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 MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



BROMAFAR

Product type 14

Case Number in R4BP: BC-KF068656-31

Evaluating Competent Authority: FR

Date: December 2021

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**Note to the reader:**

This consolidated PAR for the minor change of the product authorisation of BROMAFAR is based on the PAR of the initial assessement of the product FAAR BLE (reference product from which BROMAFAR is a same product) evaluated by FR CA and the subsequent successive assessments.

The summary of product characteristics (SPC) is indicated in part 3 of this PAR and it corresponds to the decision for the ongoing minor change application (2021).

Each section contains the initial assessment and the subsequent successive assessments. The assessments related to the ongoing minor change application (2021) are indicated at the end of each section and are highlighted in grey.

**Disclaimer regarding user category**

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

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

Consequently, in Part 2 of the SPC for major change, uses for “professionals” are mentioned according to the agreed standard SPC, but they are not relevant in France. It is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

# 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 | NA | 18/06/2013 | First authorisation FAAR BLE |
| NA-BBS | FR | NA | 19/06/2013 | Same biocidal product BROMAFAR |
| NA-MIC | FR | BC-CD002455-67 | 14/03/2014 | Minor change: addition of a new packaging form (bulk for professional users) and a new user category (non professional users with product conditioned in bags (sachets) in polyethylene) |
| NA-MIC | FR | BC-RR008128-21 | 04/11/2015 | Minor change: modification of composition. Replacement of the cereal ”wheat” by ”crushed corn” |
| NA-RNL | FR | BC-TA015418-49 | 08/02/2018 | Renewal of the authorisation |
| NA | FR | NA | NA | Post-authorisation data (received on the 01/03/2019) |
| NA-MIC | FR | BC- VN050668-09 | 01/10/2019 | Minor change: increase of the shelf life to 24 months (not approved: efficacy data missing) |
| NA-MIC | FR | BC- KF068656-31 |  | Minor change: increase of the shelf life to 24 months |

NA: not applicable

**Post-authorisation data (2019)**

This consolidated PAR includes the assessment of the post authorization data requested in the decision of the product.

The following post authorization requests have been made:

* *The authorisation holder must provide the results of the long term-stability study within 1 year post authrorisation.*
* *The authorisation older must provide an analytical fully validated method for the product within 1 year post authorisation.*

The results of the long terme stability and the analytical method have been provided on 01/03/2019. Results are reported in the PAR (the corresponding sections are titled “post authorisation (2019)”). Storage stability study results are acceptable. The biocidal product (new formulation) is stable 2 years at ambient temperature with an HDPE bag.

**Minor change (2019)**

French competent authorities (FR CA) considers that the elements presented in the dossier confirm the efficacy of the product BROMAFAR against house mice (*Mus musculus*) and black rats (*Rattus rattus*) with a 24 months aged product.

Nevertheless, according to the Efficacy guidance Volume II – Parts B+C, to support a storage duration of 24 months (of the new formulation without preservative), efficacy should be demonstrated on all the species claimed. In the absence of efficacy data with a 24 months aged product against *Rattus norvegicus,* FR CAconsiders the efficacy of the product after a storage duration of 24 months is not validated.

Results are reported in the PAR (the corresponding sections are titled “minor change (2019)”).

**Minor change (2021)**

**Efficacy**

FR CA consider that the elements presented in the dossier confirm the efficacy of the product BROMAFAR (0.005 % w/w bromadiolone) against mice (*Mus musculus*) and rats (*Rattus norvegicus, Rattus rattus*) for indoor use by professional users, with a shelf-life up to 24 months.

**Phys Chem**

The change of shelf life from 12 to 24 months is acceptable as a long term storage stability study for 30 months at ambient temperature that was already submitted showed that the product is stable for 30 months.

# General information about the product application (initial PAR – 2012)

## Applicant

|  |  |
| --- | --- |
| Company Name: | TRIPLAN SA |
| Address: | BP 258 La Poste Française |
| City: | Andorra La Vella |
| Postal Code: | AD500 |
| Country: | Andorre |
|  |  |
|  |  |
| E-mail address: | triplan@andorra.ad |

## Current authorisation holder[[1]](#footnote-1)

|  |  |
| --- | --- |
| Company Name: | TRIPLAN SA |
| Address: | BP 258 La Poste Française |
| City: | Andorra La Vella |
| Postal Code: | AD500 |
| Country: | Andorre |
|  |  |
|  |  |
| E-mail address: | triplan@andorra.ad |
| Letter of appointment for the applicant to represent the authorisation holder provided (yes/no): | yes |

## Proposed authorisation holder

|  |  |
| --- | --- |
| Company Name: | TRIPLAN SA |
| Address: | BP 258 La Poste Française |
| City: | Andorra La Vella |
| Postal Code: | AD500 |
| Country: | Andorre |
|  |  |
|  |  |
|  |  |
| Letter of appointment for the applicant to represent the authorisation holder provided (yes/no): | yes |

## Information about the product application

|  |  |
| --- | --- |
| Application received: | 30/06/2011 |
| Application reported complete: | 29/07/2011 |
| Type of application: | Product authorisation |
| Further information: |  |

## Information about the biocidal product

### General information

|  |  |
| --- | --- |
| Trade name: | FAAR BLE |
| Manufacturer’s development code number(s), if appropriate: | SOFAR FRANCE |
| Product type: | PT14 - Rodenticide |
| Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex): | Active substance’s identity and content: Bromadiolone 0.005% w/w  No substance of concern |
| Formulation type: | VIII.3.1 Granular bait |
| Ready to use product (yes/no): | Yes |
| Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no);  If yes: authorisation/registration no. and product name:  or  Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no): | No  No |

### Information on the intended use(s)

|  |  |
| --- | --- |
| Overall use pattern (manner and area of use): | FAAR BLE is intended to be used for control of mice, brown rats and black rats in buildings included farm buildings.  The treatment with FAAR BLE is applied by trained professional users and by non-professional users. |
| Target organisms: | I.1.1 Murids : *Muridae*  I.1.1.1 Brown rat: *Rattus norvegicus*  I.1.1.2 Black rat: *Rattus rattus*  I.1.1.3 House mouse: *Mus musculus* |
| Category of users: | V1 Non professional / general public  V.2 Professional |
| Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area: | VI.2 Covered application  VI.2.1 in bait stations  VI.2.2 other covering  The product is ready-to-use (cereal grains) so with no dilution and no other substances added for application. It is supplied in sachets or in bulk and manually applied in bait boxes or bait stations with a shovel in the case where the baits are supplied in bulk.  Rats :  180-200 g grains/secured bait point separated by 5-10 m.  Mice:  30-40 g grains/secured bait point separated by 1-2 m.  Over a period of 28 days for application, cleaning, refilling and collect of dead rodents.  The control of rats and mice is carried out inside buildings, so the environmental conditions in which rodents are found tend to be similar relating to geographical areas. |
| Potential for release into the environment (yes/no): | No |
| Potential for contamination of food/feedingstuff (yes/no) | No |
| Proposed Label: | Control of rats (black rats and brown rats) and mice indoors. |
| Use Restrictions: | Use only indoors in secured bait stations out of reach of children and domestic animals. |

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

* **Minor change - 2014**

|  |  |
| --- | --- |
| **Overall use pattern (manner and area of use):** | BROMAFAR is a ready to use grain bait supplied in bulk and in sachets. The product is applied by professional and non-professional users. The product is applied manually at measured amount in secured bait boxes or other types of covered bait stations. The product is used indoor and outdoor. |
| **Target organisms / stages:** | * Rattus norvegicus-Adults-Brown rat * Rattus norvegicus-Juveniles-Brown rat * Rattus rattus-Adults-Roof rat * Rattus rattus-Juveniles-roof rat * Mus musculus-Adults-house mouse * Mus musculus-Juveniles-house mouse |
| **Category of users:** | Professional and non-professional users |
| **Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:** | **Rats** (*Rattus rattus* & *Rattus norvegicus*):   * + High infestation: 200 g of product / bait station distances of 5 meters apart   + Low infestation: 200 g of product / bait station distances of 10 meters apart   **House mouse** (*Mus musculus*):   * + High infestation: 40 g of product / bait station distances of 1 meter apart   + Low infestation: 40 g of product / bait station distances of 2 meters apart |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no)** | No |
| **Proposed Label:** | See the label |
| **Use Restrictions:** |  |

### Information on active substance(s)[[2]](#footnote-2)

|  |  |
| --- | --- |
| Active substance chemical name: | Bromadiolone |
| CAS No: | 28772-56-7 |
| EC No: | 249-205-9 |
| Purity (minimum, g/kg or g/l): | > 96.9 % w/w |
| Inclusion directive: | 2009-92-CE |
| Date of inclusion: | 01/07/2011 |
| Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no): | Yes |
| Manufacturer of active substance(s) used in the biocidal product: | Activa |
| Company Name: | Dr Tezza S.r.l. |
| Address: | Viale del lavoro, 326 |
| City: | Angiari vr |
| Postal Code: | 37050 |
| Country: | Italy |
| Telephone: | 0456069004 |
| Fax: | 0442660041 |
| E-mail address: | pier@drtezza.eu |

* **Renewal (2017):**

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

A comparative assessement has been carried out at the European level. According to Article 1 of Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council. In the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.

Therefore, the authorisation of this product will be renewed for 5 years.

* **Minor change (2019):**

The applicant has provided post authorisation data which were requested to validate the shelf life. Storage stability study results are acceptable. The biocidal product (new formulation) is stable 2 years at ambient temperature with an HDPE bag. The product being a solid, if it is compatible with a type of packaging, it is considered compatible with every types of packaging.

Results are reported in the PAR.

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

There is no substance of concern.

## Documentation

### Data submitted in relation to product application

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

Physico-chemical properties studies and analytical methods on the biocidal product FAAR BLE were provided by TRIPLAN. Complementary data for the validation of the analytical method performed on another formulation (FAAR BLOCK SP) have also been provided.

* **Minor changes ( 2015)**

In the framework of the modification of composition, the new composition BROMAFAR cannot be considered as similar as old composition of BROMAFAR without data on bulk density, dustiness, attrition, flowability and particle size distribution. Data wwere submitted in February 2015:

* **Renewal (2017):**

For renewal of authorization of BROMAFAR, no additional data has been submitted.

* **Post authorisation (2019):**

Post authorisation data (shelf life study with the new formulation at 50 ppm) have been submitted.

Results are reported in the PAR.

**Efficacy data**

* **First authorisation (2013):**

The following efficacy studies were submitted:

* Efficacy and palatability laboratory study of the rodenticide FAAR BLE containing 0.005% bromadiolone on albino house mice (*Mus musculus*).
* Efficacy field study of FAAR BLE rodenticide containing 0.005% bromadiolone on black rats (*Rattus rattus*). The test is performed in a pig farm
* Efficacy field study of FAAR AVOINE rodenticide containing 0.005% bromadiolone and 0.001 % denatonium benzoate on albino wild mice (*Mus musculus*). The test is performed in a farm (food storage room and cellar)).
* Efficacy field study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone on brown rats (*Rattus norvegicus*). The test is performed in pheasant’s aviaries.

The field study on house mice (*M. musculus*) has been done on the product FAAR AVOINE. The differences between the compositions of the products FAAR AVOINE and FAAR BLE are slight. It consists on a change in cereal support (oat instead of whole wheat) and the withdrawal of a stabilisant agent. So we can consider that the difference of composition between the two formulations doesn’t have any influence on efficacy. Therefore, results from this study can be extrapolated to the current formulation of FAAR BLE.

The field study on brown rats (*R. norvegicus*) has been done on the product FAAR BLOC SP. This product is a block bait containing the same amount of active substance bromadiolone. Since block baits are less palatable than grain baits (this was confirmed by the lab test on albino mice) and efficacy of the product FAAR BLE has been confirmed on black rats that are used to be more suspicious than brown rats, results from this field study can be extrapolated to the current formulation of FAAR BLE.

The field study on FAAR BLE has been done with 2 month-aged baits but field study on FAAR AVOINE has been done on a 14 month-aged bait. As compositions of these two products are similar, we can conclude that FAAR BLE can be considered as effective after a 14 months storage period.

The 24 months storage period claimed by the applicant must be demonstrated with a field study realized with a 24 month-aged product.

* **Renewal (2017):**

The following efficacy studies were submitted:

* A free-choice laboratory test was carried out with house mice (***Mus musculus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone) for 4 days.
* A free-choice laboratory test was carried out with brown rats (***Rattus norvegicus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone) for 4 days.
* A free-choice laboratory test was carried out with black rats (***Rattus rattus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone) for 4 days.
* A field test (Italie) was carried out with brown rats (***Rattus norvegicus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone).
* A field test (Italie) was carried out with black rats (***Rattus rattus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone).
* A field test (Italie) was carried out with house mice (***Mus musculus***), with exposure to **BROMAFAR** (0.005 % w/w bromadiolone).
* **Minor change (2019):**

The following efficacy studies were submitted:

* A field test was carried out with house mice (*Mus musculus*), with exposure to a 2 year aged product BROMAFAR (0.005 % w/w bromadiolone).
* A field test was carried out with roof rat (*Rattus rattus*), with exposure to a 2 year aged product BROMAFAR (0.005 % w/w bromadiolone).
* **Minor change (2021):**

The following efficacy studies were submitted:

* A field test was carried out with norway rat (***Rattus norvegicus***), with exposure to a 2 year aged product BROMAFAR (0.005 % w/w bromadiolone).
* A laboratory choice test was carried out with norway rat (***Rattus norvegicus***), with exposure to a 3 year aged product BROMAFAR (0.005 % w/w bromadiolone).
* A field test was carried out with house roof rat (***Rattus rattus***), with exposure to a 4 year aged product BROMAFAR (0.005 % w/w bromadiolone).
* A laboratory choice test carried out with house mice (***Mus musculus***), with exposure to a 3 year aged product BROMAFAR (0.005 % w/w bromadiolone).

**Toxicology data**

The applicant submitted toxicological data on another formulation (FAAR BLOC SP). The results of these data can be extrapolated to the biocidal product FAAR BLE.

**Residue data**

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

**Ecotoxicology data**

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

### Access to documentation

A letter of access from Activa Srl has been submitted. Access is granted for all the data generated by the bromadiolone task force for the inclusion of bromadiolone into annex I.

# Summary of the product assessment

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

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

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

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

## Identity related issues

The source of the active substance used in the biocidal product FAAR BLE is different from the source used for annex I inclusion. However, a technical equivalence was assessed by RMS (SE) in 2010 between the used source and the reference source.

## Classification, labelling and packaging

### Classification of the active substance

No harmonised classification is currently available but a classification with specific concentration limits is proposed in the Competent Authority Report.

Bromadiolone does not have classification relating to its physico-chemical properties.

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | Acute Tox. 1 H300, H310, H330  STOT RE 1 H372  Repr. 1A H360D  Acute Cat. 1 H400  Chronic Cat. 1 H410  M-factor 1 |
| Precautionary statements | - |
| Specific concentration limits for human health: | |  |  | | --- | --- | | C ≥ 0.01%  0.001% ≤ C < 0.01% | STOT RE 1; H372  STOT RE 2; H373 | |

* **Renewal (2017):**

Harmonised classification of the active substance according to the ATP 9 of the CLP regulation is as follows:

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | Acute Tox. 1 H300, H310, H330  STOT RE 1 H372  Repr. 1B H360D  Acute Cat. 1 H400  Chronic Cat. 1 H410  M-factor 1 |
| Precautionary statements | - |
| Specific concentration limits: | STOT RE 1; H372: C ≥ 0,005 %  STOT RE 2; H373: 0,0005 % ≤ C < 0,005 %  Repr. 1B; H360D: C ≥ 0,003 % |

### Harmonised classification of the biocidal product

French agency considers, based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification\*, FAAR BLE is classified as follows:

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | STOT RE 2; H373 |
| Precautionary statements | P260 Do not breathe dust  P314 Get Medical advice/attention if you feel unwell  P501 Dispose of contents/container in accordance with national regulations |

\* According to the RAC opinion adopted March 14, 2014 ,for proposal of an harmonized classification for bromadiolone , product FAAR BLE should be classified:

- RETRY 1B - H360D : May damage fertility or the unborn child .

- STOT RE 1 - H 372 - blood risky Causes damage to organs through repeated exposure or prolonged exposure.

However, this classification is not applied until the harmonized classification of bromadiolone is published in a new ATP of CLP regulation.

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

|  |  |
| --- | --- |
| **Classification - Directive 67/548/EEC** |  |
| Class of danger | Xn |
| R phrases | R20  R48/20/21/22 |
| S phrases (proposed by the RMS) | none |

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | STOT RE 2; H373 |
| Precautionary statements (proposed by the RMS) | P260  P314  P501 |

* **Renewal (2017):**

BROMAFAR is classified as follows:

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

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | |
| Hazard statement | Repr. 1B; H360D: May damage the unborn child  STOT RE 1; H372; Causes damage to organs (blood) through prolonged or repeated exposure |
| Precautionary statements) | P201: Obtain special instructions before use  P202: Do not handle until all safety precautions have been read and understood.  P260 Do not breathe dust  P264: Wash … thoroughly after handling  P270: Do not eat, drink or smoke when using this product  P280: Wear protective gloves/protective clothing/eye protection/face protection  P308 + P313: IF exposed or concerned: Get medical advice/ attention.  P314 Get Medical advice/attention if you feel unwell.  P405: Store locked up  P501 Dispose of contents/container in accordance with national regulations |

### Labelling of the biocidal product

* **Major change (2016):**

|  |  |
| --- | --- |
| Pictograms: |  |
| Signal words: | Warning |
| Hazard statements: | STOT RE 2; H373 |

If the proposed classification and specific concentration limits for “active substance” is agreed at the ECHA level, the following labelling according to Directive 67/548/EEC should apply:

|  |  |
| --- | --- |
| Symbols: | Xn |
| Indications of danger: | Harmful |
| Risk phrases: | Xn R20  Xn R48/20/21/22 |
| Safety phrases: | none |

*No classification was proposed by the Applicant. Nevertheless, due to specific concentration limits for bromadiolone, FAAR BLE has to be classified as mentioned above.*

If the proposed classification and specific concentration limits for “active substance” is agreed at the ECHA level, the following labelling according to the CLP regulation should apply:

|  |  |
| --- | --- |
| Pictograms: |  |
| Signal words: | Warning |
| Hazard statements: | STOT RE 2; H373 |

* **Renewal (2017):**

The following labelling according to the CLP regulation should apply:

|  |  |
| --- | --- |
| Pictograms: |  |
| Signal words: | Danger |
| Hazard statements: | Repr. 1B; H360D  STOT RE 1; H372 |

### Packaging of the biocidal product

* **First authorisation (2013):**

The primary packagings of the biocidal product as deposited by the notifier are:

**For professional users:**

FAAR BLE is supplied in opaque packaging in sachet or loose.

PE sachets (25-100g) are packed in:

* Bags (paper/PE) (20-25 kg)
* Bucket (PE) (5-20kg)
* Carton box (carton) (5-20 kg)

Loose baits are packed in:

* Bags (paper/PE) (20-25 kg)
* Bucket (PE) (5-20kg)
* Carton box (carton) (5-20 kg)

**For non professional users:**

FAAR BLE is supplied in (PE) sachets (25-100g) packed in:

* Bucket (PE) (0.5-1.5 kg)
* Carton box (carton) (0.2-1.5kg)
* Metal box (0.2- 1.5kg)
* Bait box
* Jug (PEHD) (0.2-1.5kg)
* **Minor change (2014):**

**Claimed new packagings**

***For professional users:***

PE sachets (20-25-40-50-100g) are packed in:

* Bags (paper/PE) (5-10-15 kg)
* Bucket (PE) (25 kg)
* Carton box (carton) (50 kg)
* Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg)

Loose baits are packed in:

* Bags (paper/PE) (5-10-15 kg)
* Bucket (PE) (25 kg)
* Sachet PE or PP (100-200-300-400-500-600-700-800-900-1000g) packed in carton box (5-20 kg)

***For non-professional users:***

sachet (PE) sachets (25-100g) are packed in:

* Bucket (PE) (0,1-0,2-0,3-0,4 kg)
* Carton box (carton) (0,1 kg)
* Metal box in electrolytic tinplate (without lacquer) (0,1 kg)
* Flacon (HDPE) (0,1 kg)

Conclusion: The new packagings claimed are acceptable.

* **Renewal (2017):**

**For professional users: BORMAFAR** is supplied in opaque packaging in sachet or loose. Acceptable packagings are the following

PE sachets (25-100g) are packed in:

* Bags (paper/PE) (5-10-15-20-25 kg)
* Bucket (PE) (5-20-25 kg)
* Carton box (carton) (5-20-50 kg)
* Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg)

Loose baits are packed in:

* Bags (paper/PE) (5-10-15-20-25 kg)
* Bucket (PE) (5-20-25 kg)
* Carton box (with inner PE liner) (5-20 kg)
  1. **Physico/chemical properties and analytical methods**
     1. **Active ingredient**
        1. **Identity, origin of active ingredient**

The source of the active substance used in the biocidal product FAAR Blé is different from the source used for annex I inclusion. However, a technical equivalence was assessed by RMS (SE) in 2010 between the used source and the reference source.

* + - 1. **Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient**
* **First authorisation (2013):**

Physical and chemical properties of the active substance and analytical methods for determination of active ingredient and impurities in the technical active substance have already been evaluated at EU level and are presented in the CAR (2011) of the active substance Bromadiolone. The notifier of the product FAAR blé is part of a task force that deposited a complete dossier for homologation of his source of Bromadiolone.

* + 1. **Biocidal product**
       1. **Identity, composition of the biocidal product**

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

Trade name: FAAR BLE

Code number: SOFAR

The composition of the product is confidential and is presented in a confidential annex. There is no substance of concern.

