 ml of methanol for RP-HPLC/MS/MS analysis (scan in SIM and SRM mode). LOQ = 0.05 µg/l for drinking and ground water, 0.5 µg/l for surface water |
| Body fluids and tissues (principle of method and LOQ) | A. Extraction from spiked samples of plasma and liver with acetonitrile:ether (9:1) and acetonitrile, respectively. Evaporation to dryness by nitrogen. Residue redissolution in 2 ml of acetonitrile. Determination by RP-HPLC with fluorescence detection, using Difenacoum as internal standard. LOQ in plasma = 0.010 mg/l, LOQ in liver tissue = 0.01 mg/kg  B. Blood serum: extraction from spiked samples (blood aqueous solution) with dichloromethane after centrifugation. RP-HPLC/MS/MS analysis. LOQ = 0.06 mg/l  Body tissues covered under food of animal origin |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Extraction from spiked samples with ethyl acetate for cucumber, wheat, and lemon, with acetone in case of oilseed-rape. Clean-up procedure (if necessary) suited to the sample properties, i.e. water/fat/acid content. Determination by LC-MS/MS. LOQ = 0.01 mg/kg in all 4 matrices |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Extraction from spiked samples with dichloromethane : acetone (7:3, v/v). Purified extracts analysed by LCMS/MS. LOQ = 0.01 mg/kg |

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

|  |  |
| --- | --- |
| **Report:** | Ricau H, 2015 |
| Title: | Validation of the analytical method for the determination of brodifacoum in BDBP12V1 In compliance with SANCO/3030/99 rev. 4 from 11/07/00 |
| Document No | 14-920010-009 |
| Test facility | DEFITRACES, Z.A des Andrès, 150, Rue Pré-Magne, 69126 Brindas, FRANCE |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Test item**

Identification: BDBP12V1 (trade name: FANGA B+ BLOC P)Batch: LLC 14-28-3

Formulation blank: BDBP12V1, batch LLC 14-28-3P

**Principle**

Samples are dissolved into methanol and determination is performed with HPLC-UV at 265nm using a Zorbax SB-phenyl column.

**Preparation of the formulation blank**

The formulation blank was previously grated.A quantity of 2.1 g (to the nearest 0.01 mg) of grated formulation blank was weighedinto a 100-mL glass flask. An exact volume of 25 mL of methanol was added.The mixture was blended for 5 minutes with a laboratory blender.The solution was kept during 72 hours at room temperature then an aliquot wasfiltered on an ashless filter for analysis.

**Preparation of the test item solution**

The specimen was previously grated.A quantity of 2.1 g (to the nearest 0.01 mg) of the grated test item was weighed into a100-mL glass flask. An exact volume of 25 mL of methanol was added.The mixture was blended for 5 minutes with a laboratory blender.The solution was kept during 72 hours at room temperature then an aliquot wasfiltered on an ashless filter for analysis.

**Preparation of the solutions for the accuracy study**

A quantity of 2.1 g (to the nearest 0.01 mg) of grated formulation blank was weighed into a 100-mL glass flask. Volumes of 0.25 mL of the REF07 solution (0.1mg/ml of brodifacoum in methanol) and 24.75 mL of methanol were added.

The mixture was blended for 5 minutes with a laboratory blender. The solution was kept during 72 hours at room temperature then an aliquot was filtered on a filter ash less for analysis (Acc 1). An identical accuracy solution was prepared with REF08 solution (0.1mg/ml of brodifacoum in methanol) (Acc 2). This fortification corresponds to approximately. 0.0012% brodifacoum/reconstituted product.

**Validation of the analytical method:**

|  |  |
| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, test item, blank formulation. No peak appears in the solvent blank and in the formulation blank.  In the reference item and in the test item, the peaks at the retention times at about 7.095 and 7.858 min represent isomers of brodifacoum (I and II). No additional peak appears in the reference item and in the test item.  Specificity is acceptable. |
| Linearity | The response of the detector during the analysis of brodifacoum was linear (n=5) within the range of 0.52 mg/L to 1.45 mg/L. The correlation coefficient was 0.9997. Linearity is acceptable. |
| Precision | Precision  The precision was determined by analysing twice five specimen samplings (test item). The content of brodifacoum for each analysis was calculated with the average value of the response factor of the two calibration solutions bracketing the test item. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated.  Mean : 0.0013% w/w  RSD: 1.89%  C HORWITZ: 1.3E-05  HORWITZ: 7.31%  Precision is acceptable. |
| Accuracy | Accuracy was performed with blank formulation fortified at 0.0012% w/w with brodifacoum. Two reconstituted products were prepared.  Accuracy 1: 98.1% (mean of two injections)  Accuracy 2: 100.4% (mean of two injections)  Results are in acceptable limits (80-120%) according to SANCO/3030/99/rev.4. |

**Specificity, linearity, precision and accuracy were checked and are found acceptable.**

**Analytical methods for determining relevant components and/or residues in differentmatrices**

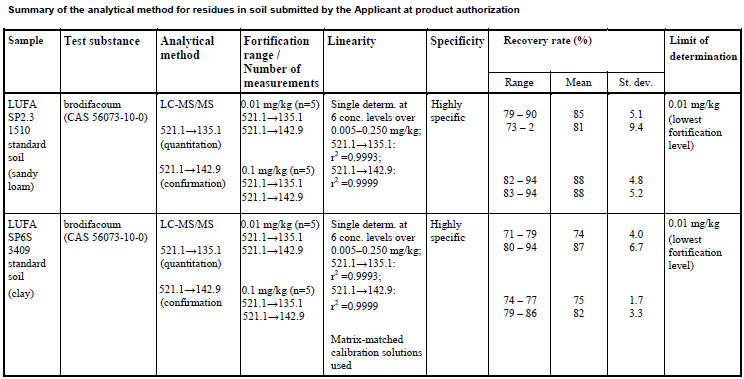
Brodifacoum (Doc IIA of the CAR)

The method for soil was not fully validated and a new method was requested as additional data to provide in post inclusion. A new method has been provided by the applicant of the active substance (see summary results below the following table).

| **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 |

For the identification/quantification of Brodifacoum residues in soil, no fully-acceptable analytical method for Brodifacoum residues in soil was available in the relevant CAR. A new study for the determination of Brodifacoum residues in soil was presented by the Applicant post Annex I inclusion and evaluated by the IT-CA only at product authorization. The submitted LC-MS/MS method for the analysis of >Brodifacoum residues down to 0.01 mg/kg in sandy loam and soil clay meets the requirements provided for by SANCO/825/00 rev8.1and the Additional Guidance to TNsG on Data Requirements on analytical methods and supports the residue definition.

The method is highly specific (LC-MS/MS, with two mass transitions validated), linear over the range 0.005–0.250 mg Brodifacoum/kg in soil, accurate (with recovery rates at LOQ and 10xLOQ in the acceptable range 70–110%) and precise (%RSDn = 5 < 20% for each fortification level). The LOQ (as the lowest validated fortification level) complies with the relevant end-point (*Eisenia fetida* 14-d LC50 > 994 mg/kg dwt, corresponding to > 879.6 mg/kg wwt). For further details, please refer to the table below.



### Efficacy against target organisms

#### Function and field of use

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+ BLOC P** 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+ BLOC P** is intended to be used in and around buildings and in open areas by professionals and non professionals users and in waste dumps / landfield area and in sewer by professional users. The products, organisms or objects to be protected are human food and animal feedstuffs and for general hygiene purposes.The products, organisms or objects to be protected arepublic and private buildings, and farms.

