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 RENEWAL OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



[TANTALE C]

Product type [14]

[Difenacoum as included in the Union list of approved active substances]

Case Number in R4BP: BC- PW049464-02

Evaluating Competent Authority: [FR]

Date: 02/2020

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**Note to the reader:**

This consolidated PAR for the renewal application of the product authorisation for TANTALE C is based on the PAR of the first authorisation of the reference product, in which all necessary addenda have been included.

In this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post authorisation data, same...). The assessments related to the renewal are at the end of each section and are highlighted in grey.

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

**Disclaimer regarding user category**

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

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

Consequently, in the SPC for major change in Part 3, 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.

* **Major change application**

Following the TANTALE C first authorisation, changes claimed in the frame of a major change application are :

* Reduction of the concentration of difenacoum (from 0.005 % to 0.0025 %),
* Addition of a user category (non-professionals).

# History of the dossier (updated PAR – 2019)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** |
| NA-APP | *FR* | n.a. | 23/02/2012 | Initial assessment: SORKIL BLOC |
| n.a | *FR* | n.a. | 21/11/2014 | *Post-authorisation data* |
| NA-BBS | *FR* | BC-HJ025316-47 | 05/04/2017 | Same product: TANTALE C |
| NA-ATT | *FR* | n.a. | 05/02/2018 | Compliance of national authorisation |
| NA-MAC | *FR* | BC-UX033259-98 | 20/12/2018 | Reduction of the concentration of difenacoum (from 0.005 % to 0.0025 %) and addition of a user category (non-professionals) |
| NA-RNL | *FR* | BC-PW049464-02 | 04/03/2020 | Renewal of the authorisation |

n.a.: not applicable

**Authorised uses (0.0025% of difenacoum) – major change 2018**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | *Rattus norvegicus* | 100 g of product at distances of 100 meters apart  200 g of product at distances of 300 meters apart | Sewers | Individual sachets  Prefilled bait station  Bulk |
| Rats (*Rattus rattus* and *Rattus norvegicus*) | 200 g of product / bait station at distances of 15 meters apart | Indoor and outdoor around buildings |
| Mice (*Mus musculus*) | 40 g of product / bait station at distances of 3 meters apart |
| Non professionals | Rats (*Rattus rattus* and *Rattus norvegicus*) | 200 g of product / bait station at distances of 15 meters apart | Indoor and outdoor around buildings | Individual sachets  Prefilled bait station |
| Mice (*Mus musculus*) | 40 g of product / bait station at distances of 3 meters apart | Indoor |

**Intended uses for renewal - 2019**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals | *Rattus norvegicus* | 100 g of product at distances of 100 meters apart  200 g of product at distances of 300 meters apart | Sewers | Individual sachets  Prefilled bait station  Bulk |
| Rats (*Rattus rattus* and *Rattus norvegicus*) | 200 g of product / bait station at distances of 15 meters apart | Indoor and outdoor around buildings |
| Mice (*Mus musculus*) | 40 g of product / bait station at distances of 3 meters apart |
| Non professionals | Rats (*Rattus rattus* and *Rattus norvegicus*) | 200 g of product / bait station at distances of 15 meters apart | Indoor and outdoor around buildings | Individual sachets  Prefilled bait station |
| Mice (*Mus musculus*) | 40 g of product / bait station at distances of 3 meters apart | Indoor |

# General information about the product application – PAR 2012

## Applicant – PAR 2012

|  |  |
| --- | --- |
| **Company Name:** | EDIALUX France |
| **Address:** | ZA Macon Est |
| **City:** | Replonges |
| **Postal Code:** | F-01750 |
| **Country:** | France |
| **Telephone:** |  |
| **Fax:** |  |
| **E-mail address:** |  |

## Current authorisation holder – PAR 2012

|  |  |
| --- | --- |
| **Company Name:** | EDIALUX France |
| **Address:** | ZA Macon Est |
| **City:** | Replonges |
| **Postal Code:** | F-01750 |
| **Country:** | France |
| **Telephone:** |  |
| **Fax:** |  |
| **E-mail address:** |  |
| **Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):** | No |

## Proposed authorisation holder – PAR 2012

|  |  |
| --- | --- |
| **Company Name:** | EDIALUX France |
| **Address:** | ZA Macon Est |
| **City:** | Replonges |
| **Postal Code:** | F-01750 |
| **Country:** | France |
| **Telephone:** |  |
| **Fax:** |  |
| **E-mail address:** |  |
| **Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):** | No |

## Information about the product application – PAR 2012

|  |  |
| --- | --- |
| **Application received:** | 01/04/2010 |
| **Application reported complete:** | 30/08/2010 |
| **Authorisation granted :** | 23/02/2012 |
| **Type of application:** | Product authorisation |
| **Further information:** | - |

## Information about the biocidal product – PAR 2012

### General information

|  |  |
| --- | --- |
| **Trade name:** | SORKIL BLOC |
| **Manufacturer’s development code number(s), if appropriate:** | EDI-575 |
| **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: Difenacoum 0.005% w/w  No substance of concern |
| **Formulation type:** | Solid block |
| **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 |

* **Major change application - 2018**

|  |  |
| --- | --- |
| **Trade name:** | TANTALE C |
| **Manufacturer’s development code number(s), if appropriate:** | EDI-575\_25 |
| **Product type:** | PT14 - rodenticide |
| **Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):** | Difenacoum 0.0025% w/w  No substance of concern |
| **Formulation type:** | Solid block |
| **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) – initial PAR 2012

|  |  |
| --- | --- |
| **Overall use pattern (manner and area of use):** | TP14 - Rodenticide  VIII.3.3 Block bait  Use in and around domestic, industrial and commercial buildings including in farm buildings.  This wax block bait is also applicable in sewers and waste water treatment plants. |
| **Target organisms:** | I.1.1.1 Brown rat: *Rattus norvegicus*  I.1.1.2 Roof rat, House rat: *Rattus rattus*  I.1.1.3 House mouse: *Mus musculus* |
| **Category of users:** | V.1 non professional/ general public  V.2 professional  V.3 specialised 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: covered application in bait stations.  The product is a ready to use wax block bait and contains 0.005¨% w/w of difenacoum.  Rat: 80 g up to 200 g of product / bait station at distances of 15 meters apart.  Mouse: 25 g up to 30 g of product / bait station at distances of 3 meters apart.  These distances, so as the number and timings of application, are in function of infestation rate and can be modified upon experience of bait uptake during the campaign.  Bait must be securely deposited in a way to minimize the risk for non-target animals and for children. Where possible, baits are secured so that they cannot be dragged away by the rodents. Bait stations will be used where the bait can't be fixed or locked up. Some blocks have a metal hook. This hook can be attached to a fixing device of the station.  The common strategy is to explore the site, locate runs, burrows, droppings or signs of damage and place the bait boxes at entry points into buildings and around areas where rats are known to feed. For the mice control, as mice are sporadic feeders, many bait points are placed throughout the areas where mice are known to feed.  Bait points are inspected frequently and replenished when bait take is observed. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. Although a professional will eventually for practical reasons synchronise his inspection frequency with a work week so keeping inspections twice or once a week, so have 3.5 to 7 days inspection interval. During the bait inspections, also a search in the zone will be done for dead rodents. These rodents will be eliminated following local requirements in order to avoid secondary poisoning of predators.  When no further bait take is observed, bait stations should not been left in place, All bait stations must be removed from the site, cleaned up and the bait and bait remainders must be disposed of in accordance with local requirements. As long as there is visual bait consumption, fresh bait will be placed. When during 5 consecutive inspections no uptake at all has been recorded and supplementary no other sign suggests the eventual presence of rodents, the campaign can be ended. Anyhow, during the first 6 months after the end, vigilance is required in order to be responsive on any re-infestation of the area. So with a minimal effort new uproar can be stopped.  Rodent control can be initiated at any moment of the year upon the presence of the target animal through direct traces/signals/markers.  Autumn and winter are more favourable times for indoor applications.  In sewers, the application dose is 100 g per manhole (*i.e.* every 100 m as the distance between two manholes may vary between 50 m to 300 m, but is generally 100 m) or 200 g every 3 manholes. The product is applied preferably in large main sewers (diameter > 30 cm). In larger sewers which can be walked in, baits can be placed along their length on available anchors or on specially installed bait trays each 100 to 300 meters.  In waste water treatment plants, the blocks are placed in temper resistant bait stations. The application dose is 100-200 g of product at distances of 15 meters apart.  In sewerage, the wax blocks are fixed using a wire attached to an existing anchor (scale bar, ring, etc.) or created one for this purpose so the blocks cannot be carried away by the rodents. The block is positioned a few centimeters above the bottom of cesspools.  Frequency of use in sewers:  For preventive treatment, there is one passage for the treatment and one visit of verification per year.  For curative treatment, a more curative campaign with a monthly inspection interval can be defined for a compartment. As long as there is visual bait consumption, fresh bait will be placed. Campaign stops when bait uptake has ended: it can last several months, with an interval of 3 to 5 years or earlier when re-infestation is noted, then the curative treatment for the specific compartment can be restarted.  Intensive treatment is, in more general way, 2-4 applications per year, with a minimal interval of 3 to 6 months between 2 applications. |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no)** | No |
| **Proposed Label:** | Control of rats and mice in and around domestic, industrial and commercial buildings including in farm buildings. This type of block is applicable in sewers and waste water treatment plants.  Rat: 80 g up to 200 g of product at intervals of 15 meters apart.  Mouse: 25 g up to 30 g of product at intervals of 3 meters apart.  For rat control in sewers: 100 g per manhole (about 100 m) up to 200 g every 3 manholes.  For rat control in waste water treatment plants: 100 up to 200 g of product at distances of 15 meters apart. |
| **Use Restrictions:** | Use only in sewers, in waste water treatment plants, in and around buildings in secured bait stations out of reach of children and domestic animals.  Good field practice of rodent control involves several measures as cleaning-up of bait and bait containers after treatment period, removing any potential harbourages, etc.  Local authorities may give according to the existing sewage infrastructure specific instructions to contractors for treatment campaigns hereby defining specific parameters as other fixing places fixing instructions, treatment frequencies, inspection frequencies, and removal instructions. Sewage networks of channels are linked to sewage treatment plant (STP). It’s advised to divide the sewage system as good as possible into smaller compartments: as an example a unit serving 10 000 persons equivalent (PE). So a control campaign can be limited to a specific area and scheduled per unit on a yearly to a 5 yearly rotation program.  So the normal rodenticide control in sewage is preventing an increase of rat populations at which the population could outgrow its sewer environment. Hereby is the structural integrity of sewers very important. Damage of sewer systems will result in rats on the surface. |

### Information on active substance(s)

|  |  |
| --- | --- |
| **Active substance chemical name:** | Difenacoum |
| **CAS No:** | 56073-07-05 |
| **EC No:** | 259-978-4 |
| **Purity (minimum, g/kg or g/l):** | 960 g/kg |
| **Inclusion directive:** | [2008/81/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0081:EN:NOT) |
| **Date of inclusion:** | 1st April 2010 |
| **Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):** | Yes |
| **Manufacturer of active substance(s) used in the biocidal product:** |  |
| **Company Name:** | Pelgar International Ltd |
| **Address:** | Unit 13, Newman Lane |
| **City:** | Alton, Hampshire |
| **Postal Code:** | GU34 2QR |
| **Country:** | Great Britain |
| **Telephone:** | + 44(0) 1420 80744 |
| **Fax:** | + 44(0) 1420 80733 |
| **E-mail address:** | info@pelgar.co.uk |

* **Major change application - 2018**

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

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

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

* **Renewal application – 2019:**

No change.