* + - 1. **Physico-chemical properties**

All studies were performed with biocidal product FAAR BLE.

**Table 1 Physico-chemical properties of the biocidal product**

| **Subsection (Annex Point IIB. 3/TNsG)** | **Method** | **Purity/ Specification** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| **3.1 Appearance (IIB3.1/Pt. I-B3.1)** |  | FAAR blé  0.046 g/kg bromadiolone |  | 10-920010-36 |
| **3.1.1 Physical state and nature** | Bait ready for use (AB) |  | Wheat grains |  |
| **3.1.2 Colour** | Visual inspection at room temperature |  | Blue/green wheat whole grains (heterogeneous colour) |  |
| **3.1.3 Odour** | *Not determined. –*  Acceptable as an odour should only be recorded if it is very apparent. | | |  |
| **3.2 Explosive properties (IIB3.2/Pt. I-B3.2)** | EC A14 (2008) | FAAR blé  0.041 g/kg  bromadiolone | The test item was not considered to have explosive properties in the experimental conditions of the test (heat, flame, shock).  Not explosive | 11-920010-004 |
| **3.3 Oxidising properties (IIB3.3/Pt. I-B3.3)** | Assement based on composition |  | FAAR BLE is not expected to have oxidizing properties.  No oxidizing properties | - |
| 3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4) | | | | |
| Flammability |  |  | Test not performed. The test should have been performed.  However, due to the DSC results (10-920010-35), the explosive test results (11-920010-004), result of flammability study on FAAR avoine and examination of composition, RMS is of the opinion that FAAR Blé is not expected to be flammable. | - |
| Self ignition temperature of solids | EC A16 (2008) | FAAR blé  0.046 g/kg bromadiolone | No self ignition temperature of the test item was observed up to 400 °C. | 10-920010-35 |
| **3.5 Acidity/Alkalinity (IIB3.5/Pt. I-B3.5)** | CIPAC MT 75.3 (2000) | FAAR blé  0.046 g/kg bromadiolone | The pH mean value of the test item at 1% m/v in standard water D is:  6.40 at 21.0°C after 1 min.  6.53 at 21.5°C after 10 min.  The pH of the test item being higher than 4 and lower than 10, CIPAC MT 191 the test was not performed. | 10-920010-36 |
| **3.6 Bulk density (IIB3.6/Pt. I-B3.6)** | CIPAC MT 186 | FAAR blé  0.046 g/kg bromadiolone | The mean pour density of the test item was 0.780 g/ml  The mean tap density of the test item was 0.794 g/ml. | 10-920010-35 |
| **3.7 Storage stability - (IIB3.7/Pt. I-B3.7)** | Storage study 14 days at 54°C:  CIPAC MT 46.3  pH : CIPAC MT 75.3  Dust content: CIPAC MT 58.3 | FAAR blé  0.046 g/kg bromadiolone | **After 2 weeks at 54°C in plastic bag:**   |  |  |  | | --- | --- | --- | |  | T0 | 2W 54°C | | Bag weight | 103.1g | 103.6g | | Appearance | No change | | | Content of AS | Not determined | | | pH | 6.4 | 6.54 | | Dust content | 0.00% | 0.08% |   Nature of plastic bag is not submitted.  Content of active substance was not determined. Therefore this study will not support the stability of biocidal product at 54°C.  pH and dust content of FAAR blé are stable after 14 days at 54°C. | 10-920010-36 |
| **Storage stability -**  **(IIB3.7/Pt. I-B3.7)** | 8 weeks at 40°C  CIPAC MT 46.3 | FAAR blé  0.039 g/kg  bromadiolone | **After 8 weeks at 40°C in PE bag:**   |  |  |  | | --- | --- | --- | |  | T0 | 8W 40°C | | Bag weight | 52.7g | 49g | | Appearance | No change | | | Content of AS | 39 ppm | 39 ppm |   No chromatograms of test item were submitted.  Content of bromadiolone at T0 is low but in the allowed range of production (+/- 25%)  FAAR blé is stable after 8 weeks at 40°C in PE bags. | 11-920010-  023 |
| **Shelf life study** |  |  | The shelf life study is in progress. The results of the study will be available at the end of 2014.  The results of this study after one year of storage will be submitted at the end of March 2013.  Data required in post registration | - |
| **Effects of light** |  |  | Not required since the product will be stored protected from light.  See comments below the table |  |
| **3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)** | | | | |
| Wettability |  |  | Data not required as the product is a ready to use grain bait |  |
| Persistent foaming |  |  | Data not required as the product is a ready to use grain bait |  |
| Suspensibility |  |  | Data not required as the product is a ready to use grain bait |  |
| Spontaneity of dispersion |  |  | Data not required as the product is a ready to use grain bait |  |
| Dilution stability |  |  | Data not required as the product is a ready to use grain bait |  |
| Dry sieve test |  |  | see particle size distribution |  |
| Wet sieve test |  |  | Data not required as the product is a ready to use grain bait |  |
| Dustiness | CIPAC MT 171 | FAAR blé  0.039 g/kg | Gravimetric collected dust: 0.5 mg (mean of 2 essays)  FAAR blé is considered as nearly dust free | 12-920010-001 |
| Attrition/friability of granules; integrity of tablets | CIPAC MT 178 | FAAR blé  0.039 g/kg | The attrition resistance of the test item was 99.8% | 12-920010-001 |
| Emulsifiability / Emulsion stability / Re-emulsifiability |  |  | Data not required as the product is a ready to use grain bait |  |
| Stability of dilute emulsions |  |  | Data not required as the product is a ready to use grain bait |  |
| Flowability | CAPAC MT 172 | FAAR blé  0.039 g/kg | After 14 days at 54°C, the test item do not drop trought the 5 mm seive.  The mean percentage of test item retained on the 5-mm sieve after 5 liftings was lower that 0.1% w/w. | 12-920010-001 |
| Pourability (including rinsed residue) |  |  | Data not required as the product is a ready to use grain bait |  |
| **3.9 Compatibility with other products (IIB3.9/Pt. I-B3.9)** |  |  | FAAR blé is not intended to be used or mixed with other products. |  |
| **3.10 Surface tension (Pt. I-B3.10)** |  |  | Data not required as the product is a ready to use grain bait |  |
| **3.11 Viscosity (Pt. I-B3.10)** |  |  | Data not required as the product is a ready to use grain bait |  |
| **3.12 Particle size distribution (Pt. I-B3.11)** | CIPAC MT 59.4 | FAAR blé  0.039 g/kg | |  |  | | --- | --- | | Test seive | % of residues | | 4mm | 3.1% | | 2.8 mm | 88.6% | | 2 mm | 7.1% | | 1.4 mm | 0.7% | | pan | 0.1% |   Acceptable.  The majority of the particles (88.6%) of the test item was between 2.8 mm and 4 mm. | 12-920010-001 |

**Storage stability:**

Results of the accelerated storage study demonstrate that the biocidal product is stable 8 weeks at 40°C in PE bags. The accelerated storage test 2 weeks at 54°C demonstrated that physical chemical properties of biocidal are stable at this temperature. The Biocidal product is therefore expected to be stable 2 years at ambient temperature. However complete shelf life study is required in post registration.

Compatibility of loose grains with carton packaging was not demonstrated. A study demonstrating this compatibility is required in post registration.

The effect of light has not been provided and FR recommends to store away from light due to the sensitivity of the active substance to light. All the claimed packagings are opaque.

**Data requirement:**

Compatibility study with carton packaging material and a shelf life study (2 years at ambient temperature) with intermediary results after 1 year according to GIFAP monograph N°17.

* **Minor change : modification of the composition (evaluated in November 2015):**

In November 2014*,* BROMAFAR was defined as a same product of FAAR BLE.

In March 2015, BROMAFAR composition is changed. This change of composition is only for BROMAFAR and is evaluated in this document.

Whole compositions new and old of BROMAFAR have been provided but MSDS of co-formulants for the previous and the new products have not been provided. All the MSDS of the co-formulants have to be provided.

Product BROMAFAR is a ready to use grain bait based on crushed corn which contains 0.005 % of bromadiolone.

There are 97.75 % of changes between the old and the new composition of BROMAFAR.

Based on the differences and on the nature of the co-formulants, the new composition of BROMAFAR cannot be considered as similar as the reference composition without bulk density, dustiness, attrition, flowability and particle size distribution. These data were submitted in February 2015 see below.

The required physico-chemical properties have been provided, the results are reported below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Properties** | **Method** | **Tested material** | **Result** | **FR Evaluation** |
| Density | CIPAC MT 186 | BMM50V1  Corn with 50ppm bromadiolone  Batch 02/15 | Pour density: 0.622 g/mL  Tap density: 0.7 g/mL | Acceptable  The pour and tap density are lower than for the old composition (pour density was 0.780 g/ml and  tap density was 0.794 g/ml |
| Particle size | CIPAC MT 170 | BMM50V1  Corn with 50ppm bromadiolone  Batch 02/15 | 5% higher than 4mm  67.9% between 2 and 4mm  21.3% between 1mm and 2mm   |  |  | | --- | --- | | Test seive | % of residues | | 4mm | 5 | | 2 mm | 67.9 | | 1 mm | 21 | | 0.5 mm | 3.2 | | 0.25 mm | 2.1 | | 0.125 mm | 0.5 | | 0.075 mm | 0.2 | | pan | 0 | | Acceptable  There is a slight difference in the particle size with old composition but the majority of the particles (89.7%) are between 2 and 4mm   |  |  | | --- | --- | | Test seive | % of residues | | 4mm | 3.1% | | 2.8 mm | 88.6% | | 2 mm | 7.1% | | 1.4 mm | 0.7% | | pan | 0.1% | |
| Flowability | Justification of non-submission of data |  | Justification submitted by applicant:  *Concernant la détermination de la faculté d’écoulement, l’état physique de la formulation est un solide non visqueux. En effet la nouvelle formulation de BROMAFAR (BMM50V1 dans les essais) est une formulation de type AB, appât en grain, prête à l’emploi. Le support maïs représente 97.75 % de la formulation. Les grains de maïs utilisés pour la formulation sont secs et non frais (donc pas humides). Les 2.25 % restant de co-formulants ne forment pas un enrobage visqueux ou modifiant la forme du grain de maïs. Le produit formulé est un produit sec et permet une fluidité des grains traités identique à celle des grains de maïs non traités.* | Acceptable |
| Dustiness | CIPAC MT 171 | BMM50V1  Corn with 50ppm bromadiolone  Batch 02/15 | 0.6mg  Nearly dust free | Acceptable  The dustiness is the same as old composition (0.5mg) |
| Attrition resistance | CIPAC MT 178 | BMM50V1  Corn with 50ppm bromadiolone  Batch 02/15 | 99.8% | Acceptable  The attrition resistance is the same as old composition |

Conclusion: There are slight differences for some physico-chemical properties nevertheless the minor change of composition is considered as acceptable.

* **Renewal (2017):**

|  |
| --- |
| **General conclusion on the physical, chemical and technical properties of the product for renewal of national authorisation applications** |

|  |
| --- |
| The product BROMAFAR is a ready to use grain bait formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable.  The appearance of the product is heterogeneous blue/green cereals and with no specific odour.  For renewal of authorization, no additional data has been submitted.  A long-terme stability study is on-going, results should be available by mid 2018. FR CA agrees to grant a 2 years shelf-life. FR CA requires that is this study is provided within 1 year after authorisation.  Compatibility of biocide product with heat is not demonstrated. A mitigation measure is added: “do not store above 30°C”.  eCA recommends to store away from light due to the sensitivity of the active substance to light.  Its technical characteristics are acceptable for a ready to use grain bait formulation. |

* **Post authorisation (2019):**

Post authorisation data (shelf life study with the new formulation at 50 ppm) have been submitted and are reported below

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **FR-CA evaluation** |
| --- | --- | --- | --- | --- | --- |
| Storage stability test –  **ambient storage (20 °C ± 2 °C)** | GIFAP Monograph No. 17  Analytical method validated in report n° 16-920010-024 | Bromadiolone grain bait (0.005% w/w)  Batch n° AB20160502 | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Initial | After 6 months | After 12 months | After 18 months | After 24 months | After 30 months | | Apparence | Heterogeneous blue/green crushed corn | | | | | | | Packaging | Transparent HDPE bag | | | | | | | AS content (% w/w) | 0.00478 | 0.00448 | 0.00466 | 0.00459 | 0.00415 | 0.00445 | | AS content variation (%) | - | - 6.3 | - 2.5 | - 4.0 | - 13.2% | -6.9 | | Weight variation (%) | - | -1.0 | -2.5 | -2.7 | -3.8 | - | | Dustiness | Categorie 1 - Nearly dust-free | | | | | | | RICAU H. 2019  Report n° 16-920010-023 | The product is stable upon storage for 30 months at ambient temperature (20 °C ± 2 °C) in commercial HDPE bag since neither the active ingredient content nor the technical properties were changed. |

|  |
| --- |
| **General conclusion on the physical, chemical and technical properties of the product BROMAFAR for renewal of national authorisation applications** |
| The product BROMAFAR is a ready to use grain bait formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is not flammable.  The appearance of the product is heterogeneous blue/green crushed corn and with no specific odour. Storage stability study results are acceptable. The biocidal product (new formulation) is stable 30 months at ambient temperature with an HDPE bag. The product being a solid, if it is compatible with a type of packaging, it is considered compatible with every types of packaging. The authorised shelf-life of 12 months is confirmed.  FR-CA recommends to store away from light due to the sensitivity of the active substance to light.  Its technical characteristics are acceptable for a ready to use grain bait formulation. |

* **Minor change (2021)**

The change of shelf life from 12 to 24 months is acceptable as a long term storage stability study for 30 months at ambient temperature that was already submitted showed that the product is stable for 30 months.

* + - 1. **Analytical method for determining the active substance and relevant component in the biocidal product**

A method to determine bromadiolone in the biocidal product FAAR Bloc sp by HPLC – UV (265nm) was submitted.

Reference: Ricau H, 2011, Report n° 10-920010-042

Validation data:

|  |  |  |  |
| --- | --- | --- | --- |
| Linearity | Precision | Recovery rate (%)  range | Specificity |
| 50-150% of nominal value  n=5  r²= 0.998 | At 52 ppm:  RSD = 1.29% | At 100% mean of recovery = 101.5% (n=4)  At 50% mean of recovery = 100.5% (n=4) | No interference in chromatograms.  Specific to bromadiolone in FAAR Bloc sp |

The specificity and accuracy of the previously validated method was tested on biocidal product FAAR Blé.

Reference: Ricau H, 2011, Report n° 10-920010-038

Validation data on FAAR blé

|  |  |  |  |
| --- | --- | --- | --- |
| Linearity | Precision | Recovery rate (%)  range | Specificity |
| Performed on FAAR Bloc | Performed on FAAR Bloc | At 100% mean of recovery = 101% (n=4)  At 50% mean of recovery = 99% (n=4) | No interference in chromatograms.  Specific to bromadiolone in FAAR Blé |

The process of validating linearity and precision on FAAR block and recovery and specificity on FAAR blé is acceptable.

The provided method is acceptable for the product FAAR Blé

* **RENEWAL 2017**

No fully validated method of determination of active substance in BROMAFAR is available to cover this product. This should have been provided for renewal of biocidal product. Demonstration of specificity and accuracy of the method for BROMAFAR is required to support renewal authorization It must be provided in post registration within one year.

* **Post Authorisation 2019**
* Method for the determination of Bromadiolone in BROMAFAR:

A new analytical method for the determination of Bromadiolone in the new formulation BROMAFAR (BMM50V1) has been provided.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Test item preparation** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Precision**  **repeatability** | **Reference** |
| **Range** |
| BROMAFAR  (BMM50V1) | Bromadiolone | HPLC with UV detection | Preparation of the test item solution:  The test item was previously crushed in form of powder with a crusher.  A quantity of 1.0 g (to the nearest 0.01 mg) of crushed test item was weighed into a 100-mL glass flask. A 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 was filtered on an ashless filter for analysis (DEF16-0249A). | See report 16-920010-012 | Retention time for Bromadiolone matches between reference item and test item, confirming the identity of the analyte.  No interference was observed in the solvent blank, the formulation blank, the reference item and the test item at the retention time of Bromadiolone.  Therefore, the analytical method showed a good specificity for Bromadiolone  analysis in BMM50V1. | Accuracy was checked by analysis of two reconstituted samples with known amounts of bromadiolone reference items at nominal content (1.85 to 1.93 mg/L in solution). The accuracy results of Bromadiolone were in conformity with SANCO/3030/99 rev. 4 requirements.  Indeed, the recovery results should be in the range 80%-120% (formulations containing less than 0.01%) and they were experimentally equal to 99.3% (mean of 2 injections of the same sample) and 99.1% (mean of two injections of the same sample). | Not performed. However repeatability was performed with another similar formulation BMB25V1 and has been found acceptable (see report n°16-920010-012). | 16-920010-024  GLP |

Linearity and repeatability have been assessed during study 16-920010-012. This method has been validated for the determination of Bromadiolone in another formulations (BMB25V1). Validation data of the methods are reported below.

* Method for the determination of Bromadiolone in BMB25V1:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Test item preparation** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Precision**  **repeatability** | **Reference** |
| **Range** |
| BMB25V1 | Bromadiolone | HPLC with UV detection | Preparation of the test item solution:  The test item was previously crushed in form of powder with a crusher.  A quantity of 2.0 g (to the nearest 0.01 mg) of crushed test item was weighed into 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 was  filtered on an ashless filter for analysis (DEF16-0097A). | Calibration solutions of the reference items at five concentrations between 50% and 150% of the expected concentration were analysed.  The response of the detector during the analysis of difenacoum was linear within the range of 0.94 mg/L to 2.82 mg/L (y = 1.31x – 0.00893; r = 0.9999). | Retention time for Bromadiolone matches between reference item and test item, confirming the identity of the analyte.  No interference was observed in the solvent blank, the formulation blank, the reference item and the test item at the retention time of Bromadiolone.  Therefore, the analytical method showed a good specificity for Bromadiolone  analysis in BMB25V1. | Accuracy was checked by analysis of two reconstituted samples with known amounts of Bromadiolone reference items at nominal content (1.85 to 1.93 mg/L in solution). The accuracy results of Bromadiolone were in conformity with SANCO/3030/99 rev. 4 requirements.  Indeed, the recovery results should be in the range 80%-120% (formulations containing less than 0.01%) and they were experimentally equal to 96.8% (mean of 2 injections of the same sample) and 98.3% (mean of two injections of the same sample). | Precision was checked by replicate analyses of the test item (n = 5).  The mean concentration of Bromadiolonein the test item was equal to 0.0025% w/w.  In the case of Bromadiolone, the precision was acceptable as the RSD. was lower than the result of the modified Horwitz equation: 0.94 < 6.60 (C = 0.000025). | 16-920010-012  GLP |

* + - 1. **Analytical methods for determining relevant components and/or residues in different matrices**

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

* 1. **Risk assessment for Physico-chemical properties**
* **First authorisation (2013):**

FAAR BLE is a ready-to-use grain rodenticide. It is not highly flammable, not auto-flammable at ambient temperature, does not have explosive and oxidizing properties.

Results of the accelerated storage study demonstrate that the biocidal product is stable 14 days at 54°C in plastic bag and 8 weeks at 40°C in PE bags. The Biocidal product is therefore expected to be stable 2 years at ambient temperature. A complete shelf life study is required in post registration.

***Measures linked to assessment of physico-chemical properties***

* Store away from light.
* Store at maximum 40°C.

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

Shelf life study (2 years at ambient temperature) with intermediary results after 1 year according to GIFAP monograph N°17.

* **Renewal (2017):**

BROMAFAR is not highly flammable, not auto-flammable (up to 400°C), not explosive and does not have oxidizing properties according to GHS guideline. FR considers these conclusions are still valid for CLP classification as no formulant is expected to be classified for PC CLP properties.

* 1. **Effectiveness against target organisms**
     1. **Function**

MG 03: Pest Control

Product Type 14: Rodenticide

* **Minor change (2014):**

According to the uses claimed by the applicant, BROMAFAR is intended to be used to control rats and mice, indoor. The target organisms to be controlled are *Mus musculus*, *Rattus norvegicus* *and Rattus rattus*.The products, organisms or objects to be protected are public and private buildings, and farms.

The application rates recommended by the applicant are the following:

Indoor use

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

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

* + 1. **Organisms to be controlled and products, organisms or objects to be protected**
* **First authorisation (2013):**

According to the uses claimed by the applicant, FAAR BLE is intended to be used to control rodents. The target organisms to be controlled are brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*) and house mouse (*Mus musculus*).

The products, organisms or objects to be protected are indoor environments (public, private buildings and farms).

The application rates recommended and uses claimed by the applicant are the following (see also annex 0a):

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Area of use | Dosage claimed | Time delay of the action of the product | Frequency and method of controls | Distance between 2 bait points, for high and low infestation | Methods of application of the bait |
| **Professional users** | | | | | | |
| Brown rat  *Rattus norvegicus* | indoor only | 180-200 g / secured bait point | 3 to 10 days | 4 refilling of bait stations over 28 days  Interval between applications (min) : 1 week | 5-10 meters | Manual application in bait stations |
| Black rat  *Rattus rattus* | indoor only | 180-200 g / secured bait point | 3 to 10 days | 5-10 meters |
| House mouse  *Mus musculus* | indoor only | 30-40 g / secured bait point | 3 to 10 days | 1-2 meters |
| **Non professional users** | | | | | | |
| Brown rat  *Rattus norvegicus* | indoor only | 180-200 g / secured bait point | 3 to 10 days | 4 refilling of bait stations over 28 days  Interval between applications (min) : 1 week | 5-10 meters | Pre-filled secured boxes  Manual application of baits in bait stations |
| Black rat  *Rattus rattus* | indoor only | 180-200 g / secured bait point | 3 to 10 days | 5-10 meters |
| House mouse  *Mus musculus* | indoor only | 30-40 g / secured bait point | 3 to 10 days | 1-2 meters |

* + 1. **Effects on target organisms and efficacy**

Anticoagulants rodenticides disrupt the blood-cutting mechanisms. Signs of poisoning in rodents are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. After feeding on bait containing the active substance for 2-3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop, the animal will lose its appetite and will remain in its burrow or nest for increasingly long periods of time. As the active substance has a long acting action, death will usually occur within 3 to 10 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

Efficacy and choice feeding tests were conducted with 2 month-aged baits FAAR BLE on albino house mice on and the results are presented in the dossier. The studies show that the product is palatable (average treated bait intake at least 79.1 % of the total food consumption) and effective (100% mortality between 3 to 10 days).