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

Rats: 180-200 g bloc/secured bait point separated by 5-10 m.

Mice: 30-40 g bloc/secured bait point separated by 1-2 m.

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

The applicant submitted the following studies:

* Study n°: 14TOX044: laboratory study:

For house mice (*Mus musculus*), the mean palatability percentage of the 3 months aged FANGA B+ BLOC P is 63 % and the mortality percentage of 100%.

* Study n°: 15TOX002: laboratory study:

For brown rats (*Rattus norvegicus*), the mean palatability percentage of the 6 months aged FANGA B+ BLOC P is 43 % and the mortality percentage of 100%.

* Study n°: 2013 BCD SAG16: laboratory study:

For brown rats (*Rattus norvegicus*), A 2 years old bait has been aged in damp condition (T°: 30-35 °C; RH: 80 %), the mean palatability percentage 20 % and the mortality percentage of 100%.

* Study n°: 14TOX043: laboratory study:

For black rats (*Rattus rattus*), the mean palatability percentage of the 6 months age FANGA B+ BLOC P is 40 % and the mortality percentage of 100%.

* Study n°2017.BCD.SAG14: field study

The study has been performed in an infested agricultural building with brown rats (*Rattus norvegicus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 200 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* Study n°2018.BCD.SAG14: field study

The study has been performed in an infested agricultural building with black rats (*Rattus rattus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 200 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* Study n°2016.BCDSAG14: field study

The study has been performed in an infested agricultural building with house mice (*Mus musculus*). The quantity of bait (FANGA B+ BLOC P, 5 months aged) applied by bait point was 100 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* Study n°2019.BCDSAG16: field study

The study has been performed in an infested agricultural building with house mice (*Mus musculus*). The quantity of bait (FANGA B+ BLOC P, 21 months aged) applied by bait point was 40 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* **Post authorisation data (2020)**
* Study n°2017.BCD.SAG18: field study

The study has been performed in an infested agricultural building with black rats (*Rattus rattus*). The quantity of bait (FANGA B+ BLOC P, 4 years aged) applied by bait point was 120 g.

The assessed bait has been very well accepted and the efficacy is estimated at 100 %.

French competent authorities (FR CA) consider that the elements presented in the dossier demonstrate the efficacy of the product against mice (*Mus musculus*), black rats (*Rattus rattus*) and brown rats (*Rattus norvegicus*) for use in and around buildings, open areas and waste dumps / landfills and in sewer.

The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product aged of 2 years maximum). Then the efficacy is not demonstrated for products aged of more than 2 years.

* **Post authorisation data (2020)**

New efficacy studies were conducted with the product FANGA B+ BLOC P, on *Rattus rattus* with aged bait, to confirm the efficacy of the biocidal product agasint this species for the shelf life of 24 months required by FR CA.

French competent authorities (FR CA) assessed that the 4 years aged product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus rattus* in and around building, in open areas on the application rate of 120 g per baiting point for a shelf life of 24 months.

All efficacy studies are presented in annex 7.

#### 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.

Death of target animal occurs 1 to 9 days after ingestion.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| **Conclusions of efficacy and risk assessment**  French competent authorities (FR CA) assessed that the product FANGA B+ BLOC Phas shown a sufficient efficacy for the control of *Rattus norvegicus, Rattus rattus* and *Mus musculus* in and around building, in open areas, in waste dumps, landfills and in sewers (only *Rattus norvegicus*) but only on the highest application rates claimed (40 per baiting point for house mice and 200 g per baiting point for rats. Indeed, the efficacy tests presented in the dossier were performed at 40 g per baiting point for house mice and 200 g per baiting point for rats (*Rattus rattus* and *Rattus norvegicus*)  The applicant claims a maximum storage duration of 4 years. But the product does not contain preservative and the efficacy tests have been performed with the product aged of 2 years maximum. Then the efficacy is not demonstrated for products aged of more than 2 years.  The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.   * **Post authorisation data (2020)**   French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus rattus* in and around building, in open areas on the application rate of 120 g per baiting point for a shelf life of 24 months. |

#### Occurrence of resistance and resistance management

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%. 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[[27]](#footnote-27); Lund, 1984[[28]](#footnote-28); Pelz et al. 1995[[29]](#footnote-29)). 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[[30]](#footnote-30)). 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[[31]](#footnote-31)).

Recent 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 (*Rattus norvegicus*) populations to coumafene. Moreover, a recent 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 bromadionone (Grandemange *et al*., 2009). More recently, 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. So, resistance to second generation anticoagulant rodenticides should not be minimized.

Only 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*”).

*Resistance management strategies*

The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003). The problem with the BCR test is that it has proven difficult to standardize and it produces both false positives and negatives (Pelz et al. 2005). In order to follow the occurrence and spread of difenacoum resistance, wild rats should be continuously monitored for resistance in the rodent controlled area.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

#### Evaluation of the label claims

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

The application rates validated are the following:

Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g bloc/secured bait point separated by 5-10 m.

Brown rats in sewers (*rattus norvegicus):* 200 g bloc/ secured bait point separated by 5-10 m.

House mice (*Mus musculus*): 40 g bloc/secured bait point separated by 1-2 meters.

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

* 3 days after the first application then weekly for use in and around buildings and open areas;
* 1 week after the first application then monthly for use in waste dumps, landfills and in sewers.

The product FANGA B+ BLOC P 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.

* **Post authorisation data (2020)**

French competent authorities (FR CA) assessed that the product FANGA B+ BLOC P has shown a sufficient efficacy for the control of *Rattus rattus* in and around building, in open areas on the application rate of 120 g per baiting point for a shelf life of 24 months.

The application rates validated are the following:

Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g bloc/secured bait point separated by 5-10 m.

Brown rats in sewers (*rattus norvegicus):* 200 g bloc/ secured bait point separated by 5-10 m.

House mice (*Mus musculus*): 40 g bloc/secured bait point separated by 1-2 meters.

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

* 3 days after the first application then weekly for use in and around buildings and open areas;
* 1 week after the first application then monthly for use in waste dumps, landfills and in sewers.

The product FANGA B+ BLOC P 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.

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

The product FANGA B+ BLOC P 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 and in sewers (only on *Rattus norvegicus*) by professional users.

Rats (*Rattus norvegicus* and *Rattus rattus*): 180-200 g bloc/secured bait point separated by 5-10 m.

Brown rats in sewers (*rattus norvegicus):* 200 g bloc/ secured bait point separated by 5-10 m.

Mice (*Mus musculus*): 30-40 g bloc/secured bait point separated by 1-2 m.

The product is a ready-to-use block 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

##### 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 *Brodifacoumvs* 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 regulation (EC) 1272/2008 |
| 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 AELacuteresultsto 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 resultsto 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 AELacuteresultsto 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 resultsto 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 termof 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 contains no substances of concern.

##### Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements.

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+ BLOC P are considered similar.

###### Percutaneous absorption

A default value of 0.047% was considered for product containing 0.005% of brodifacoum, as mentioned in the brodifacoum assessment report.

This value has been considered relevant for the product FANGA B+ BLOC P containing 0.0012% 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.

###### Acute toxicity

*Oral route*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level | LD50 | Study reference |
| Oral | OECD 423 | Rat 3 males and 3 females | 2000mg/kg bw | >2000 mg/kg bw | Colas S. (2012), GLP study |

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.

*Dermal route*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level | LD50 | Study reference |
| Dermal | OCDE 402 | Rat 5 males and 5 females | 2000 mg/kg bw | >2000 mg/kg bw | Colas S. (2012), GLP study |

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.