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

SORKIL BLOC does not contain any substance of concern according to the Technical Notes for Guidance on data requirements.

* **Renewal application – 2019:**

No change.

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

* **Renewal application - 2019**

Based on available information, and considering the legal deadline for biocidal product authorization, it is not possible to conclude whether the biocidal product is considered to have ED properties (please refer to confidential annex). The assessment of one co-formulant must be further assessed in the frame of REACH. Once the conclusion regarding ED properties of this co-formulant is available, the applicant must inform eCA/rMS. If needed, the conditions of authorization shall be revised.

## Documentation – PAR 2012, updated 2017

### Data submitted in relation to product application

**Identity, physicochemical and analytical method data**

Physico-chemical studies on SORKIL BLOC were provided by Edialux: appearance, explosive properties, oxidising properties, autoflammability, flammability properties, density and storage stability.

An analytical method to determine the active substance in the formulation SORKIL BLOC has been provided by Edialux.

Data on the active substance required at the product authorization stage as stated in the AR about the active substance have been provided by Pelgar:

* Appearance of the active substance
* A validated method for the analysis of difenacoum in animal and human tissues
* Validation data for the determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs)
* Validation data for the determination of difenacoum in sediment

**Post-authorisation data:**

- Attestation\_appearence:\_ EDI-575\_Sorkil Bloc\_140718

- Mo3931\_EDI-575\_PP Bucket\_Final: Determination of physico-chemical properties and storage stability test for EDI-575 [Wax Block Exotic Seed (block bait, BB)] packed in PP bucket 8 weeks at 40°C and 24 months at ambient conditions

- Denka\_2Y\_EDI-575 PE bags: 2 year storage stability test under room temperature of Sorkil bloc = EDI-575 in polyethylene (PE) bags

- Denka\_2Y\_EDI-575 PP buckets: 2 year storage stability test under room temperature of Sorkil bloc = EDI-575 in polystyrene (PP) bucket

- Denka\_2Y\_EDI-575 PS trays: 2 year storage stability test under room temperature of Sorkil bloc = EDI-575 in polystyrene (PS) trays

- Attestation light: EDI-575\_140718

- Attestation resistance: Sorkil Bloc\_EDI-575\_140404.

* **Major change application - 2018**

The following studies were submitted:

* Report n° 17-904017-001. 2017. Chemical stability during and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on EDI-575\_25.
* Report n° 17-904017-002. 2017. Storage procedure for 6 months at 20±2 °C.
* Report n° 17-904017-004. 2017. Validation of analytical method for the determination of difenacoum in EDI-575\_25.
* **Renewal application – 2019:**

The following study was submitted:

* Updated Report n° 17-904017-002. 2018. Storage procedure for 12 months at 20±2 °C.

**Efficacy data**

The following efficacy studies were submitted:

* Bait choice - EDI 575 BB-ROD fresh bait with 0.005% difenacoum, Mice (*Mus musculus*)
* Bait choice - EDI 575 BB-ROD fresh bait with 0.005% difenacoum, Rats (*Rattus norvegicus*)
* Bait choice - EDI 575 BB-ROD aged bait with 0.005% difenacoum, Mice (*Mus musculus*)
* Bait choice - EDI 575 BB-ROD aged bait with 0.005% difenacoum, Rats (*Rattus norvegicus*)
* Efficacy assessment for use in damp conditions of Wax Block Exotic Seed (EDI-575 BB-ROD) containing 50 mg.kg-1 difenacoum, using CD albino Norway rat
* **Major change application - 2018**

The following studies were submitted:

* A free-choice laboratory test was carried out with house mice (*Mus musculus*), with the product EDI-575\_24 (24 ppm difenacoum).
* A free-choice laboratory test was carried out with brown rats (*Rattus norvegicus*), with the product EDI-575\_24 (24 ppm difenacoum).
* A free-choice laboratory test was carried out with black rats (*Rattus rattus*), with the product TANTALE C.
* A free-choice laboratory test was carried out with black rats (*R. rattus*), with the product EDI-575\_24 (24 ppm difenacoum), aged of 26 months.
* A field test was carried out with house mice (*M. musculus*), with the product EDI 575\_24 (24 ppm difenacoum).
* A field test was carried out with brown rats (*R. norvegicus*), with the product EDI-575\_24 (24 ppm difenacoum).
* A field test was carried out with black rats (*R. rattus*), with the product TANTALE C
* **Renewal application – 2019:**

No new study has been submitted for the Efficacy section.

**Toxicology data**

The applicant did not submit new toxicological data on active substance. Both SORKIL BLOC and SORICIDE DB are both block bait formulations containing 0.005% (w/w) difenacoum with the same use and user type. The comparison of the compositions of SORICIDE DB and SORKIL BLOC shows that a read-across from SORICIDE DB data to SORKIL BLOC dossier is acceptable.

**Ecotoxicology data**

The applicant has not provided ecotoxicological study with the biocidal product. The environmental risk assessment for SORKIL BLOC has been done by the Reference Member State, Competent Authority Report on the active substance difenacoum supported by the Task Force Activa/Pelgar.

### Access to documentation

In the frame of the authorization of SORKIL BLOC supported by EDIALUX France, the applicant EDIALUX France has submitted a letter of access to all data on difenacoum submitted by Pelgar International Ltd under directive 98/8/EC for the purpose of Annex I listing.

# Summary of the product assessment

## Identity related issues – PAR 2012

A new 5-batch analysis has been submitted by Pelgar at the EU level in the frame of the work conducted by the PA&MRFG, after annex I inclusion and prior to the product authorization stage. The assessment of the technical equivalence of the new 5-batch analysis versus the reference source of Pelgar used for annex I inclusion has been performed. The conclusion is that the source of Pelgar with the new specifications used in SORKIL BLOC is technically equivalent to the source of Pelgar assessed for annex I inclusion.

The confidential document is attached to this PAR as the addendum to the CAR of difenacoum is not available yet. See the confidential appendix “Technical equivalence Difenacoum Pelgar (new specifications)” for detailed information.

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

## Classification, labelling and packaging – PAR 2012, updated 2018

### Harmonised classification of the biocidal product

No classification is required for SORKIL BLOC.

* **Major change application - 2018**

| **Classification** | |
| --- | --- |
| Hazard category | STOT RE 2 |
| Hazard statement | H373: May cause damage to organs through prolonged or repeated exposure |

### Labelling of the biocidal product

No labelling is required for SORKIL BLOC.

* **Major change application - 2018**

|  |  |
| --- | --- |
| **Labelling** | |
| Signal words | Warning    GHS 08 |
| Hazard statements | H373: May cause damage to organs through prolonged or repeated exposure |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand\*.  P102: Keep out of reach of children\*.  P103: Read label before use\*.  P314: Get medical advice/attention if you feel unwell.  P501: Dispose of contents/container to … [*… in accordance with local/regional/national/international regulation]* |
|  | |
| Note | \*required as the product is for non-professional use |

* **Renewal application for TANTALE C – 2019**

No change is **required** for the classification of the product.

### Packaging of the biocidal product

Primary packaging:

SORKIL BLOC is supplied

* in small individual bait bags from 20 to 100 grams
  + of polypropylene (PP) foil
  + of polyethylene (PE) foil
* in extruded polystyrene (PS) trays (containing 1 to 30 blocks from 20 to 100 grams) with a size range from 80 g to 2.5 kg.

SORKIL BLOC is also supplied in bulk without being packed in smaller individual bait bags:

* in bucket of polypropylene (PP) from 200 g to 10 kg
* in one big bag of polyethylene (PE) foil, this bag functions as a liner inside the cardboard box from 200 g to 10 kg.

SORKIL BLOC is also supplied in prefilled bait station in polypropylene (PP) from 20 to 200 g without being individually packed. Several blocks could be in one bait station.

Secondary packaging :

* Bucket of polypropylene (100 g – 10 kg)
* Cardboard box of corrugated cardboard (80 g – 10 kg)

Packaging size and category of users:

|  |  |
| --- | --- |
| Category of users | Packaging size |
| Professional | >3 kg |
| Non professional | < 3 kg |

Packaging size and target organisms:

Excluding the prefilled bait stations, the different kind of packaging are destined for both type of target organisms, rats and mice.

Prefilled mouse bait stations have a size range from 20 grams to 150 grams (i.e. 1 to 3 blocks of 20, 22.5, 25, 30, 35, 40 or 50 grams).

Prefilled rat bait stations have a size range from 50 grams to 200 grams (i.e. 1 to 5 blocks of 20, 22.5, 25, 30, 40, 50, 60, 80, or 100 grams).

These prefilled bait stations are grouped into 1 to 5 units per cardboard box.

* **Major change application - 2018**

**For professional users:**

Minimum pack size of 3 kg

(In France only: minimum pack size of 5 kg)

TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk.

They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).

Blocks can also be supplied in PE pre-filled bait stations:

* for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g;
* for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g.

**For non-professional users:**

Maximum pack size of 300 g

TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g).

They are then packed in PP buckets or in cardboards with PE liner (up to 300 g).

Blocks can also be supplied in PE pre-filled bait stations:

* for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g;
* for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g.
* **Renewal application – 2019:**

The applicant reports no change in the packaging during the renewal application.

**For professional users:**

Minimum pack size of 3 kg

(In France only: minimum pack size of 5 kg)

TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20, 25, 28, 30, 40, 50, 70, 80, 100, 150 or 200 g) or in bulk.

They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).

Blocks can also be supplied in PE pre-filled bait stations:

* for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g.
* for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g.

**For non-professional users:**

Maximum pack size of 300 g for rats and 100 g for mice

TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20, 25, 28, 30, 40, 50, 70, 80, 100, 150, 200 g).

They are then packed in PP buckets or in cardboards with PE liner.

Blocks can also be supplied in PE pre-filled bait stations:

* for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g.
* for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g.

## Physico/chemical properties and analytical methods

Data on the active substance difenacoum were required at the product authorization stage as stated in the AR about the active substance and were provided by Pelgar:

* Appearance of the active substance

Results of the assessment: for appearance, the data provided are acceptable. The results are reported in 2.3.1.