A field test was conducted with 2 month-aged baits FAAR BLE on black rats and the results are also presented in the dossier. This study was performed in a pig farm. The rats ate satisfactorily during the baiting phase, which lead to a satisfying efficacy rate (80.2%). The arrival of young rats consuming in bait stations during post-baiting stage has probably distorted the efficacy assessment. The operator should have gone on the poisoning; this would have probably led to a higher efficacy rate. This field study has been conducted according to the standard, the acceptability and efficacy on *Rattus rattus* in field was sufficient.

A field study was conducted to assess the efficacy of 14 month-aged baits FAAR AVOINE (oat containing 0.005% bromadiolone) against mice (*M. Musculus*). The differences between the compositions of the products FAAR AVOINE and FAAR BLE are slight. The active substance and most of the components are at exactly the same concentration in FAAR BLE and FAAR AVOINE. FAAR AVOINE doesn’t contain any stabilisant and his support is oat grains instead of whole wheat grains. Therefore, results from this study could be extrapolated to the current formulation of FAAR BLE because differences don’t have any influence on the efficacy. This study was performed in a farm with an estimated population size of about 150 mice. The assessed efficacy on mice was of 100%.

A field study was conducted to assess the efficacy of 7 month-aged baits FAAR BLOC SP (block bait containing 0.005% bromadiolone) against brown rats (*R. norvegicus*). The active substance and some of the components are at exactly the same concentration in FAAR BLOC SP and FAAR BLE. A choice feeding tests proceeded with FAAR BLOC SP and FAAR BLE on albino mice confirmed that FAAR BLOC SP is less palatable than FAAR AVOINE, i.e. 47.4% against 79.1% respectively. A lab study has also shown that FAAR BLE is efficient on albino house mice (mice are less sensitive to anticoagulants than brown rats). Furthermore, efficacy of FAAR BLE has been confirmed on black rats that are used to be more suspicious than brown rats and thus, more difficult to control. Therefore, results from this study could be extrapolated to the current formulation of FAAR BLE. This field study conducted according to the standard, has given very good results, 92.8 % for a very large population (> 1000 individuals). The efficacy of FAAR BLOC SP against *Rattus norvegicus* in field was well demonstrated.

The product is applied in bait stations by professional and non-professional users in discrete locations within the infested area. Distances between each bait station, so as the number and timings of application and the amount of product depends of several factors: the treatment site, the size and severity of the infestation.

On the basis of the efficacy data submitted, the level of efficacy of the product FAAR BLE for the intended uses presented in the table below is acceptable.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Dosage claimed | Distance between 2 bait points, for high and low infestation | Time delay of the action of the product | Frequency and method of controls | Area of use | Methods of application of the bait |
| **Professional users** | | | | | | |
| Rats  *Rattus norvegicus*  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | indoor only | Manual application in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |
| **Non professional users** | | | | | | |
| Rats  *Rattus norvegicus*  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | indoor only | Pre-filled secured boxes  Manual application of baits in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |

The field study on FAAR BLE has been done with 2 month-aged baits but field study on FAAR AVOINE has been done on a 14 month-aged bait. As compositions of these two products are similar, we can conclude that FAAR BLE can be considered as effective after a 14 months storage period.

The 24 months storage period claimed by the applicant must be demonstrated with a field study realized with a 24 month-aged product.

All efficacy studies are presented in annex 9.

* **minor change (2015):**

The composition of the product BROMAFAR has been modified to change the support (cereal wheat has been replaced by crushed corn). In order to demonstrate that this change doesn’t affect the palatability and the efficacy of the product, the applicant submitted following studies:

* **Study n°15TOX004 (laboratory study):**

For brown rats (*Rattus norvegicus*), the mean palatability percentage is 46 %, and the mortality percentage is 90 %.

* **Study n°15TOX005 (laboratory study):**

For black rats (*Rattus rattus*), the mean palatability percentage is 51 %, and the mortality percentage is 100 %.

* **Study n°15TOX003 (laboratory study):**

For house mice (*Mus musculus*), the mean palatability percentage is 53 % and the mortality percentage is 90 %.

In laboratory tests, efficacy criteria of the TNsG on product evaluation PT14 (palatabilité ≥20 % and mortality ≥90 %) are fulfilled for the three species.

* **Study n°2009.BCD.SAG15: field study in Italie (farm)**

For brown rats (*Rattus norvegicus*), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* **Study n°2008.BCD.SA15: field study in Italie (farm)**

For black rats (*Rattus rattus*), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

* **Study n°2010.BCD.SAJ15: field study in Italie (farm)**

For house mice (*Mus musculus*), 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 are sufficient to demonstrate the efficacy of the product against *Rattus norvegicus, Rattus rattus and Mus musculus* and then the change of cereals in the composition is acceptable.

* **Renewal (2017):**

2 studies performed with a 2 year-aged bait have been submitted in order to demonstrate that the product is still effective after a 2 year storage period.

- Study n° 2041.BCD.SAG17: field study in Italie (farm)

For black rats (*Rattus rattus*), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

- Study n°2010.BCD.SAJ15: field study in Italie (equestrian centre

For house mice (Mus musculus), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

All efficacy studies are presented in annex 3.

Uses and doses validated for BROMAFAR are the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Target organisms** | **Application rate and intervals** | **Use area** |
| BROMAFAR  Bait containing 0.005% w/w of bromadiolone. | Rats (*Rattus norvegicus* and *Rattus rattus)* | 200 g / bait point separated by 5-10 meters | Inside buildings |
| Mice (*Mus musculus*) | 40 g / bait point separated by 1-2 meters |

* **Minor change (2019):**

2 studies performed with a 2 year-aged bait have been submitted in order to demonstrate that the product is still effective after a 2 year storage period.

- Study n° 2041.BCD.SAG17: field study in Italie (farm)

For black rats (*Rattus rattus*), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

- Study n°2010.BCD.SAJ15: field study in Italie (equestrian centre)

For house mice (*Mus musculus*), the assessed bait has been very well accepted and the efficacy is estimated at 100 %.

All efficacy studies are presented in annex 3.

Uses and doses validated for BROMAFAR are the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Target organisms** | **Application rate and intervals** | **Use area** |
| BROMAFAR  Bait containing 0.005% w/w of bromadiolone. | Rats (*Rattus rattus)* | 200 g / bait point separated by 5-10 meters | Inside buildings |
| Mice (*Mus musculus*) | 40 g / bait point separated by 1-2 meters |

According to the Efficay guidance - Volume II PartsB+C, to support a storage duration of 24 months (of a new formulation without preservative), palatability data tested in field trial of the product at the end of maximum storage for all target organisms are required. Therefore, test with a 24 months aged product should be submitted. Without efficacy data against brown rat (*Rattus norvegicus)*, the maximum storage duration of 24 months cannot be validated.

* **Minor change (2021):**

New studies were submitted on *Mus musculus*, *Rattus norvegicus* and *Rattus rattus,* in order to support the 2 years storage period of the product BROMAFAR containing 0.005 % w/w bromadiolone. The study is summarized in annex 9.

French competent authorities (FR CA) consider that the elements presented in the dossier confirm the efficacy of the product BROMAFAR (0.005 % w/w bromadiolone) against mice (*Mus musculus)* andrats *(Rattus norvegicus, Rattus rattus*) for indoor use by professional users, with a shelf-life up to 24 months.

* + 1. **Mode of action including time delay**

Bromadiolone is a second-generation single dose anticoagulant which prevents blood clotting in the target.

Bromadiolone acts as a vitamin K1 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.

Bromadiolone 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.

Clinical signs are progressive and occur three days after the ingestion of a toxic dose, leading to the death of target animal within 1 to 14 days after, according to the laboratory tests performed.

* + 1. **Occurrence of resistance**

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

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

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

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

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants (Greaves et al., 1982[[3]](#footnote-3); Lund, 1984[[4]](#footnote-4); Pelz et al. 1995[[5]](#footnote-5)). 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[[6]](#footnote-6)). 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[[7]](#footnote-7)).

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

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

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

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

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

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

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

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

* + 1. **Evaluation of the Label Claims**

French Competent Authorities (FR CA) assessed that the product FAAR BLE has shown a sufficient efficacy for the control of mice and rats for an indoor use in domestic, industrial and commercial buildings including farm buildings.

The application rates validated are presented in annex 0b.

In addition to the bulk packaging, FAAR BLE is also supplied in sachets and pre-filled bait stations of different amounts. The applicant has to adapt the amount per sachet and bait boxes to the efficient doses. The amount of bait per bait station must not exceed the recommended application rates.

In order to reflect the efficacy data of the product labels has to be revised as following:

- Inspections of bait points have to be made three days after the first application then weekly

- The time delay of the product’s action should be added on the basis of efficacy tests (3 to 10 days).

- The application rates must be mentioned as authorized (see above).

- It should be precised that the shelf life of the product is 14 months.

Because of cross-resistances occurrence to second-generation anticoagulants, the product label has to contain information on resistance management for rodenticides **(**see *Specific use restriction and issues accounted for product labelling* below).

**RENWAL 2017**

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

The application rates validated are the following:

House mice: 40 g baiting point separated by 1-2 m

Rats: 200 g per baiting point separated by 5 -10 m.

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

**MINOR CHANGE 2019:**

French competent authorities (FR CA) considers that the elements presented in the dossier confirm the efficacy of the product BROMAFAR against house mice (*Mus musculus*) and black rats (*Rattus rattus*) with a 24 months aged product.

Nevertheless, according to the Efficacy guidance – Volume II Parts B+C, to support a storage duration of 24 months (of a new formulation without preservative), efficacy should be demonstrated on all the species claimed. In the absence of efficacy data with a 24 months aged product against *Rattus norvegicus,* FR CAconsiders the efficacy of the product after a storage duration of 24 months is not validated.

* **Minor change (2021):**

French competent authorities (FR CA) consider that the elements presented in the dossier confirm the efficacy of the product BROMAFAR (0.005 % w/w bromadiolone) against mice (*Mus musculus)* andrats *(Rattus norvegicus, Rattus rattus*) for indoor use by professional users, with a shelf-life up to 24 months.

### Conclusion of the efficacy assessment

The product FAAR BLE has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* and rats (*Rattus norvegicus* and *Rattus rattus*) inside domestic, industrial and commercial buildings including farm buildings. Nevertheless, a monitoring of the resistance phenomenon of rodent populations toward the active substance bromadiolone and resistant strategies management must be put in place. The collected information must be sent every 2 years to Anses within the framework of a post-authorization monitoring. Furthermore, it can conclude that the product FAAR BLE can be considered as effective after a 14 months storage period. The 24 months storage period claimed by the applicant shall be demonstrated.

**Conditions of use :**

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

The authorization holder has to report any observed resistance to bromadiolone to Anses or other appointed bodies involved in resistance management every two years.

**Further required information:**

Concerning the efficacy of the product, the 24 month storage period claimed by the applicant must be demonstrated with a field study realized with a 24 month-aged product at latest 2 years after the authorization of the product.

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

* **Minor change (2014):**

The efficacy initially assessed for the first authorization of products FAAR BLE / FAAR AVOINE can be considered as valid for this application.

Uses and doses validated for FAAR BLE / FAAR AVOINE are the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Produit** | **Targets organism** | **Application rate and intervals** | **Use area** |
| **FAAR BLE**  **FAAR AVOINE**  Bait (cereals) containing 0.005% p/p of bromadiolone. | Rats (*Rattus norvegicus and Rattus rattus*) | 200 grammes/bait point separated by 5 to 10 meters | Indoor in secured bait station |
| Mice (*Mus musculus*) | 40 grammes/bait point separated by 1 to 2 meters | Indoor in secured bait station |

*Conditions of use linked to efficacy assessment are detailed in section 3 of this PAR.*

* **Renewal (2017):**

The product BROMAFAR has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* and rats (*Rattus norvegicus* and *Rattus rattus*).

The authorization holder has to report any observed resistance to bromadiolone to Anses or other appointed bodies involved in resistance management at the renewal of the authorisation.

* **Minor change (2019):**

French competent authorities (FR CA) considers that the elements presented in the dossier confirm the efficacy of the product BROMAFAR against house mice (*Mus musculus*) and black rats (*Rattus rattus*) with a 24 months aged product.

Nevertheless, according to the Efficacy guidance Volume II – Parts B+C, to support a storage duration of 24 months (of the new formulation without preservative), efficacy should be demonstrated on all the species claimed. In the absence of efficacy data with a 24 months aged product against *Rattus norvegicus,* FR CAconsiders the efficacy of the product after a storage duration of 24 months is not validated.

* **Minor change (2021):**

French competent authorities (FR CA) consider that the elements presented in the dossier confirm the efficacy of the product BROMAFAR (0.005 % w/w bromadiolone) against mice (*Mus musculus)* andrats *(Rattus norvegicus, Rattus rattus*) for indoor use by professional users, with a shelf-life up to 24 months.

* 1. **Description of the intended use(s) – Initial PAR 2012**

Bromadiolone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

The validated application rates and intended uses are the following:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Dosage claimed | Distance between 2 bait points, for high and low infestation | Time delay of the action of the product | Frequency and method of controls | Area of use | Methods of application of the bait |
| **Professional users** | | | | | | |
| Rats  *Rattus norvegicus*  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | indoor only | Manual application in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |
| **Non professional users** | | | | | | |
| Rats  *Rattus norvegicus*  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | indoor only | Pre-filled secured boxes  Manual application of baits in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |

The product FAAR BLE is intended to be used for control of mice *(Mus musculus)*, brown rats *(Rattus norvegicus)* and black rats *(Rattus rattus)* indoor. The control of mice and rats is based on the principle of applying baits in infested areas with obvious tracking of faeces, and smears next to holes and harbourages.

The product is ready-to-use grain bait with no dilution and or other substances added for application. It is manually applied by trained professional users and by non-professional users in bait stations. Pre-filled secured bait boxes are also available for non-professional users.

* **Renewal (2017):**

Bromadiolone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

The validated application rates and intended uses are the following:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Dosage claimed | Distance between 2 bait points, for high and low infestation | Time delay of the action of the product | Frequency and method of controls | Area of use | Methods of application of the bait |
| Professional users | | | | | | |
| Rats  *Rattus norvegicus*  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | In buildings | Manual application in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |

The product is ready-to-use grain bait with no dilution and or other substances added for application. It is manually applied by trained professional users.

* **Minor change (2019):**

Bromadiolone is used as rodenticide (product type PT14 according to EU Biocidal Product Directive).

The validated application rates and intended uses are the following:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Dosage claimed | Distance between 2 bait points, for high and low infestation | Time delay of the action of the product | Frequency and method of controls | Area of use | Methods of application of the bait |
| Professional users | | | | | | |
| Rats  *Rattus rattus* | 200 g / secured bait point | High infestation:  5 meters  Low infestation:  10 meters | 3 to 10 days | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | In buildings | Manual application in bait stations |
| House mice  *Mus musculus* | 40 g / secured bait point | High infestation:  1 meter  Low infestation:  2 meters |

The product is ready-to-use grain bait with no dilution and or other substances added for application. It is manually applied by trained professional users.

* 1. **Risk assessment for human health – PAR 2012, updated 2016 and 2017**

No new human exposure studies have been submitted. In the dossier, Triplan assessed the human exposure based on the TNsG on human exposure, section 7.2 of part 3 – June 2002. This document only contains a series of examples for human exposure assessment and should not be considered as reference data. Therefore, since Triplan provided a letter of access for the unpublished CEFIC study “*Chambers J.G. and Snowdon P.J. Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*”, the FR CA decided to base the human exposure assessment for professionals on this study as done by the RMS (Finland) of the active substance in the Assessment report on bromadiolone. This study examined the inhalation and dermal exposures associated with all activities involved in using a grain bait (decanting material from a large container to a pail, filling and placing bait points, and clean-up and disposal of bait points). The used grain bait containing coumatetralyl was selected as a worst case representative product of all cereal-based rodenticide baits. In this study, 10 replicates were performed at 1, 5 and 10 manipulations. Therefore, the FR CA decided to use the exposure estimations issued from the CEFIC study for the assessment of FAAR BLE.

For non professional users, the same CEFIC study and assumptions were used for the estimation of human exposure since the values available in the TNsG and User Guidance (Human exposure to biocidal products – TNsG June 2002 – version 1) are considered as unrealistic.

Additionally, the Human Exposure Expert Group (HEEG) opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMIII 2010 and the HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TMII 2011 were taken into account for the estimation of exposure for professionals and non professionals.

* + 1. **Hazard potential**

1. **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** CAR.

Bromadiolone (CAS no. 28772-56-7) was notified as an existing active substance, by a first applicant LiphaTech S.A.S, hereafter referred to as LiphaTech, and by a second applicant Bromadiolone Task Force, hereafter referred to as Task Force, 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 bromadiolone.

No oral absorption value could be set on the LiphaTech study, but the absorption was > 70 % of the administered dose, based on (carcass, bile- and urinary excretion, Task Force study). The major route of excretion was via the faeces accounting for ca 50-60 % of the dose, whilst approximately 1-5 % was excreted via urine. Bile investigations showed that biliary elimination plays a major role in the excretion. No parent bromadiolone was excreted in bile or urine. The main retention site was the liver. A non-guideline study in three cows was completed (LiphaTech). According to this study bromadiolone does not seem to accumulate into milk. The information from the ADME studies was not enough to propose a full metabolism pathway for any of the applicants but the study provided by LiphaTech identified one major metabolite in faeces as a hydroxylated analogue of bromadiolone; hydroxylation was proposed on the benzylic carbon atom.

No dermal absorption study were performed on the active substance alone (it was only provided for the formulated product or mixed with bait), but a default value of 10% could be used if considered necessary.

Dermal penetration in humans was estimated as < 1.6% for a powdered product.

Based on data from in vitro human skin studies with two representative products containing bromadiolone, the dermal absorption was less than 0.3% for the wax block formulations.

In acute oral toxicity studies, bromadiolone was very toxic to rats with a LD50 to the rat of between 0.56 and 1.31 mg/kg bw. Bromadiolone is slightly less toxic to dogs with a LD50 value of 8.1 mg/kg bw. The symptoms were observed 1-2 days prior to death and included signs of internal haemorrhage, which were confirmed at necropsy.

Bromadiolone was also acutely toxic by dermal administration, with an LD50 of 1.71 mg/kg bw in rabbits (LiphaTech) and with a combined sexes dermal LD50 value of 23.3 mg/kg in rats (Task Force).

The LC50 by inhalation, in rats was 0.43 μg/L (LiphaTech). Waiving of inhalation studies has been accepted for Task Force, since operator exposure through inhalation is unlikely to occur based in the information presented concerning production procedures and based on the physical chemistry data showing low vapour pressure. However, a classification as R26 ‘Very toxic by inhalation’ is warranted based on the other applicant’s data (LiphaTech).

Bromadiolone is not considered to be a skin or eye irritant or a skin sensitiser.

Repeated dose oral studies showed that at doses as low as 20 μg/kg/day in the dog, lethal effects developed after 64 to 85 days administration. The clinical signs, haematological and post mortem data were consistent with the known pharmacological action of the active substance; impairment of the clotting cascade and increased prevalence of haemorrhage leading to death. There were no indications of other secondary toxicities: histopathology revealed no hypertrophy or hyperplasia of the target organ, the liver.

In the 90-day oral exposure study in rabbits (data provided by Task Force), a significant increase in prothrombin time was seen in the 1 μg/kg dose group.

The overall NOAEL for repeat dose effects for both applicants is 0.5 μg/kg/day based on the absence of adverse effects in this dose group.

Route-to-route extrapolation based on data from the acute oral and dermal studies does not indicate that dermal exposure constitutes a greater risk than oral exposure. Therefore, waiving of a repeat dose dermal toxicity study has been accepted.

Also, due to that bromadiolone has a low vapour pressure, waiving of the repeat dose inhalation study has been accepted.

The subchronic dermal toxicity study is also waived.

A subchronic oral study has been performed for bromadiolone using the rabbit as test species, which may be used in route-to-route extrapolation. The highly cumulative nature of the material means that lower doses, administered over several days, can also be predicted to cause death. In all cases death

was caused by the specific pharmacological action of the molecule, inducing fatal haemorrhage. The mechanism of clotting inhibition caused by hydroxy coumarin type anticoagulant rodenticides is dependent on inhibition of vitamin K epoxide or vitamin K reductases and is unaffected by route of application. Therefore specific repeat dose dermal or inhalation studies would not provide any additional useful information to that obtained in various species in repeat dose and subchronic studies by the oral route.

A non-guideline study in the dog submitted by LiphaTech demonstrated that after ingestion of a single lethal dose or repeated administration of sublethal doses of bromadiolone on five occasions at 48 hour intervals, antidotal therapy consisting of slow intravenous injection of vitamin K followed by 7 days of oral administration of vitamin K resulted in rapid and complete recovery.