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

###### Irritation and corrosivity

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level |  | Study reference |
| skin | OECD 404 | Rabbit NZ  3 females | 0.5 g | No irritant | Colas S. (2012), GLP study |
| eye | OCDE 405 | Rabbit NZ  3 females | 0.1 g | No irritant | Colas S. (2012), GLP study |

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

###### Sensitisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Route | Method | Species | Dose level |  | Study reference |
| skin | OECD 429 | Mice16 (12 for the treated groups) | Topical way of induction:  5, 10, 25% of the test item | No skin sensitizing | Colas S. (2012), GLP study |

Based on the results of the LLNA, no classification is required for FANGA B+ BLOC P.

###### Other studies

No other studies are performed on FANGA B+ BLOC P.

#### Human exposure assessment

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 significant | Negligible |

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

###### Exposure of professional users

FANGA B+ BLOC P is used for the control of rats and mice for use indoor and outdoor, with the purpose of protecting human food and animal feedstuffs, and for human hygiene.

The product is supplied in bulk and sachets (PE or PP). Considering the nature of sachet, a dermal exposure during cleaning is taken into account. Exposure assessment has been realized with the dose of 200 g of product for the control of rats. This assessment covers the assessment for mice as the intended doses are lower.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII2011, the amount of product on fingers/hands **during the loading**of 5 wax blocks of 20g per one manipulation was 27.79 mg. The following parameters were taken into account:

* active substance in product: 0.0012 %,(w/w);
* number of blocks per bait site[[32]](#footnote-32): 50 for control of rats
* dermal absorption: 0.047 %,
* body weight: 60kg.

Thus, the systemic dose of brodifacoum per placing of one bait site is 2.61 x10-8mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 60loading are done per day, the systemic dose via skin is 1.57 x10-6 mg a.s/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 TMII2011, the amount of product on fingers/hands **during the cleaning** of one bait site is 5.70mg. The following parameters were taken into account:

* active substance in product: 0.0012 %,(w/w);
* dermal absorption: 0.047 %,
* body weight: 60kg.

Thus, the systemic dose of brodifacoum per cleaning of one bait site is 5.36 x10-10mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 15 cleaning are done per day, the systemic dose via skin is 8.04 x10-9 mg a.s/kg bw/day for the control of rats and micebecause the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at 1.58 x10-6 mg/kg bw/day without PPE for the control of rats and mice.

###### Exposure of non-professional users

The product is only supplied in sachets for non professionnal users. Considering the nature of sachet (PE or PP), a dermal exposure during cleaning is taken into account. Exposure assessment has been realized with the dose of 200 g of product for the control of rats. This assessment covers the assessment for mice as the intended doses are lower.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII2011, the amount of product on fingers/hands **during the cleaning** of one bait site is 5.70mg. The following parameters were taken into account:

* active substance in product: 0.0012 %,(w/w);
* dermal absorption: 0.047 %,
* body weight: 60kg.

Thus, the systemic dose of brodifacoum per cleaning of one bait site is 5.36 x10-10mg/kg bw/event for control of rats and mice (because the amount of disposed bait is not taken into account).

The harmonized number of manipulations for rodenticides anticoagulant set in the HEEG opinion agreed at TM III 2010 was used to assess the overall exposure systemic dose. Considering 5 cleaning are done per day, the systemic dose via skin is 2.68 x10-9 mg a.s/kg bw/day for the control of rats and micebecause the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at 2.68 x10-9 mg/kg bw/day without PPE for the control of rats and mice.

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

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 10kg and an oral absorption of 75% (as stated in the Assessment report of brodifacoum), ingestion of more than 7.4 mg of product per day by an infant is needed to exceed the AEL.

#### 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 6.7 x10-6 mg/kg bw/day for short-medium 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+ BLOC P, even if gloves are not worn (%AEL at 48%) for the control of rats and, by extension, of mice.

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 2.7.3-1: Summary of risk characterisation for professionals for the control of rats

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL**  **(mg/kg bw/d)** | **Exposure**  **(mg/kg bw/d)** | **%AEL** | **Risk** |
| **Bulk formulation (exposure during loading and cleaning phases)** | | | | |
| Professionnal  (without gloves) | 3.3 x10-6 | 1.58 x 10-6 | 48% | Acceptable |

###### 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+ BLOC P (%AEL at 0.04%) for the control of rats and, by extension, of mice.

Table 2.7.3-1: 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 (PE or PP) (exposure during the cleaning phase)** | | | | |
| Non Professionnal | 6.7 x10-6 | 2.68 x 10-9 | 0.04% | Acceptable |

##### Risk for indirect exposure

Based on a reverse scenario, more than 7.4 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+ BLOC P contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainablefor children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

##### Summary of risks characterisation of the product for human health

Based on the risk assessment of the active substance, the risk for professional and non-professional users resulting from the intended use is acceptable for FANGA B+ BLOC P for the control of rats and mice.

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

##### Exposure to residues in food

In Annex 6 “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.

#### Risk for consumers via residues in food

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

### Risk assessment for the environment

As the product contains no substance of concern except brodifacoum, it is considered that risks posed to environment following the use of FANGA B+ BLOC P 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+ BLOC P is a rodenticide in wax block bait form (packaged in sachet or bulk) containing 0.0012% brodifacoum (0.01 g/kg). The product is in the form of a block (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+ BLOC P 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);
* Sewer (professional use only)

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

The physico-chemical input parameters which were used are as follows:

|  |  |  |
| --- | --- | --- |
| **PHYSICO-CHEMICAL PROPERTIES** | **Value** | **Unit** |
| Molecular weight | 523.4 | [g.mol-1] |
| Vapour pressure at test temperature | << 1 x 10-6 | [Pa] |
| Temperature at which vapour pressure was measured | 20 | [°C] |
| Octanol-water partition coefficient | 6.12 | [log10] |
| Organic carbon-water partition coefficient | 9155 | [L.kg-1] |
| Half-life in soil | Not biodegradable\* | [d] |
| BCF fish | 35645 | L.kg-1 |
| Solubility in water | 0.058 | mg/L-1, PH7, 20°C |

*\**according to EUSES, the default DT50 value for soil to be used for risk assessment is 1.0E+06 d when the substance is not biodegradable

#### 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[[33]](#footnote-33).

##### 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 Guidance of BPR Vol. IV Part B IV Part B[[34]](#footnote-34), 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 at 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; Guidance of BPR Vol. IV Part B IV Part B).

The terrestrial BCF has been estimated with calculation method:

**BCFearthworm = 15 820 L/kg**(according to Equation 82d; Guidance of BPR Vol. IV Part B 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[[35]](#footnote-35).

##### 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 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 Guidance of BPR Vol. IV Part B, 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.

**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 Guidance of BPR Vol. IV Part B 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 theGuidance of BPR Vol. IV Part B 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: 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 PNECmicoorganisms

According to Guidance of BPR Vol. IV Part B when an EC10 from a respiration inhibition test is used, an assessment factor of 10 must be applied and a PNEC STP microorganisms > 0.0058 mg a.s/L can be derived.

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 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 Guidance of BPR Vol. IV Part B.

**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 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 **0.4mg a.s. /kg bw** (recalculated into **LC50 = 8 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the Guidance of BPR Vol. IV Part B is the lowest value for the acute toxicity)is provided by another applicant. 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 applicant. 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 applicant 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 Guidance of BPR Vol. IV Part B, 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 toxicitybased 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 Guidance of BPR Vol. IV Part B, 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 applicant. 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. ANOEC = 0.0038 mg brodifacoum /kg diet and a NOEL = 3.85E-04 mg Brodifacoum/kg bw/d are derived.