### Physico-chemical properties

Table 1: Physico-chemical properties of the active substance:

|  | Method/ Guideline | Purity/Specification | Result | Reference |
| --- | --- | --- | --- | --- |
| Physical state | Visual assessment in accordance with Council Directive 98/8/EC, Annex IIA, III, 3.3 | Purity: 99.5% w/w difenacoum,  Batch number 04253 | Slightly clumping powder at 20.0 ± 0.5°C | Walker JA and Mullee, DM (2007)  Difenacoum: Determination of General Physico-chemical Properties  SafePharm Laboratories Report No. 2109/0005 |
| Colour | Off-white at 20.0 ± 0.5°C |
| Odour | No determination was performed as the test material was considered to be harmful by inhalation |

Other physico-chemical properties are presented in the CAR of Difenacoum of the Activa / Pelgar Brodifacoum and Difenacoum Task Force. Edialux has a letter of access for these data.

Table 2: Physico-chemical properties of the biocidal product (evaluated in the PAR 2012)**:**

|  | Method | Purity/Specification | Results | Reference |
| --- | --- | --- | --- | --- |
| Physical state and nature | Visual inspection | EDI-575  0.00516% Difenacoum | Wax cuboids with cereal grain enclosure  See comment and conclusion below | Broda, J |
| Colour | Visual inspection | EDI-575  0.00516% Difenacoum | Reddish | Broda, J |
| Odour | Comparison to other characteristic odors | EDI-575  0.00516% Difenacoum | Weak grain odor | Broda, J |
| Explosive properties | Expert statement |  | Not explosive | Vinot, D. Ambrosi, D. |
| Oxidizing properties | Expert statement |  | No oxidizing properties | Vinot, D. Ambrosi, D. |
| Flash point | Not applicable |  |  |  |
| Autoflammability | EC A.16 | EDI-575  0.00516% Difenacoum | No self-ignition temperature was observed up to 400°C. | Domhagen J. |
| Other indications of flammability | EC A.10 | EDI-575  0.00516% Difenacoum | The product is not highly flammable | Domhagen J. |
| Acidity / Alkalinity |  |  | See comment and conclusion below the table |  |
| Relative density / bulk density | EC A.3 (OCDE 109) | EDI-575  0.00516% Difenacoum | D422 = 1.2 | Domhagen J. |
| Storage stability – stability and shelf life | 2-years storage stability study |  | The study is on going until 13th week 2012  See conclusion below the table |  |
| Effects of temperature | 8 weeks at 40°C | EDI-575  0.00516% Difenacoum | The weight loss of the test item after storage for 8 weeks at 40°C was < 0.4%. No other significant change in the appearance was observed  Difference of content of the active substance: -0.8% deviation from T=0 value after the accelerated storage procedure for 8 weeks at 40°C  See comment and conclusion below the table | Broda, J. |
| Effects of light | Not submitted |  | See conclusion below the table |  |
| Reactivity towards container material | Visual description (integrity, sealing, leakage, dimensional stability) | EDI-575  0.00516% Difenacoum  Container material PP bucket | The appearance of the packaging was unchanged throughout the study. The sample stayed in sound condition, sealed and without leakage after 8 weeks at 40°C.  See conclusion below the table | Broda, J. |
| Other  Melting point | EC A.1 (OECD 102) | EDI-575  0.00516% Difenacoum | The DSC shows that the product starts melting at 30°C (first peak at 40°C and second peak at 60.5°C). | Domhagen J. |
| Technical characteristics in dependence of the formulation type | Not applicable |  |  |  |
| Compatibility with other products |  |  | The product is a ready to use product and is not intended to be added to any other product. |  |
| Surface tension | Not applicable |  |  |  |
| Viscosity | Not applicable |  |  |  |
| Particle size distribution | Not applicable |  |  |  |

Appearance:

There are blocks with different weights: from 20 to 100g but the different sizes (length, width and height) have not been provided.

Acidity/Alkalinity:

The fact that the product is solid and is not intended to be dispersed in water is not an acceptable justification for non submission of the pH and acidity/alkalinity.

pH value (1% in water) should have been provided and acidity/alkalinity too if relevant (depending of the pH).

Storage stability:

Storage stability was realized at 40°C for 8 weeks. The appearance of tests items was observed after 8 weeks at 40°C and no significant changes were observed.

Due to the melting range of the product, it is necessary to advise storage at ambient temperature (max 40°C).

Reactivity towards container material:

The compatibility of SORKIL BLOC in individual polypropylene (PP) bag and polyethylene (PE) bag, in extruded polystyrene (PS) tray, in big bag of PE foil and in prefilled bait station in PP has not been tested.

Only the compatibility of SORKIL BLOC in individual polypropylene (PP) bag and polyethylene (PE) bag of 20g and in extruded PS tray of 80g with 4 blocks is required.

The result of the compatibility in PE bag of 20g could be used to accept the big bag of PE foil and the result of the compatibility in PP bag of 20g could be used to accept the PP pre-filled bait station.

**Conclusion (PAR 2012):**

Precision about the appearance of the product have to be provided (different sizes and detailed description of blocks).

A 2-years storage stability study is on-going and have to be provided. Results shouldbe given with test items in quantity sufficient to overcome the heterogeneity. Intermediate results at one year have to be provided.

pH (acidity and alkalinity if relevant), compatibility of SORKIL BLOC in individual polypropylene (PP) bag and polyethylene (PE) bag of 20g, in extruded PS tray of 80g with 4 blocks, and effect of light have to be provided also.

Due to the melting range of the product, it is necessary to advise storage at ambient temperature (max. 40°C).

* **Assessment of the submitted post-authorisation data (PAR addendum, 2014):**

**Table 3: SORKIL BLOC technical characteristics**

|  |  |
| --- | --- |
| **Weight (g)** | **Dimensions**  **Side x Side x height (cm)** |
| 20 | 3.5 x 3.5 x 1.8 |
| 22.5 | Unavailable on French market |
| 28 | 5.5 x 2.5 x 2 |
| 30 | Unavailable on French market |
| 40 | Unavailable on French market |
| 50 | 4.5 x 4.5 x 2.5 |
| 60 | Unavailable on French market |
| 80 | 9 x 4.5 x 2 |
| 100 | 4.5 x 4.5 x 4.5 |

Appearance:

Data about product appearance have been submitted and are considered by Anses as acceptable.

Light effect :

The notifier has provided an explanation for non submission of light effect data. Indeed, SORKIL BLOC is conditionned in white opaque film. The packagings are opaque and the product is placed in boxes away from the light.

Then, light is not expected to have any impacts on this biocidal product.

Anses considers this argument as acceptable.

Long term storage stability study:

* In PP buckets:

Table 4: Determination of physico-chemical properties and storage stability test for EDI-575 [Wax block exotic seed (block bait, BB)] packed in PP buckets, S. Manka, 2012, batch n° LB080310. 8 weeks at 40°C and 24 months at ambient conditions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **T0** | **After 8 weeks at 40°C** | **After 12 months at 25°C** | **After 24 months at 25°C** |
| **Appearance** | wax cuboids with cereal grain enclosure, reddish, weak wax and grain odor | No change | No change | No change |
| **Appearance of packaging** | sample in sound condition, sealed and without leakage, | No change | No change | No change |
| **Variation of weight** | / | +0.35% | -0.06% | -0.09% |
| **Content of AS**  **(% w/w)** | 0.00516 | 0.00512 | 0.00463 | 0.00443 |
| **Variation of AS (%)** | / | -0.8% | -10.3% | -14.1% |

Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.

Conclusion : The study is acceptable, the product is stable 2 years at room temperature and 8 weeks at 40°C in PP buckets.

Table 5: 2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polyproplene (PP) buckets, G. Van Middendorp, 2014, batch n° 4171B

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **T0** | **After 6 months at 25°C** | **After 12 months at 25°C** | **After 24 months at 25°C** |
| **Appearance** | wax cuboids red | No change | No change | No change |
| **Appearance of packaging** | sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change |
| **pH of 1% suspension** | 6.4 | 6.4 | 6.2 | 6.2 |
| **Content of AS**  **(% w/w)** | 0.0050 | 0.0051 | 0.0049 | 0.0055 |
| **Variation of AS (%)** | / | +2.0% | -2.0% | +10% |

Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.

Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PP buckets.

* In PE bags:

Table 6: 2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polyethylene (PE) bags, G. Van Middendorp, 2014, batch n° 4171a

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **T0** | **After 6 months at 25°C** | **After 12 months at 25°C** | **After 24 months at 25°C** |
| **Appearance** | wax cuboids red | No change | No change | No change |
| **Appearance of packaging** | sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change |
| **pH of 1% suspension** | 6.4 | 6.4 | 6.2 | 6.2 |
| **Content of AS**  **(% w/w)** | 0.0051 | 0.0048 | 0.0049 | 0.0048 |
| **Variation of AS (%)** | / | -5.9% | -4.0% | -5.9% |

Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.

Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PE bags.

* In PS trays:

Table 7: 2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polystyrene (PS) trays, G. Van Middendorp, 2014, batch n° 4171a

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **T0** | **After 6 months at 25°C** | **After 12 months at 25°C** | **After 24 months at 25°C** |
| **Appearance** | wax cuboids with exotic seed integrated wire, red | No change | No change | No change |
| **Appearance of packaging** | sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change |
| **pH of 1% suspension** | 6.8 | 6.8 | 6.8 | 6.8 |
| **Content of AS** | 0.0056 | 0.0050 | 0.0057 | 0.0059 |
| **Variation of AS (%)** | / | -10.8% | +1.7% | +5.4% |

Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.

Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PS trays.

Biocidal product is demonstrated stable 2 years at room temperature in PE bags, PS trays and PP buckets. The product being a solid, if it is compatible with a type of packaging, it is considered compatible with every types of packaging. The product is thus compatible with bag in PP.

All datas evaluated in this addendum to the PAR are summarized in Table 8.