A study in rat with bromadiolone pellets (50 ppm end use product) submitted by LiphaTech also showed that vitamin K can reverse the effects. However, the effectiveness varied with the duration of exposure to bromadiolone.

Bromadiolone was not mutagenic in a standard range of in vitro and in vivo tests.

The carcinogenicity study and the chronic toxicity study were waived.

Performing long-term exposure studies is technically difficult when studying highly toxic substances such as bromadiolone, since dose levels, at which toxicity is identifiable but without rendering high levels of lethality, are hard to predict. The waiving is accepted, also considering the lack of genotoxicity.

The molecules both have significant structural similarity to vitamin K. This structural similarity is responsible for the ability to interfere with i.e. block the enzymes used to regenerate vitamin K. The major differences in the active substances lie in their ‘tails’, which have varying degree of lipophilicity. There is long term experience with warfarin, widely used in anti-clotting therapy in humans for over forty years, with no association with increased incidence of cancer. The absence of adverse effects in millions of humans following four decades of long term warfarin therapy is considered sufficient evidence that warfarin is not carcinogenic. The structural similarity of bromadiolone to warfarin, together with the negative results in the guideline mutagenicity tests, indicates that bromadiolone is not carcinogenic.

In addition, evidence is presented to show that it would not be possible to perform a meaningful long-term study in any species because of the accumulative nature and high toxicity of the active substance.

Reproductive effects of bromadiolone can not be excluded by the submitted two-generation reproduction toxicity study (Task Force), but since long term exposure studies are technically hard to perform for such highly toxic substances as bromadiolone, no new study will be required. As with carcinogenicity, the primary reason for not requiring such a study is the long term use of the structurally similar molecule warfarin in humans without association with adverse effects on fertility.

The 2-generation study is therefore accepted as waived for both applicants.

A teratogenicity study on rabbit showed severe fetal malformations following exposure to maternally toxic levels of bromadiolone (Task Force). However, the possibility that the effects seen may have been due to non-specific influences such as generalised toxicity cannot be excluded. Bromadiolone was not embryotoxic or teratogenic in guideline studies in rat and rabbit (LiphaTech).

However, based on the structural similarity to and the same mode of action as warfarin, bromadiolone is considered as a possible developmental toxicant. The Commission Working Group of Specialised Experts on Reproductive Toxicity has unanimously recommended that all AVK rodenticides should collectively be regarded as human teratogens due to the structural similarity to and the same mode of action as the known developmental toxicant warfarin (meeting in Ispra, 19-20 September 2006). Therefore based on read across data from warfarin, bromadiolone is considered to be a possible developmental toxicant and requires the classification as Reprotoxic with the labelling R61, may cause harm to the unborn child.

The toxicological studies do not indicate any neurotoxic effects. A neurotoxicity study would be scientifically unjustified and would not provide any new data. Based on this and animal welfare grounds it is deemed unnecessary to conduct a neurotoxicity study and applicant’s justification is accepted. Also, the mechanism for bromadiolone as an anticoagulant is well known and no mechanistic studies were considered necessary.

There are no case reports from the manufacturer concerning adverse effects in users applying the products. The Task Force submitted data on poisoning cases with bromadiolone. During the time period 1996–1999 a total of 115 calls concerning bromadiolone were received by the Milan Poisons Center, 98 of which involved clinical cases among humans or animals. The most common route of exposure was through ingestion and in 55% of the cases children under the age of four years were exposed. The symptoms were reported in eleven human cases and included vomiting, gastric pyrosis and itching. Only one case was reported with haematological problems. Vitamin K1 is the antidote, and it is important to monitor the clotting ability of the blood (prothrombin time) to continue the treatment long enough. If diagnosis is made quickly and appropriate therapy is instituted the prognosis is good.

The derivation of an acceptable level of exposure value for single use (AELacute) is based on the teratogenicity study in rabbits submitted by Task Force. It is based on the LOAEL of 2 μg/kg bw, using a safety factor of 600 (10 for interspecies and 10 for intraspecies variability, 2 for using LOAEL instead of NOAEL and an extra factor of 3 for severity of effects) and with correction of 70% oral absorption, resulting in an **AELacute of 0.0023 μg/kg bw**.

It was decided at TM III, 2006 that an extra AF of 3 will be used for all AVKs, while it was recognised that this factor is not scientifically derived. At TM I, 2007 it was further decided that a factor of 3 is considered sufficient to provide safe margins to cover for the use of subchronic studies for chronic exposure scenarios.

To derive an AELmedium, for repeated exposure, the subchronic study in rabbit submitted by Task Force is used, since it was performed in the most sensitive species. The NOAEL in this study is 0.5 μg/kg bw based on the prolonged prothrombin time seen at 1 μg/kg bw. With a safety factor of 300 and with correction of of 70% oral absorption, this would lead to an **AELmedium of 0.0012 μg/kg bw**.

To set an AELchronic the same NOAEL as for AELmedium will be used as no chronic studies have been performed. An extra safety factor of 3 will cover for the differences in exposure time.

1. **Toxicology of the substance(s) of concern**

Considering the following definition of a substance of concern set in the TNsG on data requirement chapter 4 (2000), “*the substance is regarded as a substance of concern if [...] it is classified as dangerous* ***and*** *its concentration in the product exceeds the classification limit set in the Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property* ***or*** *the other classification limit indicated for the substance in a preparation set in Annex I of Council Directive 67/548/EEC* ***or*** *causes that the overall sum of the concentrations of dangerous substances in the product exceeds the limit for classification of the preparation set in Council Directive 88/379/EEC, as amended by Directive 1999/45/EC, for a particular dangerous property*”, FAAR BLE does not contain any substance of concern.

* **Renewal (2017):**

Considering the definition of a substance of concern set in the Guidance on the BPR Volume III Humana Health – Part B Risk Assessment, BROMAFAR does not contain any substance of concern.

1. **Toxicology of the biocidal product**

New data:

Acute oral and dermal toxicity, skin and eye irritation and skin sensitisation studies have been provided on the product FAAR BLOC SP.

* Acute oral and dermal toxicity

In the acute oral toxicity study, no mortality occurred up to 2000 mg/kg bw/day (daily examination during 14 days) and no systemic clinical signs related to the administration of FAAR BLOC SP were observed. The body weight evolution of the animals remained normal throughout the study. In addition, the macroscopically examination of the animals at the end of the study did not reveal treatment-related changes.

No mortality was observed in the dermal acute toxicity study (LD50 > 2000 mg/kg bw/day). A depilation was noted on the treatment site on day 1 in two males (2/5). Erythema was noted on the treatment site in two females on day 2 and in all females on day 3 (5/5) associated with dryness. These cutaneous reactions were totally reversible on day 7.

Based on these results, no classification is required either for FAAR BLOC SP or for FAAR BLE.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Route | Species  Strain  Sex  No/group | Dose levels  Duration of exposure | Value LD50/LC50 | Remarks |
| Oral | Rat  Sprague Dawley (SPF Caw)  6 female/group | Single dose at 2000 mg/kg bw  Post exposure period: 14 days | At 2000 mg/kg bw: no death  LD50>2000 mg/kg bw | FAAR BLOC SP |
| Dermal | Rat  Sprague Dawley (SPF Caw)  5/sex/group | Single dose of 2000 mg/kg bw, applied to 10% body surface for 24 hours | At 2000 mg/kg bw: no death  LD50>2000 mg/kg bw  Dermal irritation consisted of depilation on day 1 (2/5 males) and erythema on day 2 (2/5 females) and on day 3 (all females) associated with dryness, except in one female. These cutaneous reactions were totally reversible on day 7. |  |

* Irritation and corrosivity

No cutaneous reactions (erythema, eschar and edema) were observed in the skin irritation study, whatever the examination times (i.e. 1, 24, 48 and 72 hours after the patch removal). However, the validity of this study is questioned since it was not specified in the study report whether the powder was moistened with water. However, since FAAR BLOC SP does not contain skin irritant ingredient above 1%, no classification with regard to skin irritation is warranted.

FAAR BLOC SP was slightly irritant to the eye of rabbit.

Based on the results of the irritation assays on rabbit’s skin and eye, no classification is required either for FAAR BLOC SP or for FAAR BLE.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Species  Strain  No/group | Average score 24, 48, 72h | | Reversibility? | Result |
| erythema | oedema |
| Rabbit  Albino New Zealand  3 females | 0.00 | 0.00 | No (no cutaneous reactions) | FAAR BLOC SP |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Species  Strain  No/group | Average score | | | | Reversibility? | Result |
| cornea | iris | Conjunctiva | |
| Redness | Chemosis |
| Rabbit  Albino New Zealand  3 females | 0.00 | 0.00 | 0.43 | 0.00 | Yes. Slight to moderate chemosis, noted 1 hour after the test item instillation and totally reversible on day 1. | FAAR BLOC SP |

* Sensitisation

A Magnusson and Kligman sensitisation test was submitted. Due to deviations from the OECD guideline 406 (use of SLS not clearly specified, no skin reaction observed at MNNC in the main test, dryness and scab at MNIC, choice of the pre-MNIC, controle positive older than 6 months), the validity of this study is questionned. However, based on the composition of FAAR BLOC SP and of FAAR BLE, no ingredients were listed as skin sensitisers. Therefore, it is expected that FAAR BLOC SP and FAAR BLE, are not skin sensitisers.

|  |  |  |  |
| --- | --- | --- | --- |
| Species  Strain  Sex | Method | Number of animals sensitized/total number of animals | Result |
| Albino Guinea pig  Dunkin-Hartley  Males | GPMT assay | Controls:16 males  Test group: 11 males | No evidence for inducing delayed contact hypersensitivity  FAAR BLOC SP |

Justification for non submission:

* Dermal absorption:

A dermal absorption of 3.1% was determined for cereal grains (value based on the results of *in vitro* study with rat skin after 24 hours of exposure – FAAR BLE\_ac-PH-10-0247-amended[[8]](#footnote-8)). As this study was not a GLP one and had several deficiencies, and although the absorption rate of the product must be considered as lower than or equal to 3.1%, a default value of 10% was considered for FAAR AVOINE, as mentioned in the bromadiolone assessment report (Final CAR, Avril 2011, Task Force).

* **Renewal (2017):**

No new dermal absorption study has been submitted for the renewal of the product.

However, the initial study has been re-assessed taking into account the EFSA guidance on dermal absorption (2012).

The dermal absorption of Bromadiolone formulated as pellet bait (containing 0.005% difenacoum) was investigated *in vitro* using human skin. The measured samples were below the limit of detection or quantification, but as a worst case, the corresponding validated LOQ value was used for the calculations of dermal absorption. The total recovery of bromadiolone was 100.6% when skin discs were exposed to 5 mg/cm2 of the product (equivalent to 250 ng a.s./cm2) for 24 hours.

The calculated standard deviation being larger than 25% of the mean it has been added to the mean value. Therefore, the percentage of absorbed Bromadiolone was 2.14% (receptor fluid + epidermis + dermis + stratum corneum). Thus, a dermal absorption value of 2% is considered for bromadiolone. The value has been rounded according to the EFSA guidance criteria.

* Acute inhalation toxicity:

Since the generation of inhalable particle is considered as possible for FAAR BLE, FAAR BLE should be classified Xn, R20 – Harmful by inhalation, according to the specific concentration limits set for bromadiolone.

* Repeated toxicity

According to the specific concentration limits set for bromadiolone, FAAR BLOC SP and FAAR BLE should be classified Xn, R48/20/21/22.

No harmonised classification is currently available but a classification according the criteria in directive 67/548/ECC with specific concentration limits is proposed in the combined assessment report. A classification proposal has been also submitted to ECHA in August 2010.

|  |  |  |  |
| --- | --- | --- | --- |
| Classification under directive 67/548/EEC | | Classification under regulation (EC) 1272/2008 | |
| T+ R26/27/28  T R48/23/24/25  Repr.Cat. 1; R61 | | Acute Tox. 1 H300, H310, H330  STOT RE 1 H372  Repr. 1A; H 360D | |
| Specific concentration limits for human health: | | Specific concentration limits for human health: | |
| C ≥ 0.5%  0.25% ≤ C < 0.5%  0.025% ≤ C < 0.25%  **0.0025% ≤ C < 0.025%** | T+; R61-26/27/28 –  T;R48/23/24/25  T+; R26/27/28 – T; R48/23/24/25  T; R23/24/25 – T; R48/23/24/25  **Xn; R20/21/22 – R48/20/21/22** | C ≥ 0.01%  **0.001%≤C<0.01%** | STOT RE 1; H372  **STOT RE 2; H373** |

Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, FAAR BLE is classified as follows:

|  |  |
| --- | --- |
| Classification under directive 1999/45/EC | Classification under regulation (EC) 1272/2008 |
| Xn R20  Xn R48/20/21/22 | STOT RE 2; H373 |

* **Renewal (2017):**

Active substance classification

|  |
| --- |
| Classification under regulation (EC) 1272/2008 |
| Acute Tox 1 – H300 ; H310 ; H330  STOT RE 1 – H372 (blood)  Repr. 1B – H360D  Aquatic Acute 1 – H400  Aquatic chronic 1 – H410  Repr. 1B; H360D: C ≥ 0,003 % STOT RE 2; H373: 0,0005 % ≤ C < 0,005 % STOT RE 1; H372: C ≥ 0,005 %  M=1  M=1 |

Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, BROMAFAR is classified as follows:

* Repr. 1B - H360D: May damage the unborn child
* STOT RE 1 - H372: Causes damage to organs (blood) through prolonged or repeated exposure.
* Other studies

The product is not used with other biocidal products. Therefore, no additional study was conducted.

The product is a solid bait only used, in buildings, in secured bait points. Collecting unconsumed baits and dead rodents must be done every week during the treatment so in these recommended conditions, no contamination is expected for feeding stuffs. Finally, according to the Assessment report on bromadiolone, “Bromadiolone baits should not be placed so that food, feeding stuffs or drinking water could be contaminated”. Therefore, no data on residue was submitted.

* + 1. **Human exposure assessment**

FAAR BLE (PT14) is a ready-to-use rodenticide containing 0.005% of bromadiolone. Baits are packaged in sachets for professional and non-professional users or in bulk for professional users.The baits are placed in bait stations in buildings (bait boxes or secured bait stations) out of reach of children and domestic animals.

* **Renewal (2017):**

Only professional uses are considered.

* + - 1. **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 applicable | For non professionals: negligible (baits in sachets).  For professionals: Exposure only during the phase of decanting from 25 kg bags. | Negligible.  Bromadiolone is not volatile; its vapour pressure is low (2.3E-8 Pa at 25°C) | Not applicable |
| Dermal | Not applicable | Direct exposure | Indirect exposure: only children and infant | Not applicable |
| Oral | Not applicable | Unrealistic exposure | Indirect exposure: only children and infants | Not applicable |

* + - 1. **Exposure of professional users**

The biocidal products are ready-to-use rodenticide containing 0.005% of bromadiolone. Baits are packaged in sachets for professional and non-professional users or in bulk for professional users.The baits are placed in bait stations in buildings (bait boxes or secured bait stations) out of reach of children and domestic animals.

FAAR BLE/FAAR AVOINE are intended to be used as ready-to-use rodenticidal bait for rodent control by professional users inside buildings.

**Primary exposure**

*Dermal exposure*

Based on a CEFIC study (Chambers *et al*., 2004[[9]](#footnote-9)) and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.

Since for the control of mice, the quantity of decanted product is 2.5 kg corresponding to one decanting time, 93 mg of product was considered. In contrast, for the control of rats, the quantity of decanted product is 12.6 kg corresponding to more than 4 decanting times, leading therefore to consider 52.3 mg of product on fingers/hands.

The following parameters were taken into account:

* Active substance in product: 0.005%,(w/w)
* Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[[10]](#footnote-10)) and 2.5 kg for mouse (40 g of grains per bait boxes; 63 loading of bait boxes),
* Dermal absorption: 0.748%,
* Body weight: 60 kg.

The quantities of 200 g for the control of rats and 40 g for the control of mice correspond to the validated efficient doses.

Therefore, the systemic dose of bromadiolone on fingers/hands during decanting is

* For the control of rats: 1.37.10-6 mg/kg bw/day,
* For the control of mice: 2.74x10-7 mg/kg bw/day.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of bromadiolone on fingers/hands during loading is 8.01x10-7 mg/kg bw/day for the control of rats and mice because the amount of disposed bait is not taken into account during loading.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of bromadiolone on fingers/hands during loading is 3.78x10-7 mg/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

In conclusion, the total systemic dermal exposure is set at 2.55x10-6 mg/kg bw/day and 1.45x10-6 mg/kg bw/day without PPE for the control of rats and mice, respectively. When gloves are worn (5% gloves penetration factor), the exposure is reduced to 1.27x10-7 mg/kg bw/day and 7.26x10-8 mg/kg bw/day for the control of rats and mice, respectively.

*Inhalation exposure*

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

The following parameters were considered:

* Duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6 kg decanted in 3 kg buckets per day) and 3 minutes per day for mice (3 minutes per decanting; 1 decanting per day)
* Inhalation rate: 1.25 m3/hour
* Inhalation absorption: 100%
* RPE: protection factor of 10
* Active substance in product: 0.005%(w/w)
* Body weight: 60 kg

Based on these assumptions, the systemic concentration of bromadiolone is 2.51x10-6 mg/kg bw/day without RPE and 2.51x10-7 mg/kg bw/day with RPE.

*Total exposure*

The total systemic exposure resulting from inhalation and dermal contacts with the product is 5.05x10-6 mg a.s/kg bw/day and 3.96x10-6 mg a.s/kg bw/day without gloves for the control of rats and mice, respectively. The systemic exposure is reduced to 3.78x10-7 mg a.s/kg bw/day and 3.23x10-7 mg a.s/kg bw/day for the control of rats and mice, respectively, with gloves and RPE.

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

Therefore, only exposure during cleaning can be considered: 3.78x10-7 mg a.s/kg bw/day without gloves and 1.89x10-8 mg a.s/kg bw/day with gloves for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | | **Dermal internal exposure**  **[mg/kg/d]** | | | **Total exposure**  **[mg/kg/d]** | | **Model** |
| Rats | Mice | Rats | Mice | | Rats | Mice |
| **Bulk formulation (exposure during decanting, loading and cleaning phases)** | | | | | | | | | | |
| Tier 1 (without PPE) | Bromadiolone | 28772-56-7 | 2.51x10-6 | 2.51x10-6 | 2.55x10-6 | | 1.45x10-6 | 5.05x10-6 | 3.96x10-6 | Cefic study |
| Tier 2 (gloves penetration factor: 5% + RPE) | Bromadiolone | 28772-56-7 | 2.51x10-7 | 2.51x10-7 | 1.27x10-7 | | 7.26x10-8 | 3.78x10-7 | 3.23x10-7 | Cefic study |
| **Sachet formulation (exposure during cleaning phase)** | | | | | | | | | | |
| Tier 1 (without PPE, dermal exposure expected only during the cleaning phase) | Bromadiolone | 28772-56-7 | Not applicable | Not applicable | 3.78x10-7 | | 3.78x10-7 | 3.78x10-7 | 3.78x10-7 | Cefic study |

**Secondary exposure**

Secondary exposure of users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because the product is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the AEL of 2.3x10-6 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 70% [as stated in the Assessment report of bromadiolone (Task Force)], ingestion of more than 0.66 mg of product per day by an infant is needed to exceed the AEL.

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

* **Renewal (2017):**

The biocidal products are ready-to-use rodenticide containing 0.005% of bromadiolone. Baits are packaged in sachets or in bulk for professional users.The baits are placed in bait stations in buildings (bait boxes or secured bait stations) out of reach of children and domestic animals.

FAAR BLE/FAAR AVOINE/BROMAFAR are intended to be used as ready-to-use rodenticidal bait for rodent control by professional users inside buildings.

**Primary exposure**

*Dermal exposure*

Based on a CEFIC study (Chambers *et al*., 2004[[11]](#footnote-11)) and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day.

Since for the control of rats, the quantity of product is higher than the quantity claimed for the control of mice, it is considered as a worst-case covering the use against mice. Only the exposure assessment corresponding to the control of rats is presented.

For the control of rats, the quantity of decanted product is 12.6 kg corresponding to more than 4 decanting times, leading therefore to consider 52.3 mg of product on fingers/hands.

The following parameters were taken into account:

* Active substance in product: 0.005%,(w/w)
* Quantity of decanted product: 12.6 kg for rat (200 g of grains per bait boxes; 63 loading of bait boxes[[12]](#footnote-12)),
* Dermal absorption: 2%,
* Body weight: 60 kg.
* Gloves protection: 95%[[13]](#footnote-13)

The quantities of 200 g for the control of rats and 40 g for the control of mice correspond to the validated efficient doses.

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

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings in professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010).

*Inhalation exposure*

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

The following parameters were considered:

* Duration of manipulation: 15 minutes per day for rats (3 minutes per decanting; 12.6 kg decanted in 3 kg buckets per day)
* Inhalation rate: 1.25 m3/hour
* Inhalation absorption: 100%
* RPE: protection factor of 10
* Active substance in product: 0.005%(w/w)
* Body weight: 60 kg

The estimations for exposure to the products in bulk represent a very worst case when the product is supplied and applied in sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.

Therefore, only exposure during cleaning can be considered for product supplied in plastic sachet.