According to Guidance of BPR Vol. IV Part B, an assessment factor of 30is 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 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 | 1.30E-04 mg/kg food  1.30E-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 | 1.10E-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; Guidance of BPR Vol. IV Part B), 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 Guidance of BPR Vol. IV Part B, brodifacoum fulfils the T criterion.

**Brodifacoum is considered as a potential PBT, according to the** Guidance of BPR Vol. IV Part B.

#### 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+ Bloc P. 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+ BLOC P, 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 organisms

Refers to section 2.2.7.2.1

##### Sediment dwelling organisms

Refers to section 2.2.7.2.1

##### STP micro-organisms

Refers to section 2.2.7.2.1

##### Atmosphere

Refers to section 2.2.7.2.1

##### Terrestrial compartment

Refers to section 2.2.7.2.1

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

Refers to section 2.2.7.2.1

##### Summary of PNECs

Refers to section 2.2.7.2.1

#### Environmental exposure assessment

As the product contains no substance of concern except brodifacoum, it is considered that risks posed to environment following the use of FANGA B+ BLOC P 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+ BLOC P is a rodenticide in wax block bait form (packaged in sachet or bulk) containing 0.001% brodifacoum[[36]](#footnote-36) (0.01 g/kg).The product is in the form of a block (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+ BLOC P 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);
* Sewer (professional use only)

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

The physico-chemical input parameters which were used are as follows:

|  |  |  |
| --- | --- | --- |
| **PHYSICO-CHEMICAL PROPERTIES** | **Value** | **Unit** |
| Molecular weight | 523.4 | [g.mol-1] |
| Vapour pressure at test temperature | << 1 x 10-6 | [Pa] |
| Temperature at which vapour pressure was measured | 20 | [°C] |
| Octanol-water partition coefficient | 6.12 | [log10] |
| Organic carbon-water partition coefficient | 9155 | [L.kg-1] |
| Half-life in soil | Not biodegradable\* | [d] |
| BCF fish | 35645 | L.kg-1 |
| Solubility in water | 0.058 | mg/L-1, PH7, 20°C |

*\**according to EUSES, the default DT50 value for soil to be used for risk assessment is 1.0E+06 d when the substance is not biodegradable

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

###### Sewer

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for sewers. If unused product, urine or excreta from target rodents or dead rodents enter the sewage system, brodifacoum may reach surface waters via the final effluent discharged from a sewage treatment plant (STP). Estimates of brodifacoum concentrations in surface water that arise from this application are calculated below.

ESD PT14 considers a typical scenario that involves a sewerage network serving a population equivalent (PE) of 10 000 and fitted with 300 access manholes. A maximum of 300 g bait is initially deployed beneath each manhole, giving a total of 90 kg formulated product distributed throughout the sewer network. The ESD PT14 scenario is a worst case because the applicant required a dose of 200 g bait/manhole. Maximum input of rodenticide into sewage water occurs during the first week of pulse baiting campaigns and EUBEES 2 indicates a figure of one third of the total deployment (i.e. 30 kg formulated product) in the first seven days. According to the ESD PT14, the default amount of product used in the control operation in sewer is 30 kg during the first 7 days of the control operation. This value is used in the following risk assessment for the use of FANGA B+ BLOC P in sewer.

In the worst case approach (default values), no metabolisation of the active substance is considered (Freleased = 0.9).

Elimination processes in STP are calculated using the Koc, the physico- chemical parameters and the results of biodegradation tests according to SimpleTreat. Due to the low vapour pressure and Henry's law constant and because difenacoum is not readily biodegradable, only relevant elimination process is partitioning to organic matters. EUSES calculations predict that 48.6 % is directed to water, 51.1 % to sludge and 0.3 % to air.

Table 6: Input values, emission and concentration in sewage water calculated according to the EUBEES 2 scenario for sewer system and the Guidance of BPR Vol. IV Part B- Worst case scenario with the default values and typical case scenario.

|  |  |  |  |
| --- | --- | --- | --- |
| Symbol | Variable/parameters | Default values | Unit |
| Qprod: | Amount of product used | 30 | [kg.camp-1] |
| Fcproduct: | Fraction of active substance in product | 0.01 | [gai.kg -1] |
| Temission | Number of emission days (realistic worst case during the control operation) | 7 | [d-1] |
| Freleased | Fraction released | 0.9 | [-] |
| Fmetabolised: | Fraction of active ingredient metabolised | 0 | [-] |
| F STP water | Fraction of emission directed to water by STP | 0.486 | [-] |
| F STP sludge | Fraction of emission directed to sludge by STP | 0.511 | [-] |
| Elocal STP | Local emission rate to the STP | 3.86E-05 | [kg.d-1] |
| Clocalinf | Concentration in untreated wastewater | 1.93E-05 | [mg.kg -1] |
| Ceff = PEC stp  (eq.33) | Concentration in the STP effluent | 9.37E-06 | [mg.L-1] |
| **Clocal water**  **(eq.45)** | **Local concentration in surface water** | **9.25E-07** | **[mg.L-1]** |
| Clocalsed (eq.50) | Local concentration in sediment | 1.85E-04 | [mg.kg-1] |

###### Other uses

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+ BLOC P 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)[[37]](#footnote-37) and the Guidance of BPR Vol. IV Part B. The ESD 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: 5 m for rats and 1 m for mice
* Number of refilling times: 5 (default value).

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 Guidance of BPR Vol. IV Part B equations. The degradation in soil was not considered in the calculations.

Table 7: PEC brodifacoum in soil and groundwater for uses in and around buildings

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Refined and specific parameters: typical scenario** | |  |
| **Symbol** | **Variable/parameters** | **Rat** | **Mouse** | **Unit** |
| **INPUTS** | | | | |
| Q*prod:* | Amount of product used in control operation for each bait box | 200 | 40 | [g] |
| Fc*product*: | Concentration of active substance in product | 0.01 | 0.01 | [g.kg-1] |
| Nsites: | Number of application sites | 10 | 10 | [-] |
| N*refil*: | Number of refilling times | 5 | 5 | [-] |
| F*release-D, soil*: | Fraction of product released directly to soil | 0.01 | 0.01 | [-] |
| F*release-ID, soil*: | Fraction released indirectly to soil | 0.9 | 0.9 | [-] |
| Koc | Organic carbon adsorption coefficient | 9 155 | 9 155 | [L.kg-1] |
| Distance | Distance between 2 bait points | 5 | 1 | [m] |
| AREA*exposed-D*: | Area directly exposed to rodenticide originating from one bait box | 0.09 | 0.09 | [m2] |
| AREA*exposed-ID*: | Area indirectly exposed to rodenticide | 510 | 110 | [m2] |
| DEPTH*soil*: | Depth of exposed soil | 0.1 | 0.1 | [m] |
| RHO*soil*: | Density of exposed soil | 1700 | 1700 | [kg.m-3] |
| **OUTPUTS** | | | | |
| Elocal*soil-campaign, direct*: | *Direct emission to soil from a campaign* | 1.00E-03 | 2.00E-04 | [g.camp-1] |
| Elocal*soil-campaign, indirect*: | *Indirect emission to soil from a campaign* | 8.91E-02 | 1.78E-02 | [g.camp-1] |
| Elocal*soil-campaign*: | *Total emission to soil from a campaign* | 9.01E-02 | 1.80E-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 | [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 | [mg.kg-1wwt] |
| **Clocal*soil*** | ***Worst case total concentration in soil =* Clocal*soil-D +* Clocal*soil-ID*** = ***PECsoil*** | **7.49E-03** | **2.26E-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)*** | **9.64E-04** | **9.64E-04** | **[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** | ***Worst case concentration in groundwater (based on the total concentration in soil)*** | **4.63E-05** | **1.40E-05** | **[mg.L-1]** |
| **PEClocal soil, porew** | ***Mean concentration in groundwater (based on mean concentration in soil)*** | **5.96E-06** | **5.96E-06** | **[mg.L-1]** |

###### Open areas

FANGA B+ BLOC P is applied in open areas inside or near the openings of the tunnels of the target rodents. According to the ESD PT14, the use near the openings of the tunnels demanding the use of bait boxes is covered by the assessment of the scenario “in and around buildings”. Thus this section “Open areas” only assesses the use inside the tunnels during which, according to the scenario presented in ESD PT14, 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+ BLOC P is intended to be applied in secured bait boxes only.