Table 8: Physico-chemical properties of the biocidal product (evaluated in the addendum to the PAR 2014)

|  | Method | Purity/  Specification | Results | Reference |
| --- | --- | --- | --- | --- |
| Acidity / Alkalinity |  |  | See comment and conclusion of “Storage stability – stability and shelf life”. |  |
| Storage stability – stability and shelf life | 2-years storage stability study | SORKIL BLOC Difenacoum (0.05 %w/w)  Batch n°LB080310  SORKIL BLOC (Difenacoum 0.05% w/w)  Batch n°4171B  SORKIL BLOC (Difenacoum 0.05% w/w)  Batch n°4171a  SORKIL BLOC (Difenacoum 0.05% w/w)  Batch n°4171a | **Determination of physico-chemical properties and storage stability test for EDI-575 [Wax block exotic seed (block bait, BB)] packed in PP buckets, S. Manka, 2012, batch n° LB080310. 8 weeks at 40°C and 24 months at ambient conditions.**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | After 8 weeks at 40°C | After 12 months at 25°C | After 24 months at 25°C | | Appearance | Wax cuboids with cereal grain enclosure, reddish, weak wax and grain odor | No change | No change | No change | | Appearance of packaging | Sample in sound condition, sealed and without leakage, | No change | No change | No change | | Variation of weight | / | +0.35% | -0.06% | -0.09% | | Content of AS  (% w/w) | 0.00516 | 0.00512 | 0.00463 | 0.00443 | | Variation of AS (%) | / | -0.8% | -10.3% | -14.1% |   Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.  Conclusion: The study is acceptable, the product is stable 8 weeks at 40°C in PP buckets packaging.  2 year storage stability was demonstrated during van middendorp study below.  **2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polyproplene (PP) buckets, G. Van Middendorp, 2014, batch n° 4171B**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | After 6 months at 25°C | After 12 months at 25°C | After 24 months at 25°C | | Appearance | Wax cuboids red | No change | No change | No change | | Appearance of packaging | Sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change | | pH of 1% suspension | 6.4 | 6.4 | 6.2 | 6.2 | | Content of AS  (% w/w) | 0.0050 | 0.0051 | 0.0049 | 0.0055 | | Variation of AS (%) | / | +2.0% | -2.0% | -10% |   Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.  Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PP buckets packaging.  **2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polyethylene (PE) bags, G. Van Middendorp, 2014, batch n° 4171a**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | After 6 months at 25°C | After 12 months at 25°C | After 24 months at 25°C | | Appearance | Wax cuboids red | No change | No change | No change | | Appearance of packaging | Sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change | | pH of 1% suspension | 6.4 | 6.4 | 6.2 | 6.2 | | Content of AS  (% w/w) | 0.0051 | 0.0048 | 0.0049 | 0.0048 | | Variation of AS (%) | / | -5.9% | -4.0% | -5.9% |   Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.  Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PE bags packaging.  **2 year storage stability test under room temperature of Sorkil bloc – EDI-575 in polystyrene (PS) trays, G. Van Middendorp, 2014, batch n° 4171a**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | After 6 months at 25°C | After 12 months at 25°C | After 24 months at 25°C | | Appearance | Wax cuboids with exotic seed integrated wire, red | No change | No change | No change | | Appearance of packaging | sample in sound condition, sealed and without leakage, dimensionally stable | No change | No change | No change | | pH of 1% suspension | 6.8 | 6.8 | 6.8 | 6.8 | | Content of AS  (% w/w) | 0.0056 | 0.0050 | 0.0057 | 0.0059 | | Variation of AS (%) | / | -10.8% | +1.7% | +5.4% |   Quantification of AS has been done by HPLC UV detection (chromatograms of standard and sample have been provided) with the method evaluated in the PAR.  Conclusion : The study is acceptable, the product is stable 2 years at room temperature in PS trays.  **Conclusion:** Biocidal product is demonstrated stable 2 years at room temperature in PE bags, PS trays and PP buckets. The product being a solid, if it is compatible with a type of packaging, it is considered compatible with every types of packaging. The product is thus compatible with PP bag. | Manka, S. (2012), Study n° Mo3931  Van Middendorp, G. (2014)  Van Middendorp, G. (2014)  Van Middendorp, G. (2014) |
| Effects of light | Non submission data submitted |  | The notifier has provided an explanation for non submission of light effect datas. Indeed, SORKIL BLOC is conditionned in white opaque film. The packagings are opaque and the product is placed in boxes away from the light. Then, light is not expected to have any impacts on this biocidal product.  Anses considers this argument as acceptable. |  |

* **Major change application - 2018**

Based on the differences and co-formulants, the new composition TANTALE C can be considered as similar as the old composition SORKIL BLOC (see confidential annex). A read across with SORKIL BLOC for physico-chemical properties of TANTALE C can be considered as acceptable.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Storage stability test – **8 weeks at 40 °C** | CIPAC 46.3 | TANTALE C  (0.0025% w/w of difenacoum)  Batch n° SB8517 | Determination of physico-chemical properties and storage stability test packed in commercial packaging:   |  |  |  |  | | --- | --- | --- | --- | |  | Initial | After 4 weeks at 40°C | After 8 weeks at 40°C | | Appearance | Heterogeneous pink grain moulded block, odourless | Heterogeneous pink grain moulded block, odourless | Heterogeneous pink grain moulded block, odourless | | Appearance of packaging | Cardboard box with PP bags inside | Cardboard box with PP bags inside | Cardboard box with PP bags inside | | Variation of weight (%) |  | -0.2% | -0.5% | | Content of AS | 0.00283% w/w | 0.00281% w/w | 0.00283% w/w | | Variation of AS (%) |  | -0.7% | -0.0% |   Quantification of AS is done by HPLC UV detection with the method evaluated in the part 2.2.4.  Conclusion: Accelerated storage stability study (8 weeks at 40°C) allows to consider that the product is stable in Cardboard box with PP bags inside.  The product being a solid, if it is compatible with a type of packaging, it is considered compatible with every types of packaging. | DEMANGEL, B. (2017), Study n°17-904017-001 |
| Storage stability test – long term storage at ambient temperature | CIPAC 46.3  3 years storage stability  GIFAP n°17  CIPAC 178  CIPAC 171.1 | TANTALE C  (0.0025% w/w of difenacoum)  Batch n° SB8517 | Determination of physico-chemical properties and storage stability test packed in commercial packaging:   |  |  |  |  | | --- | --- | --- | --- | |  | Initial | After 6 months at 20±2 °C | After 3 years at rt | | Appearance | Heterogeneous pink grain moulded block, odourless | Heterogeneous pink grain moulded block, odourless | The study is currently ongoing. | | Appearance of packaging | Cardboard box with PP bags inside | Cardboard box with PP bags inside | | Variation of weight (%) |  | -0.4% | | Content of AS | 0.00283 | 0.00275 | | Variation of AS (%) |  | -2.8% |   Quantification of AS is done by HPLC UV detection with the method evaluated in the part 2.2.4. | DEMANGEL, B. (2017), Study n°17-904017-002 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product TANTALE C is an RB ready to use bait formulation. All studies will be performed in accordance with the current requirements. It is not explosive and has no oxidising properties. The product is not flammable.  The product is stable 8 weeks at 40°C and according to the read across with the product SORKIL BLOC, a shelf life of 2 years at ambient temperature can be granted for the biocidal product. Long-term storage stability test is currently on progress and results are requested post-authorization to confirm the stability of the product.  eCA recommends to store at a temperature below 40°C and away from light due to the sensitivity of the active substance to light.  Its technical characteristics are acceptable an RB ready to use formulation. |

* **Renewal application – 2019:**

A new study has been submitted for the physicochemical section:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Storage stability test – **long term storage at ambient temperature** | CIPAC 46.3  3 years storage stability  GIFAP n°17  CIPAC 178  CIPAC 171.1 | TANTALE C  (0.0025% w/w of difenacoum)  Batch n° SB8517 | Determination of physico-chemical properties and storage stability test packed in commercial packaging:   |  |  |  |  | | --- | --- | --- | --- | |  | Initial | After 12 months at 20±2 °C | After 2-3 years at rt | | Appearance | Heterogeneous pink grain moulded block, odourless | Heterogeneous pink grain moulded block, odourless | The study is currently ongoing. | | Appearance of packaging | Cardboard box with PP bags inside | Cardboard box with PP bags inside | | Variation of weight (%) | - | +0.1% | | Content of AS | 0.00283 | 0.00285 | | Variation of AS (%) | - | +0.7% |   Quantification of AS is done by HPLC UV detection with the method evaluated in the part 2.2.4. | DEMANGEL, B. (2018), Updated Study n°17-904017-002 |

**Conclusion:**

The product TANTALE C is an RB: ready to use bait block formulation. All studies are performed in accordance with the current requirements. It is not explosive and has no oxidising properties. The product is not flammable.

The product is stable 8 weeks at 40°C. For the product SORKIL BLOC (same composition with 50 ppm difenacoum), a shelf life of 2 years at ambient temperature was granted. The long-term storage stability test for TANTALE C is currently on progress. Intermediate results (12 months) were furnished during the renewal application. Based on these results, and considering a read across with SORKIL BLOC, a shelf life of 2 years at ambient temperature is at this time granted by physico-chemical properties section for the biocidal product but final results are requested as soon as available to confirm the stability of the product.

eCA recommends to store at a temperature below 40°C and away from light due to the sensitivity of the active substance to light.

Its technical characteristics are acceptable an RB ready to use formulation.

### Risk assessment for Physico-chemical properties

* **Major change application - 2018**

Based on the differences, the physico-chemical hazards of the product TANTALE C are similar between the old and new composition.

Therefore refer to the product assessment report related to SORKIL BLOC product authorisation under Regulation UE n° 528/2012 for the physico-chemical hazards of the product.

* **Renewal application – 2019:**

No new study has been submitted for the physicochemical section. TANTALE C is not classified on a physico-chemical point of view.

### Analytical methods – PAR 2012

Data on the active substance difenacoum were required at the product authorization stage as stated in the AR of the active substance and were provided by Pelgar:

* A validated method for the analysis of difenacoum in animal and human tissues,
* Validation data for the determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs) ,
* Validation data for the determination of difenacoum in sediment.

Results of the assessment of the analytical methods provided by Pelgar on the active substance as required in the CAR:

- A validated method for the analysis of difenacoum in animal and human tissues

Results of the assessment: The method is validated and is acceptable.

- Validation data for the analytical method for determination of residues of difenacoum in meat and oil-seed rape (food/feeding stuffs)

Results of the assessment: The data provided were not validation data based on the analysis method already provided in the dossier, as requested. The submitted study report provided a new method with validation data. This new method is validated and is acceptable.

- Validation data for analytical method for determination of difenacoum in sediment (based on the analysis method for difenacoum in soil)

Results of the assessment: The data provided were not validation data based on the analysis method for difenacoum in soil, as requested. The submitted study report provided a new method with validation data. This new method is validated and is acceptable.

|  |  |
| --- | --- |
|  | Principle of method |
| Technical active substance as manufactured: | Difenacoum quantified in technical grade material by HPLC with UV detection at 254 nm using an internal standard. |
| Impurities in technical active substance: | Impurities in technical grade material quantified by HPLC with UV detection using either an internal or external standard. |
| active substance in the formulation: | HPLC-UV |

**Technical active substance as manufactured:**

The determination of the active substance was performed by HPLC with method of the internal standard, using the UV detector. It is based on the comparison between the ratio of the difenacoum analytical standard peak area versus 1.3.5-triphenylbenzene internal standard peak area and the same ratio determined in the sample under examination where a known amount of internal standard (I.S) was added. The analytical method is considered to be acceptable.

**Impurities in technical active substance:**

The analytical method and the related validation data for the determination of impurities in the difenacoum technical substance described in the reference A4.1(2) is also considered to be acceptable but is confidential and can be found in Annex for Confidential Data and Information in the CAR of Difenacoum of Activa/Pelgar Brodifacoum and Difenacoum Task Force.

**Active substance in the formulation:**

After extraction in methanol, which is further boiled under reflux for 1 hour, the active substance content is determined by high performance liquid chromatography (HPLC) with UV detection at 254 nm according to the internal standard method. The analytical method provided is validated.