*Total exposure*

The total systemic exposure resulting from inhalation and dermal contacts with the product, considering the use against rats, is as follows:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Inhalation exposure**  **(mg/kg bw/d)** | **Demal exposure**  **(mg/kg bw/d)** | **Total systemic exposure**  **(mg/kg bw/d)** |
| **Bulk formulation (exposure during decanting, loading and cleaning phases)** | | | |
| Tier 1 (without PPE) | 2.51 x 10-6 | 6.81 x 10-6 | 9.32 x 10-6 |
| Tier 2 (gloves penetration factor: 5% + RPE) | 2.51 x 10-7 | 3.41 x 10-7 | 5.91 x 10-7 |
| **Sachet formulation (exposure during cleaning phase)** | | | |
| Tier 1 (without PPE) | n.a | 1.01 x 10-6 | 1.01 x 10-6 |

**Secondary exposure**

Secondary exposure of users could result in the handling of dead rodents. However, this scenario is excluded due to unrealistic assumptions (very low amount of bromadiolone is expected on the fur because the product is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for bromadiolone).

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the AEL of 2.3x10-6 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 70% [as stated in the Assessment report of bromadiolone (Task Force)], ingestion of more than 0.68 mg of product per day by an infant is needed to exceed the AEL.

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

* + - 1. **Exposure of non-professional users and the general public**

FAAR BLE is intended to be used as a ready-to-use rodenticidal bait for rodent control by non-professionals inside buildings.

**Primary exposure**

FAAR BLE is only supplied and applied in sachets for non professional users. As a worst case, exposure has been assessed in a first step approach considering FAAR BLE supplied as loose grains. In a second step, the protection of a sachet has been considered. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.

This approach is to assess the necessity of the sachet packaging related to risks.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 4.52 mg/manipulation for the assessment of 1 to 4 cleanings per day and 3.79 mg/manipulation for the assessment of 1 to 4 cleanings per day. According to the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010, 5 cleanings per day is considered for non-professional use. However, since the CEFIC study was designed for professional users and that the agreed number of cleanings for non-professionals is closed to 4, the amount of 4.52 mg/manipulation was used for exposure assessment. Therefore, the systemic exposure is 1.9x10-6 mg a.s/kg bw/day for the control of both rats and mice because the amount of disposed bait is not taken into account during cleaning.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | **Dermal internal exposure**  **[mg/kg/d]** | **Total exposure**  **[mg/kg/d]** | **Model** |
| Control of rats and mice - Sachet considered (exposure only during cleaning) | | | | | | |
| Non professional | Bromadiolone | 28772-56-7 | Not applicable | 1.9x10-6 | 1.9x10-6 | Cefic study |

* **Renewal (2017):**

General public uses are no longer claimed for the renewal of authorisation.

Only professional uses are considered.

#### Indirect exposure via residues in food

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

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

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

* + 1. **Risk assessment for human health**
       1. **Risk for Professional Users**

The estimated exposures for the professional users are compared to the systemic AELlong-term of bromadiolone set in the Assessment report (1.2x10-6 mg/kg bw/day for long-term exposure).

**Primary exposure**

The risk for professional users resulting from the intended use is unacceptable when FAAR BLE is supplied in bulk, even if gloves are worn (%AEL at 351% and 123% for the control of rats and mice, respectively, with a gloves penetration factor of 5%).

For FAAR BLE supplied and applied in sachet, the risk resulting from the intended use is acceptable when professionals are wearing gloves with a penetration factor of 10% (%AEL at 42% for the control of rats and 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.

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 decanting, loading and cleaning phases)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 3.7x10-5 | 3048 | Unacceptable |
| Professional (with gloves ; penetration factor of 10 %) | 1.2x10-6 | 5.9x10-6 | 493 | Unacceptable |
| Professional (with gloves ; penetration factor of 5 %) | 1.2x10-6 | 4.2x10-6 | 351 | Unacceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 5.1x10-6 | 421 | Unacceptable |
| Professional (with gloves ; penetration factor of 10 %) | 1.2x10-6 | 5.1x10-7 | 42 | **Acceptable** |

Summary of risk characterisation for professionals for the control of mice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Bulk formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 2.0x10-5 | 1661 | Unacceptable |
| Professional (with gloves ; penetration factor of 10 %) | 1.2x10-6 | 2.4x10-6 | 204 | Unacceptable |
| Professional (with gloves ; penetration factor of 5 %) | 1.2x10-6 | 1.5x10-6 | 123 | Unacceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 5.1x10-6 | 421 | Unacceptable |
| Professional (with gloves ; penetration factor of 10 %) | 1.2x10-6 | 5.1x10-7 | 42 | **Acceptable** |

* **Minor change (2014):**

The risk for professional users resulting from the intended use is acceptable when the product is supplied in bulk, when gloves and RPE are worn (%AEL at 31% and 27% for the control of rats and mice, respectively, with a gloves penetration factor of 5% and a respiratory protection factor of 10).

For the product supplied and applied in sachet, the risk resulting from the intended use is acceptable for professionals without PPE (%AEL at 31% for the control of rats and 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.

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 decanting, loading and cleaning phases)** | | | | | |
| Professional (without gloves) | 1.2x10-6 | 5.05 x 10-6 | | 421 | Unacceptable |
| Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | 1.2x10-6 | 3.78 x 10-7 | | 31 | **Acceptable** |
| **Sachet formulation (exposure during cleaning phase)** | | | | | |
| Professional (without gloves) | 1.2x10-6 | 3.78 x 10-7 | 31 | | **Acceptable** |

Summary of risk characterisation for professionals for the control of mice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Bulk formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 3.96x10-6 | 330 | Unacceptable |
| Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | 1.2x10-6 | 3.23x10-7 | 27 | **Acceptable** |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professional (without gloves) | 1.2x10-6 | 3.78 x 10-7 | 31 | **Acceptable** |

**Secondary exposure**

No relevant secondary exposure is expected for professional users, thus no unacceptable risk has been identified.

* **Renewal (2017):**

The estimated exposures for the professional users are compared to the systemic AELlong-term of bromadiolone set in the Assessment report (1.2x10-6 mg/kg bw/day for long-term exposure).

**Primary exposure**

The risk for professional users resulting from the intended uses is acceptable when the product is supplied in bulk, when gloves (penetration factor of 5%) and RPE (protection factor of 10) are worn (%AEL at 49%) for the control of rats, and by extension the control of mice.

For the product supplied and applied in sachet, the risk resulting from the intended use is acceptable for professionals without PPE (%AEL of 84%) for the control of rats, and by extension the control 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.

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 decanting, loading and cleaning phases)** | | | | | |
| Tier 1  (without PPE) | | 1.2 x 10-6 | 9.32 x 10-6 | 777% | Unacceptable |
| Tier 2 (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | | 1.2 x 10-6 | 5.91 x 10-7 | 49% | **Acceptable** |
| **Sachet formulation (exposure during cleaning phase)** | | | | | |
| Tier 1 (without PPE) | 1.2 x 10-6 | | 1.01 x 10-6 | 84% | **Acceptable** |

**Secondary exposure**

No relevant secondary exposure is expected for professional users, thus no unacceptable risk has been identified.

* + - 1. **Risk for non-professional users and the general public**

The estimated exposure for the non-professional users is compared to the systemic AELlong-term of bromadiolone set in the Assessment report (1.2x10-6 mg/kg bw/day for long-term exposure).

**Primary exposure**

The risk for non-professional users resulting from the intended use is unacceptable (% AEL at 157% for the control of rats and mice). However, the risk calculation is based on a default dermal absorption of 10% for bromadiolone. This value is likely lower as demonstrated in an *in vitro* dermal absorption study performed with FAAR BLE (a dermal absorption of 3.1% was determined). But, due to deficiencies, this study was not considered as valid.

Summary of risk characterisation for non professionals for the control of rats and mice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Non-professional (without gloves) | 1.2x10-6 | 1.9x10-6 | 157 | Unacceptable |

* **Minor change (2014):**

The risk for non-professional users resulting from the intended use is acceptable without PPE when the product is supplied in sachet (% AEL at 12% for the control of rats and mice).

Summary of risk characterisation for non professionals for the control of rats and mice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scénario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Non-professional (without gloves) | 1.2x10-6 | 1.41x10-7 | 12 | **Acceptable** |

**Secondary exposure**

* **First authorisation (2013):**

Based on a reverse scenario, more than 0.66 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 FAAR BLE contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

* **Minor change (2014):**

Based on a reverse scenario, more than 0.66 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 FAAR BLE contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

* **Renewal (2017):**

General public uses are no longer claimed for the renewal of authorisation.

#### Risk for consumers via residues

Considering the intended uses no dietary risk assessment is necessary.

#### Risk for combined exposure

Not relevant.

#### Conclusion of the risk assessment for human health

The risk resulting from the intended use is acceptable when professionals are wearing gloves and when FAAR BLE is supplied and applied in sachet.

The risk for non-professional users resulting from the intended use is unacceptable. Consequently, the use is restricted to professionals.

Finally, there is a significant risk of poisoning for infants, thus, the baits should be unattainable for children.

***Measures to protect man***

* Wear protective gloves when handling the product and dead rodents.
* Do not open the sachets.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* For professional users, covered bait stations could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Do not place tamper-resistant bait boxes and covered bait stations on surfaces in contact with food, feed or drinks and beverages.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.
* **Renewal (2017):**

For bulk formulation, the risk is considered acceptable for professionals wearing gloves and RPE. Moroever, to limit inlahalation exposure when handling loose grains, the packaging should be restricted to 10kg.

For sachet formulation, the risk is considered acceptable for professionals without PPE.

General public uses are no longer claimed for the renewal of authorisation.

## Risk assessment for the environment – initial PAR 2012

### Fate and distribution in the environment

The summary of information about the active substance bromadiolone is carried out with the data from the CAR of bromadiolone supplied by the notifier Task Force (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011). No new ecotoxicological information on the active substance bromadiolone has been submitted in the product dossier.

#### Degradation

##### Abiotic degradation

###### Hydrolysis in function of pH

According to the test OECD 111 bromadiolone is considered stable to hydrolysis with a DT50 hydrolysis value > 1 year at environmentally relevant temperatures for all pH. Hydrolytic degradation is not expected to be a significant process in the environment.

###### Photolysis in water

Photolysis of bromadiolone in water is rapid and follows a biphasic pattern. Complete photolysis occurs within two hours. Several metabolites are observed in the photolysis study. Nevertheless, it was stated that they were not identified because of limited exposure of the aquatic compartment by bromadiolone and since it is not likely that a substance with a specific mode of action will have metabolite more toxic than the parent compound. It is stated in the CAR of bromadiolone that it should be considered that in natural waters photolysis will have only a minor impact on the degradation of bromadiolone, and in accordance with TGD II, the impact of photodegradation will be considered as negligible in the risk assessment.

###### Photolysis in soil

Not relevant for bromadiolone.

###### Photodegradation in air

Photodegradation characteristics of bromadiolone were estimated using EPIWIN v 3.12. The indirect photolysis half-life of bromadiolone reacting with OH radicals is 2.090 hours with a rate constant of 61.422\*10-12 cm3/molecule/s and 2.015 hours with a rate constant of 13.650 cm3/molecule/s when reacting with ozone. This shows that bromadiolone photodegrades rapidly in air. Moreover, the vapour pressure of bromadiolone at 25° C is 1\*10-7 Pa and Henr’s law constant is 4.25\*10-4 Pa\*m3/mol. Hence, bromadiolone is not expected to volatilise to, or persist in, air in significant quantities.

##### Biotic degradation

###### Aquatic compartment

According to the OECD tests bromadiolone is not readily or inherently biodegradable.

In addition, no degradation of bromadiolone occurred in a test for anaerobic degradation ISO 11734 but the study indicated that bromadiolone inhibits microbial activity, and therefore it can possibly have a negative impact on microorganisms in an STP. No studies on aerobic degradation in STP or further degradation studies in water and sediments have been performed. The applicants justifications referring to the limited exposure of these compartments for bromadiolone have been found acceptable in the CAR of the bromadiolone.

Hence, for the aquatic compartment, bromadiolone is assumed to be not biodegradable under environmentally relevant conditions. So the risk assessment in aquatic compartment is based on the assumption that bromadiolone is not biodegradable and a half-life is over 365 days.

###### Terrestrial compartment

Degradation studies in soil have not been performed with the justification that bromadiolone will be degraded by light and that the release of bromadiolone is only local. The justification has been found acceptable in the CAR of bromadiolone regarding its second part at active substance level. Nevertheless, soil degradation studies are required at the product authorisation stage because the effect of sunlight on degradation of bromadiolone in soil has not been shown and the degradation in soil has not been quantified for the active substance inclusion. However due to the intended use of FAAR BLE, which is only as rodenticide inside buildings, the exposure of the soil is limited and no risk assessment for soil is conducted for this product. Subsequently no soil degradation studies including degradation rates and formation of major metabolites is required for the product FAAR BLE.

It is stated in the CAR of bromadiolone that risk assessment for soil is based on that bromadiolone is not degraded according to ready and inherently biodegradability tests.

#### Distribution

Bromadiolone is strongly adsorbed to soil and the experimentally determined Koc values (OECD 106) are ranged between 3530 and 41600 mL/g.On the basis of this study bromadiolone is practically ‘non mobile’ in soil.

Therefore it is assumed that bromadiolone will not reach groundwater in significant quantities.

This assessment is considered sufficient at active substance level. However, it is stated in the CAR of bromadiolone that in order to clarify the distribution properties of bromadiolone soil degradation studies including degradation rates and formation of major metabolites are required at the product authorisation stage. Due to the intended use of FAAR BLE, which is only as rodenticide inside buildings, the exposure of the soil is limited. Subsequently no soil degradation studies including degradation rates and formation of major metabolites is required for the product FAAR BLE.

#### Accumulation

Bromadiolone has a high Log Kow (3.8), it does not degrade and its molecular weight indicates no hindrance for uptake by organisms.

The aquatic BCF has been estimated with calculation method because the fish bioconcentration test was not reliable. The measured value of log Kow value (3.8) allows to calculate an estimated BCF for fish :

**BCFfish = 339 L/kg**

(according to Equation 74, TGD).

In conclusion bromadiolone has potential for bioaccumulation in organisms.

#### Behaviour in air

**Volatilisation**

The vapour pressure of bromadiolone at 25°C is 1\*10-7 Pa and Henry's law constant is 4.25\*10-4 Pa\*m3/mol. These figures show that bromadiolone not is expected to volatilise to air in significant quantities.

**Global warming**

Bromadiolone (with absorption at 263 nm) is not likely to contribute to global warming since it has no absorption in the atmospheric window.

**Stratospheric - Tropospheric ozone**

Bromadiolone, which has a short atmospheric half-life, will not have any negative effects on stratospheric and tropospheric ozone.

**Acidification**

Due to low expected emissions to air and due to the fact that bromadiolone does not contain any of the acidifying substances mentioned in TGD II, section 3.7.2 it is not likely that bromadiolone will have any effect on acidification of the receiving soil or surface water.

In summary, bromadiolone is not expected to volatilise to air from soil or water, and no negative effects of bromadiolone are expected in the air compartment.

### Effects on environmental organisms for active substance

The summary of information about the active substance bromadiolone is carried out with the data from the CAR of bromadiolone owned by the Task Force (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011). No new ecotoxicological information on the active substance bromadiolone has been submitted in the product dossier.

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

##### Aquatic organisms

Bromadiolone is acutely toxic to fish (*Oncorhynchus mykiss*) with an LC50 of 2.86 mg/L in nominal concentration as the measured concentrations of bromadiolone were all within the range 95-102 % of nominal. EC50 for *Daphnia magna* was 5.79 mg/L (nominal concentration), i.e. the same order of magnitude as that for fish. The alga *Pseudokirchneriella subcapitata* was found to be the most sensitive of the three aquatic organisms tested, with an ErC50 of 1.14 mg/L. Due to the rapid photolysis of the test substance, the test concentrations used to express the results were calculated according to the OECD Guidance document on aquatic toxicity testing of difficult substances and mixtures. However, it is very likely that the degradation is much faster than what can be seen as a disappearance in 72 h, so it was considered in the CAR of substance active bromadiolone owned by Task Force that the resulting effect value (ErC50) is most probably an underestimation of toxicity. Therefore, an extra assessment factor of 3 was applied to the ErC50 to compensate for this uncertainty. The Technical Meeting has earlier (TM II-07, CAR based on the other notifier of bromadiolone, LiphaTech S.A.S) agreed to use an extra assessment factor of 3 based on a similar uncertainty. DMSO was used to increased the solubility of bromadiolone in invertebrate and algae studies.

The table below summarise the results of these tests.

Table 2.8.2.1.1 Toxicity to freshwater aquatic organisms

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint** | **Results (mg a.s/l)** | **Reference** |
| OECD 203 / semi-static system | *O. mykiss* fish | 96 hour LC50 | 2.86\* | CAR a.s. III‑A 7.4.1.1 |
| OECD 202 / static system | *D. magna* aquatic invertebrate | 48 hour EC50 | 5.79\* | CAR a.s. III‑A 7.4.1.2 |
| OECD 201 / static system | *Pseudo-kirchneriella subcapitata*  algae | 72 hour EbC50  72 hour ErC50 | 0.66\*\*  1.14\*\* | CAR a.s. III‑A 7.4.1.3 |

\* Nominal concentration

\*\* Geometric mean of the initial concentration and LOQ/2

Justification of PNECwater :

On the basis of acute toxicity data of the active ingredient bromadiolone for fish, invertebrates and algae, the PNEC is derived from the lowest L/EC50 value (algae ErC50 = 1.14 mg/l). An assessment factor of 1000 is appropriate when only results from acute studies are available (TGD II, section 3.3 table 16). As discussed above, an additional assessment factor of 3 is introduced due to uncertainties regarding photolytic degradation of bromadiolone in the light conditions used in the test.

This gives a PNECfreshwater of 1.14/1000/3 = 3.8\*10-4 mg/L.

**PNECfreshwater = 3.8 10-4 mg a.s./L.**

Additional endpoints: The PNEC values for freshwater from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECfreshwater = 1.7 10-5 mg a.s./L** than the PNEC derived in the final CAR of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

##### Sediment dwelling organisms

No ecotoxicological data for sediment-dwelling organisms are available in the Task Force dossier. As the exposure to the aquatic compartment is low, it was stated that no tests on these organisms was requested.

Justification of PNECsediment

The PNEC for sediment dwelling organisms was calculated with the equilibrium partitioning method according to TGD II, section 3.5.2.3., equation 70 as no tests are available. The average Koc value of **14770 mL/g** was calculated using the experimentally determined Koc values (OECD 106) ranging between **3530 and 41600 mL/g.**

**PNECsediment = 0.83 mg a.s./kg ww**

Additional endpoints: Not relevant.

##### STP micro-organisms

The toxicity to microorganisms in a sewage treatment plant (STP) was estimated by a respiration inhibition test (OECD 209) and an EC50 was found to be 132.8 mg/L.

Table 2.8.2.1.3: Toxicity to STP micro-organisms

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species / Inoculum** | **Endpoint / Type of test** | **Exposure** | | **Results (mg a.s/l)\*** | | | **Reference** |
| **design** | **duration** | **EC20** | **EC50** | **EC80 NOEC**  **(EC15)** |
| OECD 209 | Activated sludge | Respiration inhibition | static | 3 hours | c.a.25\* | 132.8 | NA\*\* NA | CAR a.s. Doc. III-A 7.4.1.4 |

\* Not calculated but estimated to be approximately 25 mg/L

\*\* NA: Not Available

Justification of PNECmicroorganisms:

Since no NOEC or EC10 was available an assessment factor of 100 was used on the EC50 in accordance with TGD II section 3.4 table 17. This gives a PNEC of 132.8/100 = 1.33 mg/L.

**PNECSTP microorganisms = 1.33 mg a.s./L**

Additional endpoints: The PNEC values for sewage treatment microorganisms from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNEC STP microorganisms = 0.32 mg a.s./L** than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

#### Atmosphere

No data are available on the biotic effects in the atmosphere. Bromadiolone 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 effects of bromadiolone, in soil concentration ranging up to 1331 mg/kg dw, were found on earthworms in a test conducted according to the guideline OECD 207. LC50 was determined to be >918 mg/kg dw, when corrected for soil humidity.

Table 2.8.2.3: Toxicity to soil organisms

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint / Type of test** | **Exposure** | | **Results (mg a.s/kg wwt soil)** | | **Reference** |
| **design** | **duration** | **NOEC** | **LC50** |
| OECD 207 | *Eisenia foetida* | LC50 | soil exposure | 13days | 918 (standardised) | > 918  (standardised) | CAR a.s.  Doc. III-A 7.5.1.2 |

Justification of PNECsoil

Since LC50 was determined to be >918 mg/kg ww, when corrected for soil humidity, an assessment factor of 1000 was used in accordance with TGD part II section 3.6 table 20 for calculation of PNEC. This would give a PNECsoil of 918 mg/kg ww/1000 = 0.918 mg/kg ww.

**PNECsoilDATA = 0.918 mg/kg wet weight**

According to TGD II section 3.6.2.1, if results from only one terrestrial study are available the PNEC should also be calculated from the aquatic toxicity data using equilibrium partitioning calculations. These calculations should be performed according to equation 72 in the TGD II.

**PNECsoilEPM = 0.099** **mg/kg wet weight**

The calculations above indicate that effects may be found at concentrations higher than 0.099 mg/kg, but empirically in the study submitted by the notifier no effects were found in tests with earthworm at concentrations of 918 mg/kg ww. In the TGD II section 3.6.2 and 3.6.2.1 it is stated that equilibrium partitioning calculations can never replace toxicity data for soil organisms but should only be used for screening and that toxicity data for aquatic organisms cannot replace data for soil dwelling organisms. However, the difference between the empirical and modelled figures is notable, especially when taking into account the PNECsoil value from the final CA report of the other notifier of bromadiolone, LiphaTech S.A.S (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008). This value was derived empirically (also in this case there was no effect at the highest tested concentration) and is considerably lower, being 0.0084 mg/kg wet soil. Due to that only one soil organism was tested and also considering the uncertainties arising from the differing data of the two applicants, the PNEC soil value derived from the equilibrium partitioning calculations may be considered as the more realistic value.