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

**Table 8: PEC of brodifacoum in soil 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 adsorption 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+ BLOC P 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 PT14 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 9: 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] |

###### Sewers

From the sewer use, an indirect exposure to soil via the STP sludge spreading on land is possible. PECsoil and subsequent concentrations in groundwater (porewater) are presented in the table below.

Table 10: PEC of brodifacoum in soil and groundwater for uses in sewer

|  |  |  |  |
| --- | --- | --- | --- |
| **Symbol** | **Variable/parameters** | **Worst case** | **Unit** |
| Q*prod:* | Amount of product used | 30 | [kg.camp-1] |
| Fc*product*: | Fraction of active substance in product | 0.01 | [gai.kg -1] |
| DT50 | Half-life time in soil | 298 | d-1 |
| Temission | Number of emission days (realistic worst case during the control operation) | 7 | [d-1] |
| F*released* | Fraction released | 0.9 | [-] |
| SLUDGRATE | Sludge production rate | 710 | [kg.d-1] |
| F *STP sludge* | Fraction of emission directed to sludge by STP | 0.511 | [-] |
| Elocal*STP* | *Local emission rate to the STP* | 3.86E-05 | [kg.d-1] |
| Csludge (eq.36) | *Concentration in dry sewage sludge* | 2.78E-02 | [mg.kg-1] |
| Csludge soil 1 (0) (eq.60) | *Concentration in agric. soil in first year at T0* | 4.08E-05 | [mg.kg-1] |
| C sludge soil 10 (0) (eq.62) | *Initial concentration in agric.soil after 10 years* | 7.12E-05 | [mg.kg-1] |
| **C sludge soil 10 (30)** | ***Twa concentration in agric. soil after 10 years over 30 days*** | **6.87E-05** | **[mg.kg-1]** |
| C sludge soil 10 (180) | *Twa concentration in agric. soil after 10 years over 180 days* | 5.81E-05 | [mg.kg-1] |
| **PEC soil porewater (eq.67)** | ***Concentration in porewater*** | **3.59E-07** | **[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+ BLOC P). 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 11: 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 PT14, 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 PT14:

**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 12: 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-1bw.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 ESD PT14, Table 3.1, Section 3.2.1.

b From ESD PT14, 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 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 PT14.

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

According to the ESD PT14, 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 13: 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***

For the sewer scenario, the contamination of the food chain via the contaminated aquatic compartment is likely after the STP. These PEC values for the aquatic compartment are therefore reported in table below, according to equation 89 of Guidance of BPR Vol. IV Part B.

According to the Guidance of BPR Vol. IV Part B, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, therefore a factor of 2 has to be applied to calculate PEC in food via aquatic food chain.

Table 14: PEC in food via aquatic chain

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Default values** | **Unit** |
| Clocal water: local concentration in surface water | | 9.25E-07 | [mg.L-1] |
| BMF: biomagnification factor | | 10 | [-] |
| BCF*fish*: bioconcentration factor | | 35 645 | [L.kgwwt-1] |
| PEC in food via aquatic food chain | | 1.65E-01 | mg/kg wet fish |

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

In and around building

According to the Guidance of BPR Vol. IV Part B, 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. 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 (Guidance of BPR Vol. IV Part B):

**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 in and around building application):

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

C porewater = 7.45 E-06 mg.L-1 (based on mean concentration in soil)

C local soil mean concentration = 1.20E-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 Guidance of BPR Vol. IV Part B, 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 15: Expected concentrations of brodifacoum in predator

|  |  |
| --- | --- |
|  | **PEC oral, predatormg/kg wet earthworm-1** |
| **In and around building** |
| ***TIER I: Worst case (based on the total concentration in soil)*** | |
| *Rat treatment* | 3.40E-01 |
| *Mice treatment* | 9.94E-02 |
| ***TIER I: Mean (based on the mean concentration in soil)*** | |
| *Rat treatment* | 5.30E-02 |
| *Mice treatment* | 4.24E-02 |
| ***TIER II: Mean (based on the mean concentration in soil) + considering degradation in soil (twa over 180 d with DT50 soil=298)*** | |
| *Rat treatment* | 5.12E-02 |
| *Mice treatment* | 4.10E-02 |

In sewers

For the sewer scenario, the contamination of the food chain *via* the contaminated terrestrial is possible after the STP These PEC values for the terrestrial compartment are therefore reported in table below.

According to the Guidance of BPR Vol. IV Part B, 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 PEClocal, soil is used in calculation, the PECoral,predator to be used in risk assessment is Cearthworm x 0.5.

Table 16: PEC in food via terrestrial chain

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Default values** | **Unit** |
| C sludge soil 10: concentration in agric. soil after 10 years – Twa over 180 days | | 5.81E-05 | [mg.kg-1] |
| PEC soil porewater: Concentration in porewater | | 3.59E-07 | [mg.L-1] |
| BCFeartworm: bioconcentration factor | | 15820 | [L.kgwwt-1] |
| PEC in food via terrestrial food chain | | 2.56E-03 | mg/kg wet earthworm |

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

According to the ESD PT14 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 17: 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 18: 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-1bw),**  **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 19: 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 (Guidance of BPR Vol. IV Part B, 2003) and “Emission Scenario document for biocides used as rodenticides” (ESD PT14).

The environmental risk characterization has been carried out for brodifacoum.

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

###### Sewers

The **Erreur ! Source du renvoi introuvable.**below presents PEC/ PNEC ratios for surface water, sediment and STP for the use of FANGA B+ BLOC P in sewer systems:

Table 20: PEC/PNEC ratios for the aquatic compartment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | PEC | PNEC | PEC/PNEC | Risk |
| Default values | Default values | |
| Surface water (mg/L) | 9.25E-07 | 4.00E-05 | 2.31E-02 | Acceptable |
| Sediment (mg/kg wwt) | 1.85E-04 | 4.30E-02 | 2.31E-01 | Acceptable |
| STP (mg/L) | 9.37E-06 | 3.80E-03 | 2.47E-03 | Acceptable |

No unacceptable risk is identified for the aquatic compartment including surface water, sediment and STP when the FANGA B+ BLOC P is used in sewer system against rodents, even when no metabolisation of the active substance is considered. For sediment, according to theGuidance of BPR Vol. IV Part B 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.

###### Other uses

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+ BLOC P in and around buildings, in open areas or in waste dump. Therefore, PEC values for brodifacoum in surface water and sediment are assumed to be negligible and have not been further considered.

##### 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+ BLOC P 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+ BLOC P bait in the scenario ‘in and around buildings’, ‘open areas’, ‘waste dump’ and ‘sewers’.