* **Major change application - 2018**

Report: Validation of the analytical method for the determination of difenacoum in EDI-575\_25 (TANTALE C), RICAU, H. 2017

Study GLP n° 17-904017-004

Test facility: DEFITRACES  
Z.A. des Andrés  
150, rue Pré-Magne  
69126 BRINDAS  
FRANCE

Principle of the method:

A method to determine difenacoum in the biocidal product EDI-575\_25 (TANTALE C) by HPLC – UV was submitted. The test item is quantified by HPLC method (Column: reversed phase) using UV detection (320 nm) after extraction.

The validation of this method was considered in compliance with SANCO 3030/99 rev 4

Validation data:

|  |  |  |  |
| --- | --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, four solutions are analysed and chromatograms have been provided for:   * Solvent blank * Formulation blank * Reference item * Test item   No interference was found: no peak appears in the formulation blank and solvent blank at the retention time of difenacoum.  The method is specific to difenacoum in EDI-575\_25. | | |
| Linearity | Linearity was studied by carrying out five concentrations between 50% and 150% of the concentration in the test item. (= between 1.21 mg/L and 3.71 mg/L). | | |
| Compound | Linearity % | |
| Difenacoum | 1.21 mg/L to 3.71 mg/L  Y = 0.412 X + 0.012  R = 0.9972  n = 5 | |
| Precision | Repeatability was evaluated by analysing twice five test item solutions. | | |
| Compound | Mean (% w/w) | Repeatability (RSD) |
| Difenacoum | 0.00285% | 1.80% (RSDr=6.47%) |
| Accuracy | Accuracy was determined by comparison of the reference items and 2 reconstituted test items solutions at 100% and 102% of the theoretical concentrations of 2.47 mg/L. Two injections of each preparation are made. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate (%) | Mean recovery rate (%) | n | | 100%  (2.47 mg/L) | 97.3-98.3 | 97.8 | 2 | | 102%  (2.51 mg/L) | 97.9-98.2 | 98.1 | 2 | | | |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Provided analytical methods is considered validated for the determination of the active substance difenacoum at 25 ppm in the product EDI-575\_25 (TANTALE C).  For the analytical methods for determining relevant components and/or residues in different matrices, please refer to the product assessment report related to SORKIL BLOC product authorisation under Regulation UE n° 528/2012. |

* **Renewal application – 2019:**

No new study has been submitted for the analytical method section.

## Effectiveness against target organisms

### Function

MG 03: Pest Control

Product Type 14: Rodenticide

### Organism(s) to be controlled and products, organisms or objects to be protected.

SORKIL BLOC is used to control rodents. The target organisms to be controlled are brown rat (*Rattus norvegicus*), roof rat or house rat (*Rattus rattus*) and House mouse (*Mus musculus*).

The products, organisms or objects to be protected are stored products or food, public health, historical buildings or technical objects, sewers and waste water treatment plants.

* **Major change application - 2018**

The product TANTALE C is authorised for use against *Mus musculu*s, *Rattus norvegicus* and *Rattus rattus*, in and around buildings by professional users, and in sewers and water treatment plants by professional users only.

In the frame of the major change, the applicant requests an authorisation for the same product but containing 0.0025 % w/w difenacoum instead of 0.005 % w/w, for a longer shelf life up to 36 months for the same uses by professional and non-professional users.

The application rates recommended by the applicant are the following:

* Rats: 80-200 g grains/secured bait point separated by 15 m.
* Mice: 25-30 g grains/secured bait point separated by 3 m.
* Brown rats in sewers: 100 g of bait every 100 m or 200 g of bait every 300 m.
* **Renewal application for TANTALE C – 2019**

The product TANTALE C is authorised for use against *Mus musculu*s, *Rattus norvegicus* and *Rattus rattus*, in and around buildings by professional users, and in sewers against *Rattus norvegicus* by professional users only. And for non-professional users against house mice (*Mus musculus*) for use indoor and against brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) for use in and around buildings;

The application rates recommended by the applicant are the following:

* Rats: 200 g product/secured bait point separated by 15 m.
* Mice: 40 g product/secured bait point separated by 3 m.
* Brown rats in sewers: 100 g of product every 100 m or 200 g of bait every 300 m.

The efficacy assessment is based on the efficacy studies submitted by the applicant for the first authorisation and the major change application.

### Effects on Target organisms

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. Death will usually occur within 3-10 days of ingesting a lethal dose and animals often die out of sight in their nest or burrow.

* **First authorisation: studies has been performed with the product SORKIL BLOC – PAR 2012**

The application rates recommended by the applicant are the following:

Rats: (*Rattus norvegicus* and *Rattus rattus)*

80 g up to 200 g product/secured bait point at intervals of 15 m apart.

Mice: (*Mus musculus*)

25 g up to 30 g product/secured bait point at intervals of 3 m apart.

For rat (*R. norvegicus*) control in sewers:

100 g per manhole (about 100 m) up to 200 g every 3 manholes.

For rat (*R. norvegicus*) control in waste water treatment plants:

100 g up to 200 g product/secured bait point at intervals of 15 m apart.

The product is applied in bait stations by professional and non-professional users in discrete locations within the infested area. In sewerage, the wax blocks are fixed using a wire attached to an existing anchor. 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.

It must be noted that total eradication in sewers is generally not achievable. The aim of rodent campaigns is to maintain acceptable population levels.

Therefore the frequency of use in sewers is different:

- For preventive treatment, there is one passage for the treatment and one visit of verification per year.

- For curative treatment, a more curative campaign with a monthly inspection interval can be defined for a compartment. As long as there is visual bait consumption, fresh bait will be placed. Campaign stops when bait uptake has ended: it can last several months, with an interval of 3 to 5 years or earlier when re-infestation is noted, then the curative treatment for the specific compartment can be restarted.

- For intensive treatment, 2-4 applications per year, with a minimal interval of 3 to 6 months between 2 applications.

The treatment is curative for the other locations (i.e. in and around domestic, industrial and commercial buildings and waste water treatment plants). So all bait stations, baits and bait reminders must be removed at the end of the treatment.

Choice feeding tests on SORKIL BLOC on brown rats and house mice with fresh and aged baits were conducted and the results are presented in annex 2. The studies show that the product is palatable (treated bait intake at least 20% of the total food consumption in choice feeding tests) and effective (90% to 100% mortality in less than 14 days in the choice feeding tests).

Efficacy assessment for use in damp conditions of SORKIL BLOC on rats was also conducted and the results are presented in annex 2. The study shows that the product is palatable (mean treated bait intake of 30% of the total food consumption) and effective (100% mortality in less than 14 days).

Only laboratory tests have been performed with the product SORKIL BLOC.

Nevertheless the TNsG on product evaluation for PT14 products expects that in case of an already authorized active substance, for an already authorized field of use, it is sufficient to submit the results of the tests which have been performed with an authorized product based on the same active substance (table 1 page 8).

We have assessed in parallel to the product SORKIL BLOC, the product SORKIL AVOINE SPECIALE (grain bait with 50 ppm difenacoum), for which field tests on brown rats and house mice (100% efficacy), a semi-field test on house mice (100% efficacy) and a semi-field test on brown rats (95% efficacy) were submitted.

Here is a brief summary of the field studies submitted in the SORKIL AVOINE SPECIALE dossier:

**House mice:**

*Field test indoor:*

- This field study was conducted to assess the efficacy of **SORKIL G GRAINS** (old formulation of SORKIL AVOINE SPECIALE) and SORKIL AVOINE SPECIALE against a wild strain of *Mus musculus*;

- The study is an adaptation of the Guideline of the Belgium Ministry of Agriculture;

- This test has been conducted in a piggery with an infestation of approximately **50 mice**.

This test shows that SORKIL G GRAINS has **an efficacy of 100%** in 29 days. Considering that the TNsG requires a decrease of population of ≥90% after 3 to 5 weeks, this product can be considered as efficient.

*Field study:*

- Study conducted with **SORKIL AVOINE SPECIALE;**

- The population size was of **8 mice** in a private house in urban environment;

- The study follows the recommendations of **TNsG TP14**. This study has enabled to show an **efficacy of 100%** in 14 days against mice.

**Brown Rats:**

*Semi-field study:*

- The semi-field study was conducted to assess the efficacy of **SORKIL G GRAINS** (old formulation) and SORKIL AVOINE SPECIALE against a wild strain of *Rattus norvegicus*;

- This test has been conducted in a warehouse with an infestation of **22 rats**;

- The study follows the **Guideline of the Belgium Ministry of Agriculture**. This study has enabled to show an **efficacy of 95%** in 16 days.

*Field study:*

- Study conducted with **SORKIL AVOINE SPECIALE;**

- The population size was of **10 rats** in a chocolate factory;

- The study follows the recommendations of **TNsG TP14**. This study has enabled to show an **efficacy of 100%** in 14 days against rats.

Moreover, based on the laboratory results of the two products (see table below), the product SORKIL BLOC is more palatable than the product SORKIL AVOINE SPECIALE for mice and equally palatable for rats, and mortality results are identical (see table below).

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | SORKIL AVOINE SPECIALE | SORKIL BLOC |
| House mice | Palatability | 63% | 83,5% |
| Mortality | 100% | 100% |
| Brown rats | Palatability | 40,5% | 39,6% |
| Mortality | 100% | 100% |

We can therefore assume that efficacy on the field is likely comparable for the products SORKIL BLOC and SORKIL AVOINE SPECIALE. Read-across based on data supplied for the product SORKIL AVOINE SPECIALE is therefore possible for the efficacy assessment of the product SORKIL BLOC and lead to conclude that the efficacy of the product SORKIL BLOC is demonstrated for the uses claimed.

* **Major change application - 2018**

For the use against brown rats (*R. norvegicus*) and house mice (*M. Musculus*), laboratory and field trials were conducted with the product EDI-575\_24, which is very similar to EDI-575\_25. The only difference is that EDI-575\_24 contains 1 ppm less active substance (replaced by 1 ppm more carrier). Therefore, results from these studies can be extrapolated to the current formulation TANTALE C (EDI-575\_25).

For the use against black rats (*R. rattus*), laboratory and field trials were conducted with the product TANTALE C (EDI-575\_25) and a laboratory trial with a 26 month-aged product, EDI-575\_24.