Additional endpoints:

The PNEC values for terrestrial organisms from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECsoil= 0.0084** **mg/kg wet weight** than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

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

The exposure of bromadiolone directly to non-target birds and mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered a critical aspect of the risk assessment

Table 2.8.2.4: Toxicity to birds and mammals (key studies)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint / Type of test / Duration** | **Results** | | **Reference** |
| **NOEC/NO(A)EL** | **LD/C50** |
| OPPTS 850.2100 | Japanese quail  (*Coturnix coturnix japonica*) | LD50/ acute oral  1 day and 14 days oservation | 31.3 mg a.s/kg bw/day | **LD50 = 134 mg a.s/kg bw**  **LC50=1070 mg a.s/kg food** | CAR a.s.  Doc. A-III 7.5.3.1.1‑03 |
| OECD 206 | Japanese quail  (*Coturnix coturnix japonica*) | Reproduction test  42 days | **NOEC = 0.039 mg a.s/kg bw/day**  **Equivalent to NOEC= 0.26 mg/L drinking water** |  | CAR a.s.  Doc. III-A 7.5.3.1.3 |
| OECD 401 | Rat | Acute toxicity to mammals | NOEL = 0.0025 mg a.s/kg bw/day  - | **LD50 = 1.31 mg a.s/kg bw**  **LC50=26 mg a.s/kg food** | CAR a.s.  Doc. III‑A 6.1.1 |
| OECD 409 | Rabbit | Repeated dose toxicity 90 days | **NO(A)EL=0.0005 mg a.s/kg bw/day**  **NOEC= (0.0005\*33.3)=0.017 mg a.s/kg food** | - | CAR a.s.Doc.III-A 6.4.1 |

##### Primary 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 as stated in the CAR of bromadiolone (owned by the Task Force).

**For mammals** the acute toxicity to rat: **LD50 = 1.31 mg a.s. /kg bw** is the lowest value for acute toxicity.

Additional endpoints:

The LD50 value for mammals from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LD50 = 0.56-0.84 mg a.s. /kg bw** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative risk assessment for comparisons with estimated daily uptakes of bromadiolone (ETE, mg a.s. /kg bw).

**For birds** the acute toxicity to Japanese quail: **LD50 = 134 mg a.s. /kg bw** is used in the qualitative assessment for comparisons with estimated daily uptakes of bromadiolone (ETE, mg a.s. /kg bw).

Additional endpoints:

No additional endpoints were used for birds.

Long-term quantitative assessment

For mammals, the most sensitive organism is the rabbit in the 90 days subchronic test with a NO(A)EL of 0.0005 mg/kg bw. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 33.3, and the AForal of 90 is applied to this NOEC, which results in a

**PNECoral for mammals = 0.0005/90 = 0.0000056 mg/kg bw/day**

**equivalent to**

**PNECoral for mammals =** 0.017/90 = **0.00019 mg/kg food**

For birds the PNECoral was determined by the NOEC value calculated from the 42-day reproduction test. According to the TGD section 3.8.3.5, the NOEC value is divided by an assessment factor of 30 which results in a:

**PNECoral for birds (dose) = 0.039/30 =** **0.0013 mg/kg bw/ day**

**equivalent to**

**PNECoral for birds (conc. In food) = 0.26/30 = 0.0087 mg/L drinking water**

Additional endpoints:

The PNEC values for bird from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECoral for birds (dose) = 0.00038 mg/kg bw/ day** (equivalent to PNECoral for birds (conc. in food) =0.0033 mg/kg food) than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Subsequently, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

##### 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 as stated in the CAR of bromadiolone (owned by the Task Force).

**For mammals** the acute toxicity to rat:LD50 = 1.31 mg a.s. /kg bw recalculated into **LC50 = 26 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the TGD II is the lowest value for the acute toxicity.

Additional endpoints:

The recalculated LC50 value for mammals from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LC50 = 11.2-16.8 mg a.s. /kg food** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative assessment for comparisons with estimated daily uptakes of bromadiolone (PEC mg a.s. /kg food).

**For birds** the acute toxicity to Japanese quail: LD50 = 134 mg a.s. /kg bw recalculated into **LC50 = 1070 mg/kg food**, using equation 77 in the TGD II and the conversion factor bw/dfi of 8 (domestic hen) from table 22 in the TGD II is the lowest value for the acute toxicity.

Additional endpoints:

The recalculated LC50 value for birds from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **LC50 = 207 mg a.s. /kg food** than the value used in the final CA of bromadiolone of the notifier Task Force. Therefore, as the data set are considered equivalent, the worst case value from the other notifier final CAR is used in the qualitative risk assessment for comparisons with estimated daily uptakes of bromadiolone (PEC mg a.s. /kg food).

These recalculations were considered acceptable in the CAR of bromadiolone owned by the Task Force.

Long-term quantitative assessment

For mammals, the most sensitive organism is the rabbit in the 90 days subchronic test with a NO(A)EL of 0.0005 mg/kg bw. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 33.3, and the AForal of 90 is applied to this NOEC, which results in a

**PNECoral for mammals = 0.017/90 = 0.00019 mg/kg food**

**equivalent to PNECoral for mammals = 0.0005/90 = 0.0000056 mg/kg bw/day**

For birds the PNECoral was determined by the NOEC value calculated from the 42-day reproduction test. According to the TGD section 3.8.3.5, the NOEC value is divided by an assessment factor of 30 which results in a

**PNECoral for birds = 0.26/30 =** **0.0087 mg/L drinking water**

**equivalent to PNECoral for birds = 0.039/30 = 0.0013 mg/kg bw/ day**

Additional endpoints:

The PNEC values for bird for secondary poisoning from the final CA report of another notifier of bromadiolone (LiphaTech S.A.S, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, March 2008) is lower: **PNECoral for birds = 0.00075 mg/kg food (**equivalent to PNECoral for birds = 0.00019 mg/kg bw/day) than the PNEC derived in the final CA of bromadiolone of the notifier Task Force. Subsequently, the worst case PNEC from the other notifier final CAR is used in the risk assessment.

#### Summary of PNECs of the active substance bromadiolone

Table 2.8.2.5: Summary of the bromadiolone (a.s.) PNECs used for risk assessment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Compartment** | | **Test Value** | **AF** | **PNEC** | **CAR** |
| Aquatic | PNECwater | LC50 =0.17 mg a.s. /L | 10 and 1000 | 1.7 × 10-5mg a.s. /L | LT |
| PNECsediment | Not available |  | 0.83 mg a.s. /kg ww sediment (Equilibrium partioning Method) | TF |
| PNECSTP | EC50 = 31.6 mg a.s. /L | 100 | 0.32 mg a.s. /L | LT |
| Terrestrial | PNECsoil | LC50 >8.4 mg a.s. /kg ww soil | 1000 | 0.0084 mg a.s. /kg ww soil | LT |
| Primary and secondary poisoning | PNECoral for birds | NOEC = 0.1 mg/kg food  NOEL = 0.01138 mg/kg bw/day | 30 | 0.0033 mg a.s. /kg food  0.00038 mg/kg bw/day | LT |
| PNECoral for mammals | NO(A)EL=0.0005 mg a.s/kg bw/day  NOEC= (0.0005\*33.3)=0.017 mg a.s/kg food  Rabbit repeated dose toxicity 90 days | 90 | 0.00019 mg/kg food  0.0000056 mg/kg bw/day | TF |

PNEC values from the final CA report of other notifier of bromadiolone are indicated when they represent worst-case value in comparison with the PNEC values presented in the CA report of the notifier Task Force.

**The lowest PNEC values is used in the risk assessment.**

#### PBT and ED assessment

Due to the properties of persistence, of toxicity and to uncertainties with regard to the B-criterion, the substance bromadiolone is considered as a potential PBT.

According to the CAR of the notifier Task Force, the active substance bromadiolone is not an endocrine disruptor.

### Effects on environmental organisms for biocidal product FAAR BLE

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product FAAR BLE. So all the effects assessment is based on the data obtained from the active substance bromadiolone (Task Force, Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Bromadiolone CAS 28772-56-7, Product Type 14 (Rodenticides), RMS Sweden, April 2011).

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 in the concentration used in the product FAAR BLE, the substance does not contribute to the classification of the biocidal product.

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

##### Aquatic organisms

Refers to section 2.8.2.1

##### Sediment dwelling organisms

Refers to section 2.8.2.1

##### STP micro-organisms

Refers to section 2.8.2.1

#### Atmosphere

Refers to section 2.8.2.2

#### Terrestrial compartment

Refers to section 2.8.2.3

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

Refers to section 2.8.2.4

#### Summary of PNECs

##### Refers to section 2.8.2.5

#### Assessment of exposure in the environment

As the product contains no substances of concern, it is considered that risks posed to environment following the use of FAAR BLE can adequately be assessed based on the evaluation conducted for the active substance. Therefore the exposure assessment is based on the data obtained from the active substance bromadiolone only.

The product FAAR BLE is a ready-to-use rodenticidal bait containing 0.005% bromadiolone. The product is constituted by cereal grains supplied in sachet or in bulk for professional and non professional users. The product is used as 40 g for mouse and 200 g for rat / bait point. The impregnated grains are placed in secured bait stations. According to the applicant, the product is intended to be used in bait boxes or bait stations inside domestic, industrial, and farm buildings. Baits are placed in secured bait point and refilled 4 times over 28 days. Dead rodents and unconsumed baits are removed each week.

As the product is applied indoor only, no environmental compartment is exposed to FAAR BLE. Nevertheless primary and secondary poisoning cannot be excluded. Indeed, pets living in treated buildings could be exposed directly to the product. Moreover even if the product is applied inside buildings, rats can live some days before dying. Therefore, they have the time to escape outside buildings and to be eaten by predators.

Primary and secondary poisoning calculations were carried out considering the ‘in and around buildings’ scenario from the EUBEES ESD PT14 as a worst case scenario in view of the fact that the product is applied inside buildings only.

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

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for indoor application of liquid poisons, residues from mixing and cleaning (ESD PT14). As FAAR BLE is a solid form and is intended to be used indoor only, indirect or direct exposure of the aquatic compartment may be considered negligible.

#### Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 1x10-7 Pa and low Henry’s law constant), bromadiolone is not expected to be present in the atmosphere in significant quantities. The exposure of air is therefore considered negligible for the application of FAAR BLE biocidal product.

#### Terrestrial compartment

As FAAR BLE is intended to be used indoor only, no exposure to soil and groundwater is expected.

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

##### Primary poisoning

As stated in the ESD (Larsen, 2003), primary poisoning hazard to mammals and birds (both wild and domestic) can be considered small when rodenticides are applied according to the label instructions. In the scenario “in and around buildings” when the product is placed in protected bait point, the risk for primary poisoning is mainly for birds and mammals of equal size or smaller as the target rodents, which may be able to enter into the bait stations. Another exposure of non-target animals may arise when target rodents carry bait away from bait stations.

Worst case exposure estimations are based on the equations and default values proposed by the ESD (Larsen, 2003). Some defaults parameters may be replaced by product-specific properties.

**Primary poisoning - Tier 1 assessment**

The Tier 1 assessment assumes that the whole day’s food requirement is satisfied by consumption of bait grains and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 50 mg.kg-1 (0.005% w/w of bromadiolone in FAAR BLE).

Hence, **the worst case Tier 1 PECoral is 50 mg.kg-1**.

**Primary poisoning - Tier 2 assessment, acute**

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

ETE = (FIR/BW) \* C \* AV \* PT \* PD (mg.kg-1bw.d-1); with

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 (-) and

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

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

Table 2.8.4.5‑1: Expected concentrations of bromadiolone in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **BW = Typical bodyweight (g)a** | **FIR = Daily mean food intake (g dry weight.day-1)** | **C = Concentration of bromadiolone in bait (mg.kg-1)** | **ETE, conc. of bromadiolone after one meal (mg.kg-1 bw.d-1)** | |
|  |  |  |  | Step 1 | Step 2 |
| Dog | 10 000 | 456b | 50 | 2.28 | 1.64 |
| Pig | 80 000 | 600a | 50 | 0.38 | 0.27 |
| Pig young | 25 000 | 600 a | 50 | 1.20 | 0.86 |
| Tree sparrow | 22 | 7.6 a | 50 | 17.27 | 12.44 |
| Chaffinch | 21.4 | 6.42 a | 50 | 15.00 | 10.80 |
| Wood pigeon | 490 | 53.1 a | 50 | 5.42 | 3.90 |
| Pheasant | 953 | 102.7 a | 50 | 5.39 | 3.88 |

a From EUBEES 2, Table 3.1, section 3.2.1

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

**Primary poisoning - Tier 2 assessment, long-term**

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

EC = ETE\*(1-El)

According to the ESD, 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 bromadiolone in non-target animals in primary poisoning scenarios after one meal followed by 24 hour elimination period.

Table 2.8.4.5‑2: Expected concentrations of bromadiolone in non-target animals in realistic worst case (Step 2) for long-term situation

|  |  |
| --- | --- |
| **Non-target animal** | **EC, conc. of bromadiolone after one day of elimination (mg.kg-1 bw)** |
|  | **Step 2** |
| Dog | 1.15 |
| Pig | 0.19 |
| Pig young | 0.60 |
| Tree sparrow | 8.71 |
| Chaffinch | 7.56 |
| Wood pigeon | 2.73 |
| Pheasant | 2.72 |

##### Secondary poisoning

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

As no exposure of the aquatic compartment is foreseen with the use of FAAR BLE inside buildings, no risk assessment for secondary poisoning through the aquatic food chain is required.

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

As no exposure of the terrestrial compartment is foreseen with the use of FAAR BLE inside buildings, no risk assessment for secondary poisoning through the terrestrial food chain is needed.

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

According to the ESD (Larsen, 2003) document, for uses ‘in and around buildings’ 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 bromadiolone 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.kg-1 bw.day-1)

This equation gives the concentration of bromadiolone 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:

ECn = Σ n-1 ETE \* (1-El)n

For the active substance bromadiolone, the default value of 0.3 is used for elimination (El) in accordance with the CAR of bromadiolone from the Bromadiolone Task Force.

Table 2.8.4.5‑3: Residues of bromadiolone in target animals at specific point in times and varying bait consumption

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Residues in target animal (mg.kg-1bw)** | | |
| **20%** | **50%** | **100%** |
| Day 1 after the first meal | 1.0 | 2.5 | 5.0 |
| Day 2 before new meal | 0.7 | 1.8 | 3.5 |
| **Day 5 after the last meal** | **2.8** | **6.9** | **13.9** |
| Day 7 mean time to death | 1.4 | 3.4 | 6.8 |

According to the ESD, the concentrations of bromadiolone 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 to birds and mammals, the PEC in rodents after 5 days is used considering that the consumption of rodenticides makes up 100 % of total consumptions (refer to Table 2.8.4.5‑3).

Table 2.8.4.5‑4: Residues of bromadiolone in target animals at specific point in times and varying bait consumption used in the long term assessment

|  |  |
| --- | --- |
|  | **PECoral**  **Bromadiolone conc. in target rodent (mg.kg-1 bw),**  **ESD default values** |
| Birds | 13.9 |
| Mammals | 13.9 |

**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 or a bird of prey after a single day of exposure presented as an illustrative example in the ESD, as no specific values were reported in the final CAR of bromadiolone from the Bromadiolone Task Force.

The amount of a.i. consumed by the non-target animal is 13.9 mg.kg-1 bw for rodents caught on day 5 and 16.6 mg.kg-1 bw for resistant 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 2.8.4.5‑5.

Table 2.8.4.5‑5: Expected concentrations of bromadiolone in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of bromadiolone in rodenticide bait 0.005%). 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. consumed by non-target animal (mg)** | **Conc.in non-target animal (mg.kg-1)** | **Amount a.i. consumed by non-target animal (mg)** | **Conc.in non-target animal (mg.kg-1)** |
| Barn owl  *(Tyto alba)* | 295 | 72.9 | 0.51 | 1.7 | 0.60 | 2.1 |
| Kestrel  *(Falco tinnunculus)* | 209 | 78.7 | 0.55 | 2.6 | 0.65 | 3.1 |
| Little owl  *(Athene noctua)* | 164 | 46.4 | 0.32 | 2.0 | 0.38 | 2.3 |
| Tawny owl  *(Strix aluco)* | 426 | 97.1 | 0.67 | 1.6 | 0.80 | 1.9 |
| Fox  *(Vulpes vulpes)* | 5700 | 520.2 | 3.61 | 0.6 | 4.31 | 0.8 |
| Polecat  *(Mustela putorius)* | 689 | 130.9 | 0.91 | 1.3 | 1.08 | 1.6 |
| Stoat  *(Mustela erminea)* | 205 | 55.7 | 0.39 | 1.9 | 0.46 | 2.3 |
| Weasel  *(Mustela nivlis)* | 63 | 24.7 | 0.17 | 2.7 | 0.20 | 3.3 |

### 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 (TGD, 2003) and 'Emission scenario document for biocides used as rodenticides' (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for bromadiolone.

#### Primary poisoning

**Tier 1 assessment**

The PEC value for Tier 1 assessment is compared to the long-term PNECs for birds and mammals. The PNECoral birds and mammals from the final CAR of the notifier Task Force represent the worst case value in comparison with values presented in final CAR from other notifier so they are used in the risk assessment.

Table 2.8.5.1‑1: Tier 1 risk characterization of primary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PEC**  **(conc. of bromadiolone in food (mg.kg-1))** | **PNEC**  **(conc. of bromadiolone in food (mg.kg-1))** | **PEC /PNEC** |
| Long-term | | | |
| Birds | 50 | 0.0033 mg/kg | 15152 |
| Mammals | 50 | 0.00019 mg/kg | 263000 |

The resulting PEC/PNEC ratios reveal a high risk for both birds and mammals of long-term primary poisoning.

**Tier 2 assessment, acute**

For the acute situation of primary poisoning only a qualitative risk assessment is carried out in accordance with the decision from TM III-06.

For the Tier 2 acute qualitative assessment, the PEC values are compared to the LD50 values in the table.

The worst case LD50 values between the final CAR from the notifier Task Force (TF) and from the notifier Liphatec S.A.S. (LT) are used for the qualitative risk assessment.

Table 2.8.5.1‑2: Tier 2 acute qualitative risk characterization of primary poisoning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **PECoral = ETE, conc. of bormadiolone after one meal (mg.kg-1)** | | **LD50 dose**  **(mg.kg-1 bw d-1)** | **PEC oral higher than LD50**  **(y/n)** | |
|  | Step 1 | Step 2 |  | Step 1 | Step 2 |
| Dog | 2.28 | 1.64 | 1.3 (TF) | **y** | **y** |
| Pig | 0.38 | 0.27 | 0.56-0.84 (LT) | n | n |
| Pig young | 1.20 | 0.86 | 0.56-0.84 (LT) | **y** | **y** |
| Tree sparrow | 17.27 | 12.44 | 134 (TF) | n | n |
| Chaffinch | 15.00 | 10.80 | 134 (TF) | n | n |
| Wood pigeon | 5.42 | 3.90 | 134 (TF) | n | n |
| Pheasant | 5.39 | 3.88 | 134 (TF) | n | n |

This comparison indicates that birds are not at risk for acute primary poisoning; while the situation for mammals is more uncertain. Dogs are at risk and pigs are at not at risk but very close to being at risk.

**Tier 2 assessment, long-term**

The PEC values are compared to the worst case PNEC value between the final CAR from the notifier Task Force (TF) and from the notifier Liphatec S.A.S. (LT).

Table 2.8.5.1‑3: Tier 2 long-term risk characterization of primary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target animal** | **PECoral = EC, conc. of bormadiolone after one day of elimination (mg.kg-1)**  **Step 2** | **PNEC**  **(mg.kg-1 bw.d-1)** | **PEC /PNEC**  **Step 2** |
| Dog | 1.15 | 0.0000056 (TF) | 205 000 |
| Pig | 0.19 | 0.0000056 (TF) | 33 900 |
| Pig young | 0.60 | 0.0000056 (TF) | 107 000 |
| Tree sparrow | 8.71 | 0.00038 (LT) | 22 909 |
| Chaffinch | 7.56 | 0.00038 (LT) | 19 895 |
| Wood pigeon | 2.73 | 0.00038 (LT) | 7 186 |
| Pheasant | 2.72 | 0.00038 (LT) | 7 147 |

Very high risk of primary poisoning at long-term are identified for both birds and mammals.

The risk characterisation indicates a very high risk to non-target mammals and birds from direct eating of bait. Primary poisoning incidents can be minimised by preventing the access of non-target animals to the baits. It is assumed in the ESD that if the rodenticide baits are used according to the label instructions, the risk for primary poisoning is negligible. However, it is stated at the EU level that it may not be possible to exclude exposure of all non-target animals, as the baits have to be accessible to target rodents, they may as well be accessible to non-target mammals and birds of equal or smaller size than the target rodents.

Nevertheless, as the product FAAR BLE is intended to be used indoor and in bait stations only, primary poisoning can therefore be considered negligible as domestic animals can be kept away from the product, and wild animals other than rats and mice are not expected to be found inside buildings.

#### Secondary poisoning

The only relevant scenario of secondary poisoning in the case of an indoor application only is for the rodent-eating mammal or bird.

**Tier 1 assessment, acute**

The PECoral are compared to the LC50 values presented in the section above for qualitative risk assessment in accordance with the decisions taken at the TMIII-06. The worst case LC50 values between the final CAR from the notifier Task Force (TF) and from the notifier Liphatec S.A.S. (LT) are used for the qualitative risk assessment.