###### Sewers

The Table 22below presents PEC/ PNEC ratios for soil and groundwater for the use of FANGA B+ BLOC P in sewer systems:

Table 21: PEC/PNEC ratios for the terrestrial compartment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | PEC | PNEC or threshold value | PEC/PNEC | Risk |
| Default values | Default values | |
| Soil(mg/kg wwt) | 6.87E-05 | 8.80E-01 | 7.81E-05 | Acceptable |
| Groundwater (mg/L) | 3.59E-07 | 1.00E-04\* | Threshold value | Acceptable |

The risk is acceptable for the terrestrial compartment when FANGA B+ BLOC P is used in sewer systems.

###### In and around building

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

Realistic worst 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 22: 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 | 7.49E-03 | 0.88 | 8.51E-03 |
| Mice treatment: | 2.26E-03 | 2.57E-03 |

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

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

Table 23: PEC groundwater due to use of FANGA B+ BLOC P 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 | 4.63E-02 | 0.1 | Acceptable |
| Mice treatment | 1.40E-02 |

###### Open areas

Exposure of the terrestrial compartment (soil) will occur when FANGA B+ BLOC P 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 24: 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 and indicate that there are no unacceptable risks to the terrestrial compartment when the product FANGA B+ BLOC P is used in the tunnels of open areas. According to the 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 above2.2.7.5.3.2), there is no unacceptable risk for the terrestrial compartment (including groundwater) when the FANGA B+ BLOC P is used near the openings of the tunnels of the target rodents.

###### “The emission to soil, leading to groundwater contamination by leaching, for the use in open area, is lower than in the scenario waste dump. Thus the risk for groundwater due to the use in open area is covered by the one for the waste dump scenario.”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 25: 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+ BLOC P is used in waste dump.

**Table 26: PEC groundwater due to use of FANGA B+ BLOC P 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 | 0.1 | 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 (Guidance of BPR Vol. IV Part B) and “Emission Scenario document for biocides used as rodenticides” (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 27: 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 | **45045** |
| **Birds** | 10 | 1.30E-04 | **76923** |

1Concentration 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 28: 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 exposure***

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 29: Tier 2 acute qualitative risk assessment of primary poisoning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **PECoral1**  mg.kg-1bw | | **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 birds and 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 exposure***

The PEC values for the Tier 2 assessment of the long-term exposure are compared to the PNEC values.

**Table 30: Tier 2 long-term risk assessment: PECoral/PNECoral for non-target animals in realistic worst case (step 2) for long-term situation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Non-target animal** | **PECoral**1  mg.kg-1bw | **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+ BLOC P 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.

For the sewer scenario, the contamination of the food chain via the contaminated aquatic compartment is possible after the STP according to EUSES 2.1.0. These PEC/PNEC values for the aquatic compartment are therefore reported in table below.

Table 31: Secondary poisoning via aquatic food chain in sewer system

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Aquatic PECoral,predator**  **mg/kg wet** | **PNEC oral**  **mg/kg food** | **Aquatic**  **PEC/PNEC** |
| **Default values** | **Default values** |
| Birds | 1.65E-01 | 1.30E-04 | 1.27E+03 |
| Mammals | 2.22E-04 | 7.42E+02 |

The risks for secondary poisoning are unacceptable via the aquatic food chain in the sewer system for birds and mammals.

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

Sewer

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

Table 32:Secondary poisoning via terrestrial food chain in sewer system

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Terrestrial PECoral, predator**  **mg/kg wet** | **PNEC oral**  **µg/kg food** | **Terrestrial PEC/PNEC** |
| **Default values** | **Default values** |
| Birds | 2.56E-03 | 1.30E-05 | 1.97E+01 |
| Mammals | 2.22E-04 | 1.15E+01 |

The risks for secondary poisoning are unacceptable via the terrestrial food chain in the sewer system for birds and mammals.

In and around buildings

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

**Table 33: 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** | **Mammals** | **Birds** | **ESD Default parameters** | |
| **Mammals** | **Birds** |
| ***TIER I: Worst case (based on the total concentration in soil)*** | | | | | |
| *Rat treatment* | 3.40E-01 | 2.22E-04 | 1.30E-04 | **1 532** | **2 615** |
| *Mice treatment* | 9.94E-02 | **448** | **765** |
| ***TIER I: Mean (based on the mean concentration in soil)*** | | | | | |
| *Rat treatment* | 5.30E-02 | 2.22E-04 | 1.30E-04 | **239** | **408** |
| *Mice treatment* | 4.24E-02 | **191** | **326** |
| ***TIER II (based on time-weight average concentration (180d) in soil)*** | | | | | |
| *Rat treatment* | 5.12E-02 | 2.22E-04 | 1.30E-04 | **231** | **394** |
| *Mice treatment* | 4.10E-02 | **185** | **315** |

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 a qualitative risk assessment in accordance with the decisions taken at the TMII-06.

**Table 34: Tier 1 long-term risk assessment of secondary poisoning**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  mg.kg-1bw | | | **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 35: Tier 1 long-term risk assessment of secondary poisoning**

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  mg.kg-1bw | **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 36: 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 | **26447** | **31574** |
| Kestrel  *(Falco tinnunculus)* | 0.52 | 0.62 | **40162** | **47949** |
| Little owl  *(Athene noctua)* | 0.39 | 0.47 | **30176** | **36027** |
| Tawny owl  *(Strix aluco)* | 0.32 | 0.38 | **24311** | **29024** |
| Fox  *(Vulpes vulpes)* | 0.13 | 0.15 | 1.10E-05 | **11504** | **13734** |
| Polecat  *(Mustela putorius)* | 0.26 | 0.31 | **23948** | **28590** |
| Stoat  *(Mustela erminea)* | 0.38 | 0.45 | **34249** | **40889** |
| Weasel  *(Mustela nivlis)* | 0.54 | 0.65 | **49420** | **59001** |

The tier 2 risk characterisation shows very high risks for secondary poisoning at long-term for birds and mammals.

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.

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

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

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Annex 0: Practical use of Biocides ex:TP14

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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+ BLOC P**  Formulation: BLOCK | Brown rat*: Rattus norvegicus* | Professionnal | In and around buildings, open areas, waste dumps, landfills, sewers | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 - 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Manual application of baits in bait stations | yes | Sachet PE or PP | 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* | Professionnal | In and around buildings, open areas, waste dumps, landfills,sewers | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 to 200g blocks in bulk | 5-10 meters | Manual application of baits in bait stations | 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 (carton) - 5-10-12-15-20 -25-50kg |  |
| Brown rat*: Rattus norvegicus* | Non professionnal | In and around buildings, open areas | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4- 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Pre-filled secured boxes  Manual application of baits in bait stations | yes | Sachet PE or PP | 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* | Professionnal | In and around buildings, open areas, waste dumps, landfills | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4- 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Manual application of baits in bait stations | yes | Sachet PE or PP | 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 |  |
| Black rat: *Rattus rattus* | Professionnal | In and around buildings, open areas, waste dumps, landfills | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 to 200g blocks in bulk | 5-10 meters | Manual application of baits in bait stations | 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 (carton) - 5-10-12-15-20 -25-50kg |  |
| Black rat: *Rattus rattus* | Non professionnal | In and around buildings, open areas | 180-200 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 - 20 - 25 -30-40- 50 - 100g sachet | 5-10 meters | Pre-filled secured boxes  Manual application of baits in bait stations | yes | Sachet PE or PP | 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* | Professionnal | In and around buildings, open areas, waste dumps, landfills | 30-40 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 - 20- 30- 40g sachet | 1-2 meters |  | yes | Sachet PE or PP | 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* | Professionnal | In and around buildings, open areas, waste dumps, landfills | 30-40 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 to 40g blocks in bulk | 1-2 meters | Manual application of baits in bait stations | 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 (carton) - 5-10-12-15-20 -25-50kg |  |
| Mice: *Mus musculus* | Non professionnal | In and around buildings, open areas | 30-40 g/secured bait point |  | 4 refilling of bait stations  Over 28 days  Interval between applications (min) : one week | 4 - 20 - 30 - 40g sachet | 1-2 meters | Pre-filled secured boxes  Manual application of baits in bait stations | yes | Sachet PE or PP | 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 65 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 1: Analytical methods residues – active substance