The results are summarized in the table below.

| **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** |
| PT 14 | Indoor and outdoor around buildings | EDI-575\_24  (24 ppm difenacoum) | House mouse  *M. musculus*  10 males + 10 females (in 2 different cages)  Wild rodents | Choice feeding test  Palatability and mortality test | Standard laboratory diet: S.A.F.E. pellet food ref. A04  After acclimation, mice exposed to the test bait on D0 and choice feeding test until D4. Test bait and standard diet placed in 2 clean pots at the animals' disposal. Places inverted each day to avoid place preference.  Measurements: global consumption per cage (g) for the bait and the standard laboratory diet Calculation: mean daily consumption per animal and per kg of animals for the bait (A) and the standard laboratory diet (B). Palatability = A / (A+B), for each sex group.  After D4, return to the standard laboratory diet. Mortality also assessed, until D9. | Mortality: 100% between D4 and D8.  Mean palatability: 0.61 for males and 0.74 for females, *i.e.* mean palatability of 0.68. | XXX  RI = 2 |
| PT 14 | Indoor and outdoor around buildings | EDI-575\_24  (24 ppm difenacoum) | Brown rat  *R. norvegicus*  5 males + 5 females (individually caged)  Wild rodents | Mortality: 100% between D6 and D9.  Mean palatability: 0.50 for males and 0.55 for females, *i.e.* a mean palatability of 0.53. | XXX  RI = 2 |
| PT 14 | Indoor and outdoor around buildings | TANTALE C | Black rat  *R. rattus*  5 males + 5 females (individually caged)  Wild rodents | Mortality: 100% between D4 and D8.  Mean palatability: 0.27 for males and 0.24 for females, i.e. a mean palatability of 0.25. | XXX  RI = 1 |
| PT 14 | Indoor and outdoor around buildings | EDI-575\_24  (24 ppm difenacoum)  26 month-aged | Black rat  *R. rattus*  5 males + 5 females (individually caged)  Wild rodents | Mortality: 100% between D6 and D9.  Mean palatability: 0.21 for males and 0.20 for females, i.e. a mean palatability of 0.21. | XXX  RI = 2 |
| PT 14 | Indoor and outdoor around buildings | EDI-575\_24  (24 ppm difenacoum) | House mouse  *Mus musculus*  Wild rodents  Estimated population: 33-34 | Field test in a closed shed in a farm | Census baiting technique: pre-treatment period (10 days) + pre-treatment lag phase (3 days) + treatment (baiting) (15 days) + post- treatment lag phase (3 days) + post-treatment (8 days).  10 feeding stations in the shed, supplied with 20 g of durum wheat semolina during the pre- and post-baiting periods. During the baiting period, feeding stations replaced by 10 lockable bait stations, located at the same places, 2 to 4.5 metres apart.  40 g of bait in each station (2 blocks).  Assessments: daily, food or bait in each station weighted and replenished.  Calculation: mean daily consumption in grams. Efficacy of the baiting treatment: reduction of consumption of food (semolina) after the baiting period = ((daily intake in the pre-baiting period plateau – daily intake in the post-baiting period) / daily intake in the pre-baiting period plateau) \* 100. | Estimated efficacy = 100 %.  Pre-baiting plateau = 170 g/day  Post-baiting = no consumption observed.  No dead mice were found on the study area. | XXX  RI = 2 |
| PT 14 | Indoor and outdoor around buildings | EDI-575\_24  (24 ppm difenacoum) | Brown rat  *R. norvegicus*  Wild rodents  Estimated population: 33-36 | Field test in a farm, in and around hen houses. | Census baiting technique: pre-treatment period (12 days) + pre-treatment lag phase (2 days) + treatment (baiting) (20 days) + post- treatment lag phase (2 days) + post-treatment (8 days).  10 feeding stations in the test area, supplied with 200 g of wheat during the pre- and post-baiting periods. During the baiting period, feeding stations replaced by 10 lockable bait stations, located at the same places, 2 to 15 metres apart.  100 g of bait (5 blocks) in each station.  Assessments: daily, food or bait in each station weighted and replenished.  Calculation: mean daily consumption in grams. Efficacy of the baiting treatment: reduction of consumption of food (wheat) after the baiting period = ((daily intake in the pre-baiting period plateau – daily intake in the post-baiting period) / daily intake in the pre-baiting period plateau) \* 100. | Estimated efficacy = 100 %.  Pre-baiting plateau = 657 g/day  Post-baiting = no consumption observed.  No dead brown rat was found on the study area. | XXX  RI = 2 |
| PT 14 | Indoor and outdoor around buildings | TANTALE C | Black rat  *Rattus rattus*  Wild rodents  Estimated population: 23-27 | Field test in a farm, in and around a sheepfold. | Census baiting technique: pre-treatment period (16 days) + pre-treatment lag phase (3 days) + treatment (baiting) (19 days) + post-treatment lag phase (2 days) + post-treatment (11 days).  Eight feeding stations in the test area, supplied with 200g of oat during the pre- and post-baiting periods.  Baiting period: feeding stations replaced by 8 lockable bait stations, located at different places, 15 metres apart.  200g of bait (4 blocks) in each station.  Assessments: daily, food or bait in each station weighted and replenished.  Calculation: mean daily consumption in grams  Efficacy of the baiting treatment: reduction of consumption of food (oat) after the baiting period = ((daily intake in the pre-baiting period plateau – daily intake in the post-baiting period) / daily intake in the pre-baiting period plateau) \* 100. | Estimated efficacy = 92 %.  Pre-baiting plateau = 463 g/day  Post-baiting = no consumption observed.  No dead black rat was found on the study area. | XXX  RI = 1 |

Regarding the claimed uses, submitted efficacy data are compliant with the requirements of the TNsG PT14 (2009), and results respect the criteria of the TNsG PT14 (2009).

French competent authorities (FR CA) consider that the product TANTALE C has shown sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) at the application rate of 200 g / bait station and, house mice (*Mus musculus*), at the claimed application rate of 40 g /bait station.

Regarding the use of the product in sewers, as there is only a change in the active substance content, palatability of the product is not assumed to be affected so FR CA considers that the study provided for the first authorisation is still acceptable.

Nevertheless, according to the TNsG for product evaluation PT14 (2009), to support a shelf life of 36 months (of the new formulation), test with a 36 months aged product should be submitted.

A free-choice laboratory test was carried out with black rats (*Rattus rattus*), exposed to a 26 months aged EDI 575\_24 formulation. The results are compliant with the criteria of the TNsG PT14 (2009).

The palatability test was performed with aged formulation on black rat, as the lowest palatability was obtained with this species when exposed to a fresh formulation of EDI 575\_24.

Then efficacy is demonstrated on a bait aged of 26 months.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) consider that the elements presented in the dossier confirm, when the concentration of active substance in the formulation is decreased to 0.0025 % w/w difenacoum, the efficacy of the product TANTALE C:  - **for professional users** against house mice (*Mus musculus*), brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) for use in and around buildings, and against brown rats in sewers;  - **for non-professional users** against house mice (*Mus musculus*) for use indoor and against brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) for use in and around buildings;  Moreover, a choice feeding test with a 26 month-aged product (new formulation) against the black rat (*Rattus rattus*) has been submitted. Regarding efficacy, a maximal storage duration of 26 months could be validated. |

* **Renewal application (2019)**

For the renewal of the product TANTALE C (0.0025 % w/w difenacoum), no change in the composition has been declared. The efficacy evaluation is based on the efficacy studies submitted by the applicant for the first authorisation and the major change application.

Based on efficacy studies and physico-chemical data available, a shelf-life of 24 months was authorized for the major change application.

Nevertheless, according to the new guidance TNsG for product evaluation PT14 (2016) in force for the renewal application, to support a shelf life of 24 months, tests with a 24 months aged product should be submitted for all target organisms claimed if the product does not contain any preservative.

As palatability tests performed with aged product on house mice (*Mus musculus*) and black rat (*Rattus rattus*) have not been submitted, only a maximal shelf life of 12 months can be allowed for efficacy section.

Consequently, the product TANTALE C (0.0025 % w/w difenacoum) has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and house mice (*Mus musculus*) at doses claimed with a shelf-life of 12 months.

**2.5.4 Occurrence of resistance (Updated 2017)**

* **Major change application - 2018**

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[[1]](#footnote-2); Lund, 1984[[2]](#footnote-3); Pelz et al. 1995[[3]](#footnote-4)). 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[[4]](#footnote-5)). 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[[5]](#footnote-6)).

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.

**2.5.5 Evaluation of the Label Claims**

The application rates validated are the following:

Rats: (*Rattus norvegicus* and *Rattus rattus)*

80 g up to 200 g product/secured bait point at intervals of 15 m apart.

Mice: (*Mus musculus*)

25 g up to 30 g product/secured bait point at intervals of 3 m apart.

For rat control in sewers: (*Rattus norvegicus)*

100 g per manhole (about 100 m) up to 200 g every 3 manholes.

For rat control in waste water treatment plants: (*Rattus norvegicus)*

100 g up to 200 g product/secured bait point at intervals of 15 m apart.

For the first authorisation, French competent authorities (FR CA) assessed that the product SORKIL BLOC has shown a sufficient efficacy for the control of house mice (*M. musculus*) and rats (*Rattus norvegicus, Rattus rattus*) for a use in and around domestic, industrial and commercial buildings including in farm buildings*;* and for the control of brown rats(*R. norvegicus*) in sewers and waste water treatment plants.

* **Major change application - 2018**

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

The application rates validated are the following:

House mice: 40 g baiting point separated by 3 m.

Rats (*R. norvegicus* and *R. rattus*): 200 g per baiting point separated by 15 m.

Brown rats in sewers: 100 g of bait every 100 m or 200 g of bait every 300 m.

As for rats, field test against black rat has been submitted at the maximal dose claimed, the range 80-200 g cannot be accepted and only the maximal dose of 200 g is validated.

As for mice, no field test has been submitted at the range dose claimed, the range 25-30 g cannot be accepted and only the application rate tested of 40 g is validated.

The use in wastewater treatment plant is included in “in and around the building”.

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

* **Renewal application – 2019**

The application rates validated are the following:

* Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g product/secured bait point separated by 15 m
* Mice (*Mus musculus*): 40 g product/secured bait point separated by 3 m.
* Brown rats in sewers: 100 g of product every 100 m or 200 g of bait every 300 m.

Shelf life: 12 months

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

## Exposure assessment

### Description of the intended use(s) – PAR 2012

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

Table 2.6.1 Summary of intended uses

|  |  |  |
| --- | --- | --- |
| MG/PT | Field of uses envisaged | Likely concentrations at which a.s. will be used |
| Main group 03;  PT 14 | Professional uses | |
| Rodenticide used indoors and outdoors in industrial and commercial buildings including in farm buildings  Use in sewerage and waste water treatment plants (only against rats) | 0.005% w/w |
| Non-professional uses | |
| Rodenticide used indoors in domestic areas | 0.005% w/w |

SORKIL BLOC is intended to be used for control of mice *(M. musculus)*, brown rats *(R. norvegicus)* and black rats *(R. rattus)* in and around domestic, industrial and commercial buildings including in farm buildings, and for control of brown rats in sewers and in waste water treatment plants. The control of mice and rats is based on the principle of applying baits on infested areas with obvious tracking of faeces, and smears next to holes and harbourages.

The product is ready-to-use block 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 secured bait boxes or bait stations or fixed using a wire attached to an existing anchor when used in sewerage.

For rat control, the recommended dose is 80 g up to 200 g of product at intervals of 15 meters apart. For mouse control, the recommended dose is 25 g up to 30 g of product at intervals of 3 meters apart.