Table 2.8.5.2‑1: Tier 1 acute qualitative risk assessment of secondary poisoning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  **Expected concentration in rodent (mg.kg-1) caught on day 5 after meal** | | | **LC50 dose**  **(mg.kg-1 food)** | **PEC oral higher than LD50**  **(y/n)** |
|  | PD=0.2 | PD=0.5 | PD=1 |  | PD=0.2;0.5 and 1 |
| Birds | 2.8 | 6.9 | 13.9 | 207 (LT) | n |
| Mammals | 2.8 | 6.9 | 13.9 | 11.2-16.8 (LT) | n |

This qualitative risk assessment indicates no risk for birds and mammals in acute situations.

**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. The worst case PNEC values between the final CAR from the notifier Task Force (TF) and from the notifier Liphatec S.A.S. (LT) are used for the qualitative risk assessment.

Table 2.8.5.2‑2: Tier 1 long-term risk assessment of secondary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-target animal** | **PECoral**  **Expected concentration in rodent (mg.kg-1) caught on day 5 after meal** | **PNECoral**  **(mg/kg food)** | **PEC /PNEC** |
|  | PD=1 |  | PD=1 |
| Birds | 13.9 | 0.00075 (LT) | 18 500 |
| Mammals | 13.9 | 0.00019 (TF) | 73 200 |

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

**Tier 2 assessment, long-term**

Table 2.8.5.2‑3: 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)* | 1.7 | 2.1 | 0.00019 (LT) | 9 070 | 10 832 |
| Kestrel *(Falco tinnunculus)* | 2.6 | 3.1 | 0.00019 (LT) | 13 776 | 16 447 |
| Little owl *(Athene noctua)* | 2.0 | 2.3 | 0.00019 (LT) | 10 349 | 12 359 |
| Tawny owl *(Strix aluco)* | 1.6 | 1.9 | 0.00019 (LT) | 8 338 | 9 957 |
| Fox *(Vulpes vulpes)* | 0.6 | 0.8 | 0.0000056 (TF) | 110 000 | 140 000 |
| Polecat *(Mustela putorius)* | 1.3 | 1.6 | 0.0000056 (TF) | 180 000 | 290 000 |
| Stoat *(Mustela erminea)* | 1.9 | 2.3 | 0.0000056 (TF) | 340 000 | 410 000 |
| Weasel *(Mustela nivlis)* | 2.7 | 3.3 | 0.0000056 (TF) | 480 000 | 590 000 |

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

It is stated in the final assessment report for bromadiolone of the notifier Task Force, that comparison with monitoring data from the literature indicates that the very high risks of secondary poisoning emerging from the calculations according to the ESD are confirmed.

However, considering the fact that FAAR BLE is intended to be used indoor only, it can be assumed that, applying use restrictions (such as collecting dead rodents), the risk for secondary poisoning will be lower.

Nevertheless, in order to reduce the risk of secondary poisoning, it is very important to follow the use instructions of the rodenticide baits. The risk reduction measures are considered in the section 2.9.

#### Conclusion of the risk assessment for the environment

No studies were conducted with the product FAAR BLE for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of bromadiolone. The environmental risk is considered as limited for the indoor use 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.

***Measures to protect environment***

* Dispose of the tamper-resistant bait boxes and covered bait stations, uneaten baits and dead rodents in accordance with local requirements.
* Never wash the tamper-resistant bait boxes and covered bait stations with water.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* For professional users, covered bait stations could be used. These stations must be placed only in areas not accessible to the general public and non-target animals.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Remove all bait points after the end of treatment.
* **Renewal (2017):**

No new ecotoxicological information has been submitted at the renewal of the approval of the active substance bromadiolone and in the product dossier

Therefore, the conclusion of the environmental risk assessment remains unchanged.

The environmental risk is considered as acceptable for the intended uses except for the primary and secondary poisoning. The specific use restriction must be applied to reduce the risk for primary and secondary poisoning

## Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC).*

# PROPOSAL FOR DECISION: MINOR CHANGE (2021)

**Summary of Product Characteristics**

## 1. Administrative information

### Trade name(s) of the product

| **Trade name(s)** |  |
| --- | --- |
| BROMAFAR |  |

### 1.2. Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SOFAR |
| **Address** | ZA DU DREVERS BP02  29190 PLEYBEN  France |
| **Authorisation number** |  | |
| **R4BP asset reference number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | SOFAR |
| **Address of manufacturer** | ZA DU DREVERS BP02  29190 PLEYBEN  France |
| **Location of manufacturing sites** | ZA DU DREVERS BP02  29190 PLEYBEN  France |

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

|  |  |
| --- | --- |
| **Active substance** | Bromadiolone |
| **Name of manufacturer** | PM TEZZA SRL |
| **Address of manufacturer** | Via tre ponti 22 37050 S. MARIA DI ZEVIO (VR)  Italy |
| **Location of manufacturing sites** | Via tre ponti 22 37050 S. MARIA DI ZEVIO (VR)  Italy |

## Product composition and formulation

### Qualitative and quantitative information on the composition of the product

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Bromadiolone | 3-[3-(4'-Bromo[1,1'- biphenyl]-4-yl)-3-hydroxy- 1-phenylpropyl]-4- hydroxy-2H-1- benzopyran-2-one | Active substance | 28772-56-7 | 249-205-9 | 0.005 |

### Type of formulation

|  |
| --- |
| Grain bait, ready to use |

## Hazard and precautionary statements according to Regulation (EC) 1272/2008

| **Classification** | |
| --- | --- |
| Hazard category | Repr. 1B  STOT RE 1 |
| Hazard statement | H360D: May damage the unborn child  H372; Causes damage to organs (blood) through prolonged or repeated exposure |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H360D: May damage the unborn child  H372; Causes damage to organs (blood) through prolonged or repeated exposure |
| Precautionary statements | P201: Obtain special instructions before use  P202: Do not handle until all safety precautions have been read and understood.  P260 Do not breathe dust  P264: Wash … thoroughly after handling  P270: Do not eat, drink or smoke when using this product  P280: Wear protective gloves/protective clothing/eye protection/face protection  P308 + P313: IF exposed or concerned: Get medical advice/ attention.  P314 Get Medical advice/attention if you feel unwell.  P405: Store locked up  P501 Dispose of contents/container in accordance with national regulations |
|  | |
| Note |  |

## Authorised use(s)

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations[[14]](#footnote-14)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Rats (*Rattus norvegicus* & *Rattus rattus*):   * High infestation: 200 g of bait per bait station separated by 5 meters. * Low infestation: 200 g of bait per bait station separated by 10 meters.   House mice (*Mus musculus*):   * High infestation: 40 g of bait per bait station separated by 1 meter.. * Low infestation: 40 g of bait per bait station separated by 2 meters. |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  Package is restricted to separately packed bags with a maximum of 10 kg per packed bag for loose grain baits.  PE sachets (25-100g) are packed in:   * Bags (paper/PE) (5-10-15-20-25 kg) * Bucket (PE) (5-20-25 kg) * Carton box (carton) (5-20-50 kg) * Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg)   Loose baits are packed in:   * Bags (paper/PE) (5-10 kg) * Bucket (PE) (5-10 kg) * Carton box (carton) (5-10 kg) |

### Use-specific instructions for use

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

### 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. |

### 4.1.4 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 # 2 (not relevant in France) – House mice – professionals – indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations[[15]](#footnote-15)  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | House mice (*Mus musculus*): 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 meter. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  PE sachets (25-100g) are packed in:   * Bags (paper/PE) (5-10-15-20-25 kg) * Bucket (PE) (5-20-25 kg) * Carton box (carton) (5-20-50 kg) * Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg)   Loose baits are packed in:   * Bags (paper/PE) (5-10 kg) * Bucket (PE) (5-10 kg) * Carton box (carton) (5-10 kg) |

### Use-specific instructions for use

|  |
| --- |
| - The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

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

### 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 # 3 (not relevant in France) – Rats – professionals – indoor

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Rats (*Rattus norvegicus* & *Rattus rattus*): 200 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  PE sachets (25-100g) are packed in:   * Bags (paper/PE) (5-10-15-20-25 kg) * Bucket (PE) (5-20-25 kg) * Carton box (carton) (5-20-50 kg) * Metal box in electrolytic tinplate (without lacquer) (0.1-0.2-0.3-0.4-0.5-0.6-0.7-0.8-0.9-1.0-1.1-1.2-1.3-1.4-1.5 kg)   Loose baits are packed in:   * Bags (paper/PE) (5-10 kg) * Bucket (PE) (5-10 kg) * Carton box (carton) (5-10 kg) |

### Use-specific instructions for use

|  |
| --- |
| - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

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

### 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

|  |
| --- |
|  |

## General directions for use

### Instructions for use

|  |
| --- |
| - 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.  - Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  ***FOR TRAINED PROFESSIONAL ONLY****- The* frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.  ***FOR PROFESSIONNALS ONLY*** Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  ***FOR PROFESSIONNALS ONLY*** Remove the remaining bait or the bait stations at the end of the treatment period.  *Instructions for use that are "bait-specific":*   * *Bait in sachets: [For non-emptiable sachets - Do not open the sachets containing the bait]*. * *Loose pellets-granules, grains: Place the bait in the baiting point by using a dosage devise. Specify the methods to minimise dust (e.g. wet wiping).* * *Loose pellets-granules, grains: Decanting is to be avoided. In case decanting cannot be avoided, an RPE of APF 10 has to be used.* |

### Risk mitigation measures

|  |
| --- |
| - 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  - ***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).*.*  - ***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. |

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

|  |
| --- |
| - This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.  - 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”  - Hazardous to wildlife. |

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

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

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

|  |
| --- |
| - Shelf life: 2 years.  - Do not store biocide product above 30°C  - Keep away from light.  - Store in places prevented from the access of children, birds, pets and farm animals. |

## Other information(s)

|  |
| --- |
| * 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. |

Annex 2: List of studies reviewed

***List of new data******[[16]](#footnote-16) submitted in support of the evaluation of the active substance – initial PAR 2012***

*No new data have been submitted in support of the evaluation of the active substance*

***List of new data submitted in support of the evaluation of the biocidal product – initial PAR 2012, updated 2017***

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| B3 | B3.2 B3.4, B3.6 | Demangel B | 2011 | PhPhysico chemical tests on FAAR BLE DEFITRACES, Report n° 10-920010-035 of 24 February 2011, GLP, unpublished. | Triplan |  |  |  |  |
| B3 | B3.1, B3.5, B3.7, B3.12 | Demangel B | 2011 | PhPhysico-chemical tests before and after an accelerated storage procedure for 14 days at 54 ± 2°C on FAAR BLE. DEFITRACES, Report n° 10-920010-036 amended of 16 June 2011, GLP, unpublished. | Triplan |  |  |  |  |
| B3 | B3.2 | Demangel B | 2011 | Explosive properties of solids on FAAR BLE in compliance with Commission Directive EEC, Commission Regulation (EC) n° 440/2008 – EC A14 method (2008). DEFITRACES, Report n° 11-920010-004 of 24 May 2011, GLP, unpublished. | Triplan |  |  |  |  |
| B3 | B 3.7 | Demangel B. | 2012 | Determination of bromadiolone content before and after an accelerated storage procedure for 8 weeks at 40 ± 2 °C in FAAR BLE (BATCH 21/11 E) In | Triplan |  |  |  |  |
|  |  |  |  | compliance with CIPAC MT 46.3 (CIPAC Handbook J - 2000). DEFITRACES Report n° 11-920010-023 of 22 February 2012. |  |  |  |  |  |
| B3 | B 3.8 | Ferron N. | 2012 | Physico chemical tests on FAAR BLE. DEFITRACES, report 12-920010-001 of 18 May 2012, GLP, non published. | Triplan |  |  |  |  |
| B4 | B4.1.1 | Ricau H | 2011 | Analytical method validation for the determination of bromadiolone in the FAAR BLOC SP in compliance with SANCO/3030/99 rev. 4 from 11/07/00.DEFITRACES, Report 10-920010-042 of 11 February 2011, GLP (unpublished). | Triplan |  |  |  |  |
| B5 | XXX | XXX | 2011 | Efficacy laboratory study of FAAR BLE rodenticide containing 0.005% bromadiolone with albino house mice (*Mus musculus*). XXX | **Triplan** |  |  |  |  |
| B5 | XXX | XXX | 2011 | Efficacy field study of FAAR BLE rodenticide containing 0.005% bromadiolone with black rats *(Rattus rattus),* XXX | **Triplan** |  |  |  |  |
| B5 | B5.10.2.1 | XXX | 2011 | Efficacy laboratory study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone with albino house mice (Mus musculus) XXX | **Triplan** |  |  |  |  |
| B5 | B5.10.2.2 | XXX | 2011 | Efficacy field study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone with brown rats (Rattus norvegicus). XXX | **Triplan** |  |  |  |  |
| B5 | B5.10.2.1/01 | XXX | 2011 | Efficacy laboratory study of the rodenticide FAAR AVOINE containing 0.005% bromadiolone with albino house mice (Mus musculus). XXX | **Triplan** |  |  |  |  |
| B5 | B5.10.2.1/02 | XXX | 2011 | Efficacy field study of FAAR AVOINE rodenticide containing 0.005% bromadiolone and 0.001% denatonium benzoate with wild mice (Mus musculus),  XXX | **Triplan** |  |  |  |  |
| B6 | B6.1.1 | XXX | 2011 | FAAR BLOC SP evaluation of acute oral toxicity in rats – acute toxic class method.  XXX | Triplan |  |  |  |  |
| B6 | B6.1.2 | XXX | 2011 | FAAR BLOC SP assessment of acute dermal toxicity in rats.  XXX | Triplan |  |  |  |  |
| B6 | B6.2.1 | XXX | 2011 | FAAR BLOC SP assessment of acute dermal irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IC-OCDE-PH-10/0422 of 19 April 2011, GLP (unpublished). | Triplan |  |  |  |  |
| B6 | B6.2.2 | XXX | 2011 | FAAR BLOC SP assessment of acute eye irritation. PHYCHER BIO DEVELOPPEMENT, study n°: IO-OCDE-PH-10/0422 of 19 April 2011, GLP (unpublished). | Triplan |  |  |  |  |
| B6 | B6.3 | XXX | 2011 | FAAR BLOC SP assessment of sensitizing properties on albino Guinea pigs, maximisation test according to Magnusson and Kligman.  XXX | Triplan |  |  |  |  |
| B6 | B6.4 | Colas S | 2011 | FAAR BLE evaluation of skin absorption: *in vitro* method (non GLP study). PHYCHER BIO-DEVELOPPEMENT, study n° AC-PH-10/0247-amended of 6 June 2011, non GLP (unpublished). | Triplan |  |  |  |  |

Annex 3 : Analytical methods residues – active substance – initial PAR 2012

**Bromadiolone**

Date: 2012

**Matrix, action levels, relevant residue and reference**

Summary taken from final CAR of task force of bromadiolone (2011):

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | HPLC-MS (LOQ 0.22 µg/kg)  LC-MS/MS (LOQ 0.01 mg/kg) |
| Air (principle of method and LOQ) | HPLC-UV (LOQ 0.5 µg/m3)  No confirmatory method available-not considered needed due to the low vapour pressure |
| Water (principle of method and LOQ) | HPLC-FD (LOQ 0.05 µg/l), HPLC-MS (LOQ 0.05 µg/l)  confirmation: LC-MS/MS |
| Body fluids and tissues (principle of method and LOQ) | LC-MS/MS (LOQs 0.05 mg/l blood, 0.05 mg/kg liver)  LC-MS/MS (LOQs 0.01 mg/l blood, 0.01 mg/kg liver) |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Multi residue method:  LC-MS/MS (LOQ 0.01 mg/kg cucumber and wheat)  Single method:  LC-MS/MS (LOQ 0.01 mg/kg lemon and oilseed rape) |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | LC-MS/MS (LOQ 0.01 mg/kg meat) |

**Methods suitable for the determination of residues (monitoring methods)**





Annex 4: Toxicology and metabolism –active substance – initial PAR 2012, updated 2017

**Bromadiolone**

Threshold Limits and other Values for Human Health Risk Assessment

* **Major change (2016):**

Date: 19.01.2016

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.0012 µg/kg/d | 90-day rabbit (Task force)  NOAEL = 0.5 µg/kg bw/day | 300\* |
| AEL medium-term | 0.0012 µg/kg/d | 90-day rabbit (Task force)  NOAEL = 0.5 µg/kg bw/day | 300\* |
| AEL acute | 0.0023 µg/kg/d | Developmental toxicity study rabbit (Task Force)  LOAEL = 2 µg/kg bw/day | 300\* |
| \*Adjusted for 70% oral absorption in rat (Task Force) | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 70% (Task Force) |
| Dermal absorption | 0.748% |

|  | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008)) | Acute tox. 1; H300, H310, H330  Repr. 1A; H360D  STOT RE 1; H372  Specific concentration limits  C ≥ 0.01% STOT RE 1; H372  0.001% ≤ C < 0.01% STOT RE 2; H373 |

A RAC opinion was adopted in march 2014.

* **Renewal (2017):**

| **Classification** with regard to toxicological data (according to the criteria in Reg. 1272/2008) | |
| --- | --- |
|  | Acute tox. 1; H300, H310, H330  Repr. 1B; H360D  STOT RE 1; H372 |
|  | Specific concentration limits  STOT RE 1; H372: C ≥ 0,005 %  STOT RE 2; H373: 0,0005 % ≤ C < 0,005 %  Repr. 1B; H360D: C ≥ 0,003 % |

**Annex 4 : Toxicology and metabolism –active substance, 2012, updated 2017**

**Bromadiolone**

Threshold Limits and other Values for Human Health Risk Assessment

* **First authorisation (2013):**

| **Summary** | | | | |
| --- | --- | --- | --- | --- |
|  | Value | | Study | SF |
| AEL long-term | 0.0012 µg/kg/d | | 90-day rabbit (Task force)  NOAEL = 0.5 µg/kg bw/day | 300\* |
| AEL medium-term | 0.0012 µg/kg/d | | 90-day rabbit (Task force)  NOAEL = 0.5 µg/kg bw/day | 300\* |
| AEL acute | 0.0023 µg/kg/d | | Developmental toxicity study rabbit (Task Force)  LOAEL = 2 µg/kg bw/day | 300\* |
| \*Adjusted for 70% oral absorption in rat (Task Force) | | | | |
| Inhalative absorption | | 100% | | |
| Oral absorption | | 70% (Task Force) | | |
| Dermal absorption | | 10% (based on MW (>500) and log Pow (>4)) | | |
| **Classification No harmonised classification is currently available** | | | | |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | | Proposed classification according to the criteria in directive 67/548/EEC:  T+; R26/27/28  T; R48/23/24/25  Repr. Cat. 1; R61  Specific concentration limits  C≥0.5% : T+;R61-26/27/28 - T; R48/23/24/25  0.25%≤C<0.5% :T+; R26/27/28 – T; R48/23/24/25  0.025%≤C<0.25% : T; R23/24/25 – T; R48/23/24/25  **0.0025%≤C<0.025% : Xn; R20/21/22 – R48/20/21/22** | | |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | | Proposed classification according to the CLP Regulation 1272/2008:  Acute tox. 1; H300, H310, H330  Repr. 1A; H360D  STOT RE 1; H372  Specific concentration limits  C≥0.01% STOT RE 1; H372  **0.001%≤C<0.01% STOT RE 2; H373** | | |

A classification proposal has been submitted to ECHA in August 2010

* **Renewal (2017):**

| **Classification (ATP9)** | |
| --- | --- |
|  | Acute tox. 1; H300, H310, H330  Repr. 1B; H360D  STOT RE 1; H372 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Specific concentration limits  STOT RE 1; H372: C ≥ 0,005 %  STOT RE 2; H373: 0,0005 % ≤ C < 0,005 %  Repr. 1B; H360D: C ≥ 0,003 % |

Annex 5 : Toxicology – biocidal product, 2012, updated 2017

**FAAR BLE**

|  |  |
| --- | --- |
| **General information** | |
| Formulation Type cereal grains |  |
| Active substance(s) (incl. content) 0.005% bromadiolone |  |
| Category |  |

| **Acute toxicity, irritancy and skin sensitisation of the preparation\* (Annex IIIB, point 6.1, 6.2, 6.3)** | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 420) | LD50>2000 mg/kg \* |  |  |  |
| Rat LD50 dermal (OECD 402) | LD50>2000 mg/kg\* |  |  |  |
| Rat LC50 inhalation (OECD 403) | No study submitted |  |  |  |
| Skin irritation (calculation rules according to Directive 1999/45/EC) | Non irritant |  |  |  |
| Eye irritation (OECD 405) | Non irritant \* |  |  |  |
| Skin sensitisation (calculation rules according to Directive 1999/45/EC)  \*read across from FAAR BLOC SP | Not 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 |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | None |  |  |  |
|  |  |  |  |  |
| Further toxicological information | None | | | |

|  |  |
| --- | --- |
| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
| Directive 1999/45/EC | Xn; R48/20/21/22 |
| Regulation 1272/2008/EC | STOT RE 2; H373 |

* **Major change (2016):**

Date: 19.01.2016

|  |  |
| --- | --- |
| General information | |
| Formulation Type | Cereal grains |
| Active substance(s) (incl. content) | 0.005% bromadiolone |
| Category | PT14 |

| Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3) | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 420) | LD50 > 2000 mg/kg \* |  |  |  |
| Rat LD50 dermal (OECD 402) | LD50 > 2000 mg/kg \* |  |  |  |
| Rat LC50 inhalation (OECD 403) | No study submitted |  |  |  |
| Skin irritation (OECD 404) | Non irritant |  |  |  |
| Eye irritation (OECD 405) | Non irritant\* |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | Not sensitizing |  |  |  |
| \*read across from FAAR BLOC SP |  |  |  |  |

| 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 |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | 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 | STOT RE 2; H373 |

* **Renewal (2017):**
* Renewal of authorisation : Repr. Cat. 1B; H360D STOT RE 1; H372

Annex 6 : Safety for professional operators - 2012, updated 2017

**FAAR BLE**

**Exposure assessment**

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

Exposure of professionals to the biocidal product containing bromadiolone as active substance is considered as acceptable provided the product is supplied in sachet and PPE are worn.