See details in section 2.2.4 of the PAR.

brodifacoum

Annex 2 : Toxicology and metabolism –active substance

<BRODIFACOUM>

Threshold Limits and other Values for Human Health Risk Assessment

Date: 16/06/2016

| **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 | 0.047% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 1 H330  Acute Tox 1 H310  Acute Tox 2 H300  STOT RE Cat 1 H372 (blood)  Repr 1A H360D  Specific limit concentrations  Rep 1A – H360D C ≥ 0.003%  STOT RE 1 – H372 (blood) C ≥ 0.02%  STOT RE 2 – H373 (blood) 0.002% ≤ C > 0.02% |

Annex 3 : Toxicology – biocidal product

<FANGA B+ BLOC P>

Date: 16/06/2016

|  |  |
| --- | --- |
| General information | |
| Formulation Type | paste |
| Active substance(s) (incl. content) | Brodifacoum (0.0012% 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) | |
| Regulation 1272/2008/EC | None |

Annex 4: Safety for professional operators

<FANGA B+ BLOC P>

Date: 16/06/2016

Exposure assessment

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

Primary exposure of professionals – FANGA B+ BLOC P – Control of rats

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| **Bulk formulation** | | | | | |
| Professionnalrat  (without gloves) | Brodifacoum | 56073-10-0 | 1.58 x 10-6 | negligible | 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 |  |
| **Bulk formulation** | | | | | | | | |
| Professionnalrat  (without gloves) | Brodifacoum | 56073-10-0 | 3.3x10-6 | 100 | 0.047 | 1.58 x 10-6 | 48% | Acceptable |

Annex 5: Safety for non-professional operators and the general public

<FANGA B+ BLOC P>

Date:16/06/2016

| General information | |
| --- | --- |
| Formulation Type | paste |
| Active substance(s) (incl. content) | Brodifacoum (0.0012% 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 0.0012% 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+ – Control of rats

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| **Sachet formulation (PP or PE)** | | | | | |
| Non Professionnal | Brodifacoum | 56073-10-0 | 2.68 x 10-9 | negligible | 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 (PP or PE)** | | | | | | | | |
| Non Professionnal | Brodifacoum | 56073-10-0 | 3.3x10-6 | 100 | 0.047 | 2.68 x10-9 | 0.04% | Acceptable |