For rat control in sewers, the recommended dose is 100 g per manhole (about 100 m) up to 200 g every 3 manholes .

For rat control in waste water treatment plants, the recommended dose is 100 g to 200 g at intervals of 15 meters apart.

* **Renewal application – 2019**

TANTALE C is intended to be used:

* by professional users against house mice (*Mus musculus*), brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) in and around buildings, and against brown rats in sewers;
* by non-professional users against house mice (*Mus musculus*) indoor only and against brown rats (*Rattus norvegicus*) and black rats (*Rattus rattus*) in and around buildings.

The application rates intended to be used are the following

* Rats (*Rattus norvegicus* and *Rattus rattus*): 200 g bait/secured bait point separated by 15 m.
* Mice (*Mus musculus*): 40 g bait/secured bait point separated by 3 m.
* Brown rats in sewers: 100 g of bait every 100 m or 200 g of bait every 300 m.

### Assessment of exposure to humans and the environment – PAR 2012

**Assessment of human exposure**

No new human exposure studies have been submitted. In the dossier, Edialux assessed the human exposure based on the default values of the TNsG on human exposure, 2007[[6]](#footnote-7). Therefore, since Edialux provided a letter of access for the CEFIC unpublished study “*Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits*” of Chambers J.G. and Snowdon P.J. (2004)[[7]](#footnote-8); 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 of difenacoum. This study examined exposure to 20 g wax block baits containing flocoumafen (five blocks/bait box) using 10 replicates for each measurement. This study is considered as representative of the human exposure of wax block rodenticide baits. Considering that a similar application/manipulation is expected for wax and cereal blocks, the FR CA decided to use the exposure estimations from the CEFIC study for the assessment of SORKIL BLOC.

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 (see argumentation in the Assessment report on difenacoum).

Additionally, the Human Exposure Expert Group (HEEG) opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant)[[8]](#footnote-9), agreed at the European Technical meeting TMII2010 was taken into account for the estimation of exposure for professionals and non professionals.

## Risk assessment for human health

* **Major change application - 2018**

The major change request is a decrease in the s.a content (from 50 ppm to 25 ppm) and the addition of a non-professional use (formulation provided in sachet PE or PP for the use against rats and mice).

TANTALE C is a ready-to-use rodenticide containing 0.0025% of difenacoum.

For professional users, blocks between 20 and 200g are naked or packaged in individual PE or PP sachet to be used in tamper-resistant bait stations or in covered and protected baiting points.

For non-professional users, blocks between 20 and 200g are packaged in individual PE or PP sachet to be used in tamper-resistant bait stations.

The baits are placed in and around buildings and in sewers.

### Hazard potential – PAR 2011, updated 2017

#### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements of Directive 98/8/EC. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 3 of this report “Toxicology and metabolism” of this report must be taken into consideration.

The following corresponds to the summary of the derivation of the AELs from the Doc I of the final CAR of difenacoum:

*“The lowest LOAEL in a repeated dose study, i.e. the teratogenicity study in rabbits, is chosen as the basis to establish the AOEL (there was no NOAEL). In this study, the maternal LOAEL was 0.001 mg/kg bw/day. Default assessment factors of 10 for inter-species variability and 10 for inter-individual variability are applied. Furthermore, due to the toxicological significance and uncertainty in the database, an additional safety factor of 3 for teratogenicity is used for all anticoagulant rodenticides according to the agreement during peer-review discussion. A further supportive argument for an additional assessment factor comes from the higher potency of the second generation anticoagulants compared to warfarin, and from the much higher vulnerability of human foetuses to vitamin K deficiency compared to rodents. To extrapolate from LOAEL to NOAEL an assessment factor of 2 is considered justified due to the deep slope of the dose response curve. After correction for bioavailability of 68%, a NOAEL for MOE (0.00034 mg/kg bw/day) and an AOEL of 0.0000011 mg/kg bw/day are used for risk characterisation. These values are applied both to acute and repeated exposure scenarios.”*

#### 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[[9]](#footnote-10), “*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*”, SORKIL BLOC does not contain any substance of concern.

* **Renewal application for TANTALE C – 2019**

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

According to the “Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)” no substance of concern is identified for the product.

#### Toxicology of the biocidal product

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

The basis for the health assessment of the biocidal product is laid out in Annex 4 of this report ”Toxicology – biocidal product”.

Both SORKIL BLOC and SORICIDE DB are block bait formulations containing 0.005% (w/w) difenacoum with the same use and user type. The comparison of the compositions of SORICIDE DB and SORKIL BLOC shows that a read-across from SORICIDE DB data to SORKIL BLOC dossier is acceptable.

The data of SORICIDE DB are the followings:

Acute dermal toxicity, skin and eye irritation and skin sensitisation studies have been carried out on the product containing 0.005% of difenacoum, according to the OECD guidelines.

Justifications for non-submission of data have been submitted for acute oral and inhalation toxicity studies and dermal absorption study.

* Acute dermal toxicity

No effects were observed during the duration of the study or noted at necropsy in the acute dermal toxicity study. Therefore, the LD50 of the test item SORICIDE DB is higher than 2000 mg/kg body weight by dermal route in the rat.

Based on the results, no classification is required for SORICIDE DB and thus, for SORKIL BLOC.

* Irritation and corrosivity

A slight erythema was observed on the treated area of two animals one hour after the patch removal. This erythematous reaction was totally reversible between day 1 and day 2. The average scores (24, 48, 72 h) were 0.11 and 0.0 for erythema and for oedema, respectively. The ocular conjunctivae reactions observed during the eye irritation study have been slight to moderate and totally reversible in the three animals.

* Based on the results of the irritation guideline assays on rabbit’s skin and eye, no classification is required for SORICIDE DB and thus, for SORKIL BLOC.
* Sensitisation
* A non-radioactive LLNA using cell counting was submitted. This method is not currently validated. Furthermore, according to the publication of Basketter *et al[[10]](#footnote-11),* the “*proposed non-RI LLNA[[11]](#footnote-12) uses cell number as a correlate of cell proliferation, but, as other modifications to the standard LLNA were also made, the method constitutes a major change*.” Therefore this test was considered non acceptable by the RMS.
* Based on the composition of SORKIL BLOC, no ingredients were listed as a skin sensitizer. Therefore, it is expected that this product is not a skin sensitizer.

Justification for non-submission:

* Dermal absorption

A dermal absorption percentage of 0.047% for wax block bait, based on an in vitro study on human skin, was used for the risk characterisation in compliance with the assessment report on difenacoum of Activa/Pelgar[[12]](#footnote-13). Consequently, the justification for non-submission of data is acceptable.

* Acute oral and inhalation toxicity

According to the CLP exemptions rules based on calculations, the product would not be classified for its acute oral toxicity.

Concerning the inhalation route, as the preparation is neither a gas nor a volatile liquid, nor a powder and the application method does not generate aerosol, particles or droplets in an inhalable size range (MMAD < 50 µm), it can be considered that inhalatory exposure is not a relevant route of human exposure.

In conclusion, the justifications for non-submission of data are considered as acceptable.

The harmonised classification of the active substance is the following:

|  |  |
| --- | --- |
| Classification under directive 67/548/EEC | Classification under regulation (EC) 1272/2008 |
| T+ R28  T R48/25  N, R50/53  No specific concentration limit | Acute Tox. 2 H300  STOT Rep. 1 H372  Aquatic. Acute 1 H400  Aquatic Chronic 1 H410  No specific concentration limit |

Based on the results of the studies, the concentration of the active substance and of the compounds contained in the product and according to the above classification, SORKIL BLOC is not classified.

* Other studies

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

In addition, the product is not intended to be used in feedingstuff and no industrial processing or domestic preparation is intended. Therefore, no data on residue was submitted.

* **Major change application - 2018**

For the major change request, no new data has been submitted.

However, a read across with the studies presented in the initial PAR for the product at 0.005% of difenacoum is proposed considering that the change will have no impact on classification because it consists in:

- A decrease of several co-formulants

- An increase of two co-formulants not classified and

- A light increase (<0.1%) of a co-formulant classified for eye irritation.

**Information on dermal absorption**

The major change request is a decrease in the s.a content (from 50 ppm to 25 ppm).

Since no new data has been submitted, a read across with the dermal absorption study provided in the initial dossier is proposed. According to the EFSA guidance, in the absence of data, a pro-rata correction, assuming a linear response of dermal absorption, should be considered appropriate.

However, due to the nature of the tested formulations (wax blocks) and the very low active substance concentrations, no major change in dermal absorption is expected. Therefore, no correction pro-rata is applied.

For the risk assessment, a dermal absorption value of 0.047% has been used.

**Conclusion on classification:**

Based on the results of the studies, the concentration of the active substance and of the co-formulants contained in the product, a classification STOT RE 2 H373 is needed.

* **Renewal application for TANTALE C – 2019**

For the renewal request, no new toxicological data has been submitted.

No change is necessary for the renewal of the product: a classification STOT RE 2 H373 is needed and the for the risk assessment, the dermal absorption value remains 0.047%.

### Exposure

SORKIL BLOC is a ready-to-use block bait with no dilution and or other substances added for application. It contains 0.005% (w/w) of difenacoum (purity: 960 g/kg). It is manually applied by trained professional users and by non-professional users in secured bait boxes or bait stations or fixed using a wire attached to an existing anchor when used in sewerage by trained professional users.

SORKIL BLOC is provided into three different kinds of packaging: block in bulk, block packed individually and pre-filled bait station. Concerning the last one, the exposure is considered as negligible during the first application. However, if they are refilled with recharge baits (bulk or individually packed), the exposure will be similar to the exposure scenario presented in the followings paragraphs for professional or non-professional users.

#### Exposure of professional users

**Primary exposure**

The product is used indoors and outdoors in industrial and commercial buildings including in farm buildings. There is a usage in sewerage and waste water treatment plants (only against rats). In the case of application in the sewers, the exposure of sewermen is considered as covered by that of professional users during the loading and cleaning of bait boxes. Consequently, the assessment below covers both modes of application (indoors/outdoors and sewerage).

During professional use, the major route of primary exposure is dermal. The inhalation exposure could be considered as a non-relevant route of human exposure considering the low vapour pressure of difenacoum (< 5x10-5 Pa at 45°C based on an Activa/Pelgar estimation) and of the other compounds. Moreover, the preparation is neither a gas nor a volatile liquid, nor a powder. The application method does not generate aerosol, particles or droplets in an inhalable size range (MMAD < 50 µm).

Based on all the measured exposure data (75th percentile) in the CEFIC study, the amount of exposure to product **during loading** of 5 wax blocks per one manipulation was 27.79 mg (value adopted by the HEEG). The following parameters were taken into account for the treatment against rats:

* Active substance in product: 0.005%,
* Number of blocks per bait site: 10
* Dermal absorption: 0.047% (value adopted by FI RMS in the CAR of difenacoum and applicable for all wax blocks),
* Body weight: 60 kg.