Primary exposure of professionals – FAAR BLE in bulk (exposure during decanting, loading and cleaning considered)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | | **Dermal internal exposure**  **[mg/kg/d]** | | | **Total exposure**  **[mg/kg/d]** | | **Model** |
| Rats | Mice | Rats | Mice | | Rats | Mice |
| Tier 1 (without PPE) | Bromadiolone | 28772-56-7 | 2.5x10-6 | 5.0x10-7 | 3.4x10-5 | | 1.9x10-5 | 3.7x10-5 | 2.0x10-5 | Cefic study |
| Tier 2 a (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | 2.5x10-6 | 5.0x10-7 | 3.4x10-6 | | 1.9x10-6 | 5.9x10-6 | 2.4x10-6 | Cefic study |
| Tier 2 b (gloves penetration factor: 5%) | Bromadiolone | 28772-56-7 | 2.5x10-6 | 5.0x10-7 | 1.7x10-6 | | 9.7x10-7 | 4.2x10-6 | 1.5x10-6 | Cefic study |

Primary exposure of professionals – FAAR BLE in sachet (exposure only during cleaning) – Control of rats and mice

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | **Dermal internal exposure**  **[mg/kg/d]** | **Total exposure**  **[mg/kg/d]** | **Model** |
| Tier 1 (without PPE) | Bromadiolone | 28772-56-7 | Not applicable | 5.1x10-6 | 5.1x10-6 | Cefic study |
| Tier 2 (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | Not applicable | 5.1x10-7 | 5.1x10-7 | Cefic study |

**Risk assessment**

**Control of rats**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| FAAR BLE in bulk | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 3.7x10-5 | 3048 | Unacceptable |
| Professional  (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 5.9x10-6 | 493 | Unacceptable |
| Professional  (gloves penetration factor: 5%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 4.2x10-6 | 351 | Unacceptable |
| FAAR BLE in sachet | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 5.1x10-6 | 421 | Unacceptable |
| Professional  (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 5.1x10-7 | 42 | Acceptable |

**Control of mice**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| FAAR BLE in bulk | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 2.0x10-5 | 1661 | Unacceptable |
| Professional  (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 2.4x10-6 | 204 | Unacceptable |
| Professional  (gloves penetration factor: 5%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 1.5x10-6 | 123 | Unacceptable |
| FAAR BLE in sachet | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 5.1x10-6 | 421 | Unacceptable |
| Professional  (gloves penetration factor: 10%) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 10 | 5.1x10-7 | 42 | Acceptable |

* **Minor change (2016):**

**Exposure assessment**

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

Exposure of professionals to the biocidal product containing bromadiolone as active substance is considered as acceptable with gloves and RPE when the product is supplied in bulk and without PPE when the product is supplied in sachet.

Primary exposure of professionals – FAAR AVOINE/FAAR BLE in bulk (exposure during decanting, loading and cleaning considered)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | | **Dermal internal exposure**  **[mg/kg/d]** | | | **Total exposure**  **[mg/kg/d]** | | **Model** |
| Rats | Mice | Rats | Mice | | Rats | Mice |
| Tier 1 (without PPE) | Bromadiolone | 28772-56-7 | 2.51x10-6 | 2.51x10-6 | 2.55x10-6 | | 1.45x10-6 | 5.05x10-6 | 3.96x10-6 | Cefic study |
| Tier 2 (gloves penetration factor: 5% + RPE) | Bromadiolone | 28772-56-7 | 2.51x10-7 | 2.51x10-7 | 1.27x10-7 | | 7.26x10-8 | 3.78x10-7 | 3.23x10-7 | Cefic study |

Primary exposure of professionals – FAAR AVOINE/FAAR BLE in sachet (exposure only during cleaning) – Control of rats and mice

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | **Dermal internal exposure**  **[mg/kg/d]** | **Total exposure**  **[mg/kg/d]** | **Model** |
| Tier 1 (without PPE) | Bromadiolone | 28772-56-7 | Not applicable | 3.78x10-7 | 3.78x10-7 | Cefic study |

**Risk assessment**

**Control of rats**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| FAAR AVOINE/FAAR BLE in bulk | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 5.05 x 10-6 | 421 | Unacceptable |
| Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 3.78 x 10-7 | 31 | **Acceptable** |
| FAAR AVOINE/FAAR BLE in sachet | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 3.78 x 10-7 | 31 | **Acceptable** |

**Control of mice**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d]** | | Risk |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| FAAR AVOINE/FAAR BLE in bulk | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 3.96x10-6 | 330 | Unacceptable |
| Professional (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 3.23x10-7 | 27 | **Acceptable** |
| FAAR AVOINE/FAAR BLE in sachet | | | | | | | | |
| Professional  (without gloves) | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 3.78 x 10-7 | 31 | **Acceptable** |

* **Renewal (2017):**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Inhalation exposure**  **(mg/kg bw/d)** | **Demal exposure**  **(mg/kg bw/d)** | **Total systemic exposure**  **(mg/kg bw/d)** |
| **Bulk formulation (exposure during decanting, loading and cleaning phases)** | | | |
| Tier 1 (without PPE) | 2,51 x 10-6 | 6,81 x 10-6 | 9.32 x 10-6 |
| Tier 2 (gloves penetration factor: 5% + RPE) | 2,51 x 10-6 | 3,41 x 10-7 | 5.91 x 10-7 |
| **Sachet formulation (exposure during cleaning phase)** | | | |
| Tier 1 (without PPE) | - | 1,01 x 10-6 | 1.01 x 10-6 |

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 decanting, loading and cleaning phases)** | | | | | |
| Tier 1  (without PPE) | 1.2 x 10-6 | 9.32 x 10-6 | | 777% | Unacceptable |
| Tier 2 (with gloves, penetration factor of 5 % and RPE, protection factor of 10) | 1.2 x 10-6 | 5.91 x 10-7 | | 49% | **Acceptable** |
| **Sachet formulation (exposure during cleaning phase)** | | | | | |
| Tier 1 (without PPE) | 1.2 x 10-6 | 1.01 x 10-6 | 84% | | **Acceptable** |

The conclusions of the risk assessment remain unchanged.

The RMMs required by the risk assessment remain also unchanged

Annex 7: Safety for non-professional operators and the general public, - 2012

**FAAR BLE**

* **Minor change (2014):**

**FAAR BLE**

| **General information** | |
| --- | --- |
| Formulation Type cereal grains |  |
| Active substance(s) (incl. content) 0.005% bromadiolone |  |
| Category |  |
| Authorisation number |  |

| **Bromadiolone** |
| --- |

| **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: non-professional use |  |
| Secondary exposure, acute: child ingesting bait |  |
| Secondary exposure, chronic: none |  |

Conclusion:

Exposure of non-professionals to the biocidal product containing bromadiolone as active substance is considered acceptable.

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 0.66 mg of product per day.

Details for the exposure estimates:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **Inhalation internal exposure**  **[mg/kg/d]** | **Dermal internal exposure**  **[mg/kg/d]** | **Total exposure**  **[mg/kg/d]** | **Model** |
| Control of rats and mice - Sachet considered (exposure only during cleaning) | | | | | | |
| Non professional | Bromadiolone | 28772-56-7 | Not applicable | 1.41x10-7 | 1.41x10-7 | Cefic study |

Risk assessment

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Total syst exposure**  **[mg/kg bw/d] [mg/m3]** | | **Risk** |
|  |  |  |  | inh | derm | Expo | %AEL |  |
| Control of rats and mice - Sachet considered (exposure only during cleaning) | | | | | | | | |
| Non-professional | Bromadiolone | 28772-56-7 | 1.2x10-6 | 100 | 0.748 | 1.41x10-7 | 12 | **Acceptable** |

* **Major change (2016):**

Date:19.01.2016

| General information | |
| --- | --- |
| Formulation Type | Cereal grains |
| Active substance(s) (incl. content) | 0.005% bromadiolone |
| Category | PT14 |
| Authorisation number |  |

| **Bromadiolone** |
| --- |

| 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 | Non-professional use |
| Secondary exposure, acute | Child ingesting bait |
| Secondary exposure, chronic | None |

Conclusion: *Please refer to the product assessment report related to FAAR BLE product authorisation (FR-2014-0020) under Regulation (UE) 528/2012.*

* **Renewal (2017):**

General public uses are no longer claimed for the renewal of authorisation.

Annex 8: Residue behaviour, 2012

**Bromadiolone**

The intended use descriptions of the product FAAR BLE indicate that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

* **Major change (2016):**

Date: 17.11.2015

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

**Active substance:** bromadiolone

**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 bromadiolone-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 9: Efficacy of the active substance from its use in the biocidal product - 2012, updated 2017

Efficacy data submitted at the first authorisation:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference\*** |
| Rodenticide | Control of rats and mice | FAAR BLE  0.005% bromadiolone | Albino house mice  (*Mus musculus)* | Laboratory  CEB n°1  Albino mice:  5 males and 5 females per lot  3 lots:  lot efficacy (no-choice food),  lot acceptance (free-choice food)  lot control animals.  Intoxication duration: 3 days with daily measurement of mortality and consumption. | Acclimation: 3 days in individual cage.  Room temperature was 22°C.  D0: food or bait biocidal product have been given:  - 30 g per animal of usual food for the controls,  - 20 g per animal of usual food + 20 g of bait for acceptance lot,  - 30 g per animal of bait for the efficacy lot,  during 3 consecutive days with daily consumption measurements.  Mortality was observed during 10 days from the first day of intoxication every 24 hours. At D10 all animals were dead. | The FAAR BLE bait containing 50 ppm bromadiolone given to albino house mice (5 males and 5 females per lot) during 3 days according to CEB n°1 protocol has demonstrated that:   * The overall average daily consumption within the free-choice food lot has been close to the control animals’ lot and that the bait has been overwhelmingly preferred to usual food (68.7 % to 87.3 % of the overall consumption during 3 days); * This overall daily consumption for the bait alone has been a little bit lower for the efficacy lot than for the controls’ one with a quick induction of the toxic effect at D2; * 100% efficacy has been reached for the both lots: from 6 to 10 days (average of 7.3 days) for acceptance and from 3 to 8 days (average of 5.6 days) for efficacy; * 0% mortality in the control animals lot.   Consequently an extrapolation to wild mice seems justified. | Barbieux S, Grolleau G, 2011, report SB-2011-003[[17]](#footnote-17) |
| Rodenticide | Control of rats and mice | FAAR BLE  0.005% bromadiolone | Black rat  (*Rattus rattus)* | Field study  CEB n° 2  The used method is relative and allows knowing the bait biocidal product efficacy on a rats ‘population without knowing the precise population size. | After habituation of an isolated wild population of black rats to their new environment, 34 stations were loaded with 500 g grains (used for pre- and post-baiting phases) and with 500 g baits for poisoning phase (8 days). The daily consumption was measured from day 28 to day 50. | The FAAR BLE bait containing 50 ppm bromadiolone given to wild black rats during 8 days according to CEB n°2 protocol has demonstrated that:  The efficacy was good (80.2%).   * Pre-baiting plateau = 5636.7 g * Post-baiting plateau = 1118.3g * Assessed efficacy = 80.2%   The number of dead rats right from the last days of poisoning and post-baiting has shown a good efficacy of the treatment. However the arrival of young rats consuming in bait stations has probably distorted the efficacy assessment (decrease in the 4th and 5th day of the post-baiting phase and increase of consumption in the 6th day of post-baiting stage).  Under practical conditions a professional would have gone on the poisoning to rid of young rats.  The assessed bait has been very well accepted by rats and effective and the results are coherent with laboratory ones. | Barbieux S, Grolleau G, 2011, report SB-2011-004[[18]](#footnote-18) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Rodenticide | Control of rats and mice | FAARBLOC SP  0.005% bromadiolone | Brown rat  (*Rattus norvegicus)* | Field study  CEB n° 2  The used method is relative and allows knowing the bait biocidal product efficacy on a rats’ population without knowing the precise population size.  Daily food consumptions are measured. | 46 empty bait stations have been placed at the beginning of the study (acclimation phase).  Pre-baiting phase: 750 g of grain were placed daily in each station.  Poisoning phase: 20 blocks of baits per day and per station during 8 days.  Post-baiting phase: 500g  of the pre-baiting grains per station and per day | A field study with brown rats conducted in pheasants aviaries (78125 Saint Hilarion) with a block containing 50 ppm bromadiolone (FAAR BLOC SP) has given excellent results:  - Pre-baiting stage: 23581.8 g  - Post-baiting stage: 1691.0g  within 8 days baiting.  **Assessed efficacy is 92.8 %.**  The field study with brown rats during 8 days of intoxication has given 92.8 % efficacy for a very large population (> 1000 individuals).  The acceptance of the product has not been assessed because the brown rats have visibly stored the bait blocks. But the excellent efficacy allowed estimating that baits have been well consumed.  The bait given in laboratory to albino house mice during 3 days had been well consumed with or without food choice and it had shown an excellent efficacy (cf. study SB-2011-002). | Barbieux S, Grolleau G. 2011. Report SB-2011-005[[19]](#footnote-19) |
| Rodenticide | Control of rats and mice | FAAR AVOINE  0.005% bromadiolone | Wild mice (*Mus musculus)* | Field trial  CEB n°2  The used method is relative and allows knowing the bait biocidal product efficacy on a wild mice population without knowing the precise population size. | After habituation of an isolated wild population of mice to their new environment, 18 stations were loaded with 50g or 100g grains per station (used for pre- and post-baiting phases) and with 50 g or 100g baits for poisoning phase (24 days). The daily consumption was measured from day 24/09 to day 03/10 then every 2 or 3 days from day 03/10 till the end of poisoning. | The FAAR AVOINE bait containing 50 ppm bromadiolone given to wild mice during 24 days according to CEB n°2 protocol has demonstrated that:  The efficacy was total (100%).   * Pre-baiting plateau = 286.25g * Post-baiting plateau = 0g * Assessed efficacy = 100%   The assessed bait has been very well accepted by mice and effective and the results are coherent with laboratory ones. | Barbieux S, Grolleau G, 2011, study 11-TOX-002[[20]](#footnote-20) |

* **Renewal (2017):**

Efficacy data requested for post authorisation with aged product (24 months) assessed at the renewal of FAAR BLE

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Test substance** | **Test organisms** | **Test system / Concentrations applied / exposure time** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference** |
| BMB50V1  0.005% bromadiolone  Aged 24 months | Brown rats (*Rattus norvegicus*) | Field study  EPPO PP1/114(2) | 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 | The trial was set up in an agricultural habitat (breeding stables for cows, 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 or outside 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 *census* 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 *census* baits during the Post-treatment phase).  According to the results of the present study, BMB50V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the *Rattus norvegicus* population present across the trial | ROVETTO I  Study: 2021.BCD.SAG15 |
| BMB50V1  0.005% bromadiolone  Aged 24 mois | House mice (*Mus musculus*) | Field study  EPPO PP1/114(2) | 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 2015-03-16 to 2015-04-26 | The trial was set up in an agricultural habitat (breeding stables for cows, fodder and equipment warehouses) 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 animals to be identified as belonging to House mouse (Mus musculus L.).  Eight bait-stations and eight tracking patches were set out on the main mice 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 census 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 census baits during the Post-treatment phase).  According to the results of the present study, BMB50V1 aged of two years showed a good acceptance level and provided a complete effectiveness (100,0%) against the Mus musculus population present across the trial | Rovetto I  Study: 2022.BCD.SAG15 |

* **Minor change (2021):**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Rodenticide | Indoor | BMM50V1 (bromadiolone 0,005% w/w)  Aged bait (2 years) | Norway rat (*Rattus norvegicus*) | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. | Acclimatization: 13 days (200 g unpoisoned food: mixture of maize grain and  poultry/pig feed)  Treatment : 200 g of bait per day in each lockable bait station (total 10 bait stations) during 19 days  Post-baiting: 5 days  (200 g unpoisoned food: mixture of maize grain and  poultry/pig feed)  Mortality was observed from the first day of intoxication and noted about every days until the end of the trial. | Estimated efficacy = 100%.  Pre-baiting plateau = 1383,8 g/day  Post-baiting = 0 g | **XXX**  R.I = 1 |
| Rodenticide | Indoor | BMM50V1 (bromadiolone 0,005% w/w)  Aged bait (4 years) | Roof rat (*Rattus rattus*) | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. | Acclimatization: 13 days (200 g unpoisoned food: mixture of poultry/pig feed)  Treatment : 200 g of bait per day in each lockable bait station (total 8 bait stations) during 16 days  Post-baiting: 5 days  (200 g unpoisoned food: mixture of poultry/pig feed)  Mortality was observed from the first day of intoxication and noted about every days until the end of the trial. | Estimated efficacy = 100%.  Pre-baiting plateau = 1211,5 g/day  Post-baiting = 0 g | **XXX**  R.I = 1 |
| Rodenticide | Indoor | BMM50V1 (bromadiolone 0,005% w/w)  Aged bait (3 years) | House mice (*Mus musculus*)  5 males  5 females | Laboratory test,  choice feeding  test | Acclimatization: 7 days in individual cage at room temperature  Day 0: reference food and bait biocidal product have been given:  - 14g of reference food for the assessment of palatability  - 14g of biocidal product during 5 consecutive days with daily consumption measurements.  Mortality was observed every 24 hours until the death of all animals. | Palatability = 44,9%  Mortality = 100% (max. 8 days) | **XXX**  R.I = 1 |
| Rodenticide | Indoor | BMM50V1 (bromadiolone 0,005% w/w)  Aged bait (3 years) | Norway rat (*Rattus norvegicus*)  5 males  5 females | Laboratory test,  choice feeding  test | Acclimatization: 7 days in individual cage at room temperature  Day 0: reference food and bait biocidal product have been given:  - 50g of reference food for the assessment of palatability  - 50g of biocidal product during 5 consecutive days with daily consumption measurements.  Mortality was observed every 24 hours until the death of all animals. | Palatability = 20,6%  Mortality = 90% (max. 9 days) | **XXX**  R.I = 1 |

Annex 10: post authorisation data regarding long term storage stability studies

**Post-authorisation data (2019)**

This consolidated PAR for the product authorization of BROMAFAR is based on the PAR of the renewal of the authorization.

The following post authorization requests have been made :

* *“The authorisation holder must provide the results of the long term-stability suitdy within 1 year post authrorisation.*
* *The authorisation older must provide an analytical fully validated method for the product within 1 year post authorisation.”*

The results of the long term stability and the analytical method have been provided on 2019/03/01. Results are detailled on page

1. Applies only to existing authorisations [↑](#footnote-ref-1)
2. Please insert additional columns as necessary [↑](#footnote-ref-2)
3. 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-3)
4. LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94. [↑](#footnote-ref-4)
5. Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus. Pestic Sci* 43, 61–67 [↑](#footnote-ref-5)
6. Greaves J. H.; Cullen-Ayres P. B. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388. [↑](#footnote-ref-6)
7. Quy R.J., Shepherd D.S., Inglis I.R. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20 [↑](#footnote-ref-7)
8. Colas S. 2011. FAAR BLE evaluation of skin absorption: *in vitro* method (non GLP study). Phycher Bio-Développement, Study AC-PH-10/0247-amended of the 6 June 2011.Non GLP, (unpublished). [↑](#footnote-ref-8)
9. J.G. Chambers, P.J. Snowdown « study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits ». Synergy LABORATORIES limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group [↑](#footnote-ref-9)
10. HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010 [↑](#footnote-ref-10)
11. J.G. Chambers, P.J. Snowdown « study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits ». Synergy LABORATORIES limited, Thaxted, UK, laboratory report number SYN/1302, 8 March 2004 Sponsor CEFIC/EBPF Rodenticides Data Development Group [↑](#footnote-ref-11)
12. HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010 [↑](#footnote-ref-12)
13. HEEG opinion 9: default protection factors for protective clothing and gloves.Agreed in TM I 2010. [↑](#footnote-ref-13)
14. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-14)
15. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-15)
16. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-16)
17. Barbieux S, Grolleau G. 2011. Efficacy laboratory study of FAAR BLE rodenticide containing 0.005% bromadiolone with albino house mice (Mus musculus). Cabinet Barbieux, report SB-2011-003 of 23 May 2011, not GLP (unpublished). [↑](#footnote-ref-17)
18. Barbieux S, Grolleau G. 2011. Efficacy field study of FAAR BLE rodenticide containing 0.005% bromadiolone with black rats *(Rattus rattus).* Cabinet BARBIEUX, report SB-2011-004 of 23 May 2011, not GLP (unpublished). [↑](#footnote-ref-18)
19. Barbieux S, Grolleau G. 2011. Efficacy field study of FAAR BLOC SP, rodenticide containing 0.005% bromadiolone with brown rats *(Rattus norvegicus).* Cabinet BARBIEUX, report SB-2011-005 of 17 June 2011, not GLP (unpublished). [↑](#footnote-ref-19)
20. Barbieux S, Grolleau G. 2011. Efficacy field study of FAAR AVOINE rodenticide containing 0.005% bromadiolone and 0.001% denatonium benzoate with wild mice *(Mus musculus)* Cabinet BARBIEUX, study 11-TOX-002 of the 6 December 2011, not GLP (unpublished). [↑](#footnote-ref-20)