Annex 6 : Residue behaviour

brodifacoum

Date: 17.11.2015

**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 and pre-fille secured boxes 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 7: 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*** |
| BDBP12V1  (FANGA B+ BLOC P)  0.0012% Brodifacoum | Black rat (*Rattus rattus*) | Laboratory study  Method based on :  Technical Notes for Guidance on Product Evaluation – Product type 14  Black rats: 10 animals (5 males and 5 females)  Intoxication duration: 4 days. | Acclimation: 4 days in individual cage.  Intoxication phase: Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (Feed "bouchon" SAFE-04) (B) in two clean pots at the animals' disposal.  Each day, the hoppers were weighted, readjusted and its places were inverted. Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. ln placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period.  Post treatment phase: After day 4 the animals should be returned to the standard laboratory diet.  Food and bait consumption were measured and mortality was observed during 20 days after the first day of intoxication. | The BDBP12V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to 10 black rats (5 males and 5 females) during 4 days according to technical notes for guidance on product evaluation – product type 14 protocol has demonstrated that:   * A mean palatability equivalent to 0.40 * A good consumption for all rats between D0 and D4 * A total efficacy, with 100% of mortality for males between D7 and D9 * and 100% of mortality for females in a period from D7 to D8   Efficacy can be considered as total for black rats. | 14TOX043[[38]](#footnote-38) | *1* |
| BDBP12V1  (FANGA B+ BLOC P)  0.0012% Brodifacoum | Brown rat  (*Rattus norvegicus*) | Laboratory study  Method:  Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products »  Brown rats: 5 males and 5 females.  Intoxication duration: 4 days | Acclimatization: 4 days in individual cage at room temperature.  Intoxication phase: 4 days  Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (Feed “bouchon” SAFE-04) (B) in two clean pots at the animals’ disposal.  Each day, the hoppers were weighted, readjusted and its places were inverted.  Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period.  Post-treatment phase: After day 4 the animals should be returned to the standard laboratory diet.  Mortality was observed during 21 days every 24 hours. | The BDBP2V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to brown rats (5 males and 5 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated:   * A mean palatability equivalent to 0.43 * A good consumption for all rats between D0 and D4 * A total efficacy, with 100% of mortality for males between D4 and D7 and 100 % of mortality for females in a period from D6 to D7.   Efficacy can be considered as total for brown rats. | Guicherd A. Study 15TOX002[[39]](#footnote-39) | *1* |
| BDBP12V1  (FANGA B+ BLOC P)  0.0012% Brodifacoum | House mice  (*Mus musculus*) | Laboratory study  Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products »  House mice:  10 males and 10 females.  Intoxication duration: 4 days. | Acclimatization: 4 days in separate cages (10 males in a cage and 10 females in a second cage) at room temperature.  Treatment phase: Standard Laboratory diet was removed and replaced by the Test Bait (A) andReference (Feed "bouchon" SAFE-04) (B) in two clean pots at the animals' disposal.  Each day, the hoppers were weighted, readjusted and its places were inverted.  Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. ln placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period.  Post treatment phase: After day 4 the animals should be returned to the standard laboratory diet.  Mortality was observed during 21 days every 24 hours or until the death of all animals. | The BDBP12V1 (FANGA B+ BLOC P) bait containing 12 ppm Brodifacoum given to house mice (10 males and 10 females) during 4 days according to the Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products » has demonstrated:  • A mean palatability equivalent to 0.64  • A good consumption between D0 and D4 for males and females  • A total efficacy, 100% of mortality for males in a period from D4 to D6  and 100% of mortality for females in a period from D1 to D9.  Efficacy can be considered as total for house mice. | Guicherd A.  Study 14TOX044[[40]](#footnote-40) | *1* |
| BDBP12V1 (FANGA B+ BLOC P)  0.0012% Brodifacoum | Black rats  (*Rattus rattus*) | Field test  EPPO PP 1/114(2) | The trial was set up in an agricultural habitat (breeding stables for hens, fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  - Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2014-11-19 to 2014-12-30 | The trial was set up in an agricultural habitat (breeding stables for hens, fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  The farm site was surveyed and a notable presence of rats over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Roof rat (*Rattus rattus* L.).  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).  On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned placebo baits during the Post-treatment phase).  According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the Rattus rattus population present across the trial site when used at the application rate of 200 g per bait station. | Rovetto I. Study n°2018.BCD.SAG14[[41]](#footnote-41) | *1* |
| BDBP12V1 (FANGA B+ BLOC P)  0.0012% Brodifacoum | Brown rats  (*Rattus norvegicus*) | Field test  EPPO PP 1/114(2) | The trial was set up in an agricultural habitat (cow breeding stables, fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  - Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment rat population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2014-11-19 to 2014-12-30 | The trial was set up in an agricultural habitat (cow breeding stables, fodder and equipment warehouses) in which rats infestation was signalled by the farmer.  The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these rats to be identified as belonging to Norway rat (*Rattus norvegicus* Berk.).  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rat population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).  On the same way it was calculated an index of the rat population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase).  According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the Rattus norvegicus population present across the trial site when used at the application rate of 200 g per bait stations. | Rovetto I. Study n°2017.BCD.SAG14[[42]](#footnote-42) | *1* |
| BDBP12V1 (FANGA B+ BLOC P)  0.0012% Brodifacoum | House mouse  (*Mus musculus*) | Field test  EPPO PP 1/114(2) | The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer  - Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment mice population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2014-11-19 to 2014-12-30 | The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer.  The farm site was surveyed and a notable mice presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these mice to be identified as belonging to *Mus musculus* L.  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the mice population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).  On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase).  According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the *Mus musculus* population present across the trial site when used at the application rate of 100 g per bait stations | Rovetto I. Study n°2016.BCD.SAG14[[43]](#footnote-43) | *1* |
| BDBP12V1  (FANGA B+ BLOC P)  0.0012% Brodifacoum  2 year aged  5 days aged in damp condition | Brown rat | Laboratory study  Test protocol VPU/15/04 and method:  Technical Notes for Guidance on Product Evaluation, Appendices to chapter 7 Product type 14 « Efficacy evaluation of rodenticidal biocidal products »  Brown rats: 5 males and 5 females.  Intoxication duration: 4 days | Acclimatization: 4 days in individual cage at room temperature.  Intoxication phase: 4 days  Standard Laboratory diet was removed and replaced by the Test Bait (A) and Reference (RM3 ground laboratory diet) (B)  Each day, the hoppers were weighted, readjusted and its places were inverted.  Losses were also weighted. Daily bait consumptions were measured and the respective consumptions of bait were determined in relation with the body weight of animals. All used Test Bait and Reference is discarded and fresh quantities of each diet are placed in clean pot. In placing the pots back in the cage, the positions of the rodenticide and the reference diet should be interchanged to avoid place preference. This procedure will be repeated every day during the choice period.  Post-treatment phase: After day 4 the animals should be returned to the standard laboratory diet.  Mortality was observed during 22 days every 24 hours. | The BDBP2V1 (FANGA B+ BLOC P) 2 years aged bait containing 12 ppm brodifacoum weathered in damp conditions (T° 30-35 °C, RH 80 %) was given to brown rats (5 males and 5 females) during 4 days The study has demonstrated:   * A mean palatability equivalent to 0.20 * A total efficacy, with 100% of mortality between D3 to D5.   In damp conditions | PRESCOTT C. V.  2013.BCD.SAG16 | *1* |
| BDBP12V1 (FANGA B+ BLOC P)  0.0012% Brodifacoum  21 months aged | House mouse  (*Mus musculus*) | Field test  EPPO PP 1/114(2) | The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer  - Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment mice population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.  - Intervals of examination: every day from 2016-04-26 to 2016-05-19 | The trial was set up in an agricultural habitat (cows breeding stable for horses, fodder and equipment warehouse) in which mice infestation was signalled by the farmer.  The farm site was surveyed and a notable mice presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these mice to be identified as belonging to *Mus musculus* L.  Eight bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the mice population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).  On the same way it was calculated an index of the mice population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase).  According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the *Mus musculus* population present across the trial site when used at the application rate of 40 g per bait station. | Rovetto I. Study n°2019.BCD.SAG16 | *1* |
| BDBP12V1 (FANGA B+ BLOC P)  Wax block bait  0.0012% Brodifacoum  4 years aged | Roof rats  (*Rattus rattus* L.) | Field test  EPPO PP 1/114(2) | The trial was set up in an agricultural habitat (cows breeding stable, fodder and equipment warehouse) in which mice infestation was signalled by the farmer  - Method for recording / scoring effects: daily bait take and tracking score during the trial period  The percentage of efficacy of the test product against the rat population was calculated using the following formula:  % efficacy = 100 – [ Post-treatment rat population size index/Pre-treatment mice population size index x 100]  where:  Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.  - Intervals of examination: every day from 2018-09-28 to 2018-11-14 | The trial was set up in an agricultural habitat (cows breeding stable for horses, fodder and equipment warehouse) in which rats infestation was signalled by the farmer.  The farm site was surveyed and a notable rats presence over the entire site was detected. The analysis of the observed runways, footprints and faeces allowed these mice to be identified as belonging to *Rattus rattus* L.  Ten bait-stations and eight tracking patches were set out on the main rat runways which were found inside the buildings.  In order to detect the efficacy of the test product against the pest, it was firstly calculated an index of the rats population size during a Pre-treatment *census* (monitoring of the daily consumption of unpoisoned *placebo* baits).  On the same way it was calculated an index of the rats population size after the Poisoning phase (monitoring of the daily consumption of unpoisoned *placebo* baits during the Post-treatment phase).  According to the results of the present study, BDBP12V1 (FANGA B+ BLOC P) showed a good acceptance level and provided a complete effectiveness (100.0%) against the *Rattus rattus* population present across the trial site when used at the application rate of 120 g per bait station. | Rovetto I. Study n°2017.BCD.SAG18 | *2* |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. Non-active substance(s), of which knowledge is essential for proper use of the product.In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance. [↑](#footnote-ref-3)
4. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
5. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-5)
6. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-6)
7. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-7)
8. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-8)
9. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-9)
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11. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-11)
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13. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-13)
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15. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-15)
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17. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-17)
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19. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-19)
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26. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-26)
27. Greaves J. H.; Shepherd D. S.; Gill, J. E. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587. [↑](#footnote-ref-27)
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32. Although the block weights 4 g and not 20 g as in the CEFIC study, it was considered that the important parameter is the number of blocks loaded rather than the weight of the block [↑](#footnote-ref-32)
33. Syngeta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force Combined Assessment Report according to the procedure of Directive 98/8/EC, active substance in biocidal products, brodifacoum CAS n°56073-10-0, product type 14 (rodenticides), RMS Italy, Revision: 16 december 2010 [↑](#footnote-ref-33)
34. : Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), Version 1.0, April 2015 [↑](#footnote-ref-34)
35. Syngeta Limited and Activa / Pelgar Brodifacoum and Difenacoum Task Force Combined Assessment Report according to the procedure of Directive 98/8/EC, active substance in biocidal products, brodifacoum CAS n°56073-10-0, product type 14 (rodenticides), RMS Italy, Revision: 16 december 2010 [↑](#footnote-ref-35)
36. Please note that a round value for the brodifacoum percentage has been used for the ERA. The validated concentration, for technical substance is 0.001209%. The PEC/PNEC ratios are slightly impacted by this approximation but the conclusions are not changed. [↑](#footnote-ref-36)
37. EUBEES 2 - Emission scenario document for biocides used as rodenticides (Larsen, 2003) [↑](#footnote-ref-37)
38. Guicherd A. 2015. Study on the palatability and efficacy of a 0.0012% w/w Brodifacoum Bloc bait in black Rat *(Rattus Rattus}. Biolytics,* Report 14TOX043of the 16 February 2015, not GLP.. [↑](#footnote-ref-38)
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