The number of blocks per bait site (10 blocks) is determined to reach a dose of at least 200 g (10 blocks of 20 g) which is the efficient dose for rat. The smallest size of block (20 g) is actually used as a worst case since the number of manipulations and thus, the exposure will be higher than for block which has a bigger size.

Consequently, the systemic dose of difenacoum per placing of one bait site is 2.18 x10-8 mg/kg bw/event.

Based on all the measured exposure data (75th percentile) in the CEFIC study, the amount of exposure to product is 5.70 mg **during the cleaning** of one bait site (value adopted by the HEEG). Considering a content of 0.005% of difenacoum in the product, a dermal absorption of 0.047% and a body weight of 60 kg, the systemic dose of difenacoum per cleaning of one bait site is 2.23x10-9 mg/kg bw/event[[13]](#footnote-14).

In application of the HEEG opinion agreed at the European Technical meeting TM III 2010 about the harmonized number of manipulations for rodenticides anticoagulant, 60 loadings and 15 cleanings per day were taken into account for the exposure assessment. Based on these values, the systemic dose via skin is 1.34x10-6 mg a.s/kg bw/day. The exposure is reduced by a factor of 10 down to 1.34x10-7 when gloves are worn (10% gloves penetration factor). According to the HEEG opinion agreed at the European Technical meeting TMI10 (default protection factors for protective clothing and gloves), a further refinement is possible considering a glove penetration factor of 5% for solids. In this case, the total systemic dermal exposure is 6.70x10-8 mg/kg bw/day.

The estimations above are representative for exposure to SORKIL BLOC in bulk but for the packaging in sachet, they represent a very worst case. In this case, it can be assumed that no exposure is expected during loading in bait points as the sachet prevents dermal and inhalative contacts. Therefore, only exposure during cleaning can be considered: 3.35x10-8 mg a.s/kg bw/day without gloves and 3.35x10-9 mg a.s/kg bw/day with gloves (10% penetration factor).

**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 difenacoum is expected on the fur because SORKIL BLOC is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for difenacoum).

In Annex 5 “Safety for professional operators” of this report, the results of the exposure calculations for the active substance for the professional user are laid out.

#### Exposure of non-professional users and the general public

**Primary exposure**

During non-professional use, the major route of exposure is dermal. The inhalation exposure could be considered as a non-relevant route of human exposure, like for professional users.

As a worst case, the same assumptions as for professional exposure was considered except for the number of manipulations set at 5 loadings and 5 cleanings per day for non-professional according to the HEEG opinion document and in the absence of PPE. The systemic exposure via skin is therefore at 1.20x10-7 mg a.s/kg bw/day.

The estimations above are representative for exposure to SORKIL BLOC in bulk but they represent a very worst case, since SORKIL BLOC is only supplied and applied in sachet for non-professional uses. It can be assumed that no exposure is expected during loading in bait points as the sachet prevents dermal contacts. Therefore, only exposure during cleaning can be considered: 1.12x10-8 mg a.s/kg bw/day.

**Secondary exposure**

Exposure of non-users, especially infants, could result from the handling of dead rodents or ingesting poison baits. The “*handling of dead rodents*” scenario is excluded due to unrealistic assumptions (very low amount of difenacoum is expected on the fur because SORKIL BLOC is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for difenacoum).

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the AEL of 1.1x10-6 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 68% (as stated in the Assesment report of difenacoum [Activa/Pelgar Study]), ingestion of more than 0.3 mg of product per day is needed to exceed the AEL.

In Annex 6 “Safety for non-professional operators and the general public” of this report, the results of the exposure calculations for the active substance for the non-professional user and the general public are laid out.

#### Exposure to residues in food

Since no contamination is expected for feeding stuffs, no residue assessment was performed (Annex 7 “Residue behaviour”).

* **Renewal application - 2019**

Since no contamination is expected for feeding stuffs, no residue assessment was performed (Annex 8 “Residue behaviour”).

Difenacoum is approved under PPP regulation 2009/70. Default MRL of 0.01 mg/kg exists on all commodities according to Art 18(1)(b) of Regulation 396/2005.

As no food exposure is expected from the intended use, no MRL exceedance is foreseen.

* **Major change application - 2018**

The product TANTALE C is a block bait, ready to use, packaged in sachets or in bulk. The product is available in several packaging and can be used by general public and professionals users.

The product can be used indoor and outdoor around buildings, in domestic, industrial and commercial buildings including farm buildings.

It can also be used by professionals in sewers against brown rats (*Rattus norvegicus*).

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

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a | No | No | n.a | n.a | No | n.a |
| Dermal | n.a | Yes | Yes | n.a | n.a | No | n.a |
| Oral | n.a | No | No | n.a | n.a | Yes | n.a |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Primary dermal exposure during loading and cleaning phases | **Primary dermal exposure**  The product is a ready-to-use product supplied in block (”naked” or in sachets); therefore exposure during loading and cleaning is considered. | Professional user |
| 2. | Primary dermal exposure during loading and cleaning phases | The product is a ready-to-use product supplied in block (in sachets PE or PP); therefore only exposure during cleaning is expected due to the presence of sachet.. | Non-professional user |
| 3. | Ingestion of product by an toddler | **Secondary exposure**  Oral exposure of toddler by ingestion of a piece of bait. | General public - toddler |

***Industrial exposure***

Not applicable.

***Professional exposure***

*Scenario [1] Primary dermal and inhalation exposure during loading and cleaning phases for professional users*

| **Description of Scenario [1]** | | | | |
| --- | --- | --- | --- | --- |
| The product is a ready to used product in PE or PP sachet or naked.  As a first tier appraoch, the sachet is not taken into account. This scenario covers the use of sachet for which only exposure during cleaning is expected.  According to the HEEG opinion 10 , an exposure phase of 60 loadings and 15 cleanings is considered.  Dermal exposure is based on the HEEG opinion 12: Harmonised approach for the assessment of rodenticides.  As a worst-case, the application dose of 200g for the use against rat considering blocks of 20g is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered. | | | | |
|  | Parameters1 | Unit | Value | Source |
| Tier 1 | Amount of exposure to product (75th percentile) during loading | mg | 27.79 | HEEG opinion 12 |
| Amount of exposure to product (75th percentile) during clean-up | mg | 5.7 | HEEG opinion 12 |
| Manipulation per day | - | 60 loading and 15 cleaning | HEEG opinion 10 |
| Dermal absorption value | % | 0.047 | - |
| Concentration of a.s in the product | % | 0.0025 | - |
| Body weight | kg | 60 | - |

**Calculations for Scenario [1]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1] | Tier 1 (no PPE) | - | 6.7 x 10-7 | - | 6.7 x 10-7 |

*Combined scenarios*

Not applicable.

***Non-professional exposure***

*Scenario [2]: Primary dermal and inhalation exposure during loading and cleaning phases for non-professional users*

| **Description of Scenario [2]** | | | | |
| --- | --- | --- | --- | --- |
| The product is a ready to used product in PE or PP sachet.  With the use of sachet, only exposure during cleaning is expected. However, as a conservative approach, exposure is determined considering the exposure during loading and cleaning phases.  According to the HEEG opinion 10 , an exposure phase of 5 loadings and 5 cleanings is considered.  Dermal exposure is based on the HEEG opinion 12: Harmonised approach for the assessment of rodenticides.  As a worst-case, the application dose of 200g for the use against rat considering blocks of 20g is taken into account; the dose for the use against mice being lower, the exposure assessment is considered covered. | | | | |
|  | Parameters1 | Unit | Value | Source |
| Tier 1 | Amount of exposure to product (75th percentile) during loading | mg | 27.79 | HEEG opinion 12 |
| Amount of exposure to product (75th percentile) during clean-up | mg | 5.7 | HEEG opinion 12 |
| Manipulation per day | - | 5 loading and 5 cleaning | HEEG opinion 10 |
| Dermal absorption value | % | 0.047 | - |
| Concentration of a.s in the product | % | 0.0025 | - |
| Body weight | kg | 60 | - |

**Calculations for Scenario [2]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2] | Tier 1 (no PPE) | - | 6.0 x 10-8 | - | 6.0 x 10-8 |

*Combined scenarios*

Not applicable.

1 Please include the Tier where relevant

***Exposure of the general public***

*Scenario [3]*

The estimation of general public exposure is considered covered by the initial assessment.

Therefore, please refer to the product assessment report related to SORKIL BLOCK product authorisation under Regulation UE n° 528/2012*.*

***Monitoring data***

*None*

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

*Not applicable*

***Aggregated exposure***

*Not applicable*

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Professionals | Tier 1 (No PPE) | 6.7 x 10-7 |
| 2. | Non professionals | Tier 1 (No PPE) | 6.0 x 10-8 |

### Risk characterisation

#### Risk for professional users

The estimated exposures for the professional users are compared to the systemic AEL of difenacoum set in the Assessment report (1.1x10-6 mg/kg bw/day for short, medium and long-term exposures).

**Primary exposure**

Based on the risk assessment of the active substance, the risk for professional users when SORKIL BLOC is supplied in bulk could be considered as acceptable only with the wear of gloves, based on the %AEL of 12% with a glove penetration factor of 10 % (122% without gloves). Moreover, gloves are recommended to help preventing rodent-borne disease.

For SORKIL BLOC supplied and applied in sachet, exposure can be expected only during cleaning. In this context, the risk resulting from the intended use is acceptable even if professionals are not wearing gloves (%AEL at 3%). Additionally, gloves are anyway recommended to help prevention against rodent-borne disease.

The conclusion is the same for the pre-filled boxes. Consequently, the rechargement of the boxes must be done with the wear of gloves in the case of bulk and without gloves for sachet. The risks are thus, considered as acceptable for professional users.

The results of the risk characterisation for mice control are, consequently, considered as acceptable for SORKIL BLOC supplied in bulk or in sachet applied by a professional user, as only one block of 25 g is sufficient to be efficient. The total dermal exposure corresponds to 14.9% of the AEL without gloves. Even if a block of 20 g exists, the potential risks is covered by those calculated for rats as only 2 blocks of 20 g would be efficient to control mice.

Furthermore gloves are recommended to help prevention against rodent-borne disease.

**Secondary exposure**

As no secondary exposure is expected for professional users, no risk has been identified.

#### Risk for non-professional users and the general public

The estimated exposure for the non-professional users is compared to the systemic AEL of difenacoum set in the Assessment report (1.1x10-6 mg/kg bw/day for short, medium and long-term exposures).

**Primary exposure**

Based on the risk assessment of the active substance, the risk for non-professional users resulting from the intended use is acceptable, even considering an exposure to a bulk (%AEL at 11%). The %AEL for a sachet is 1%. For the pre-filled boxes, the risks are thus, considered as acceptable for non-professional users.

The results of the risk characterisation for mice control are, consequently, considered as acceptable for SORICIDE DB supplied in bulk or in sachet applied by a non-professional user, as only one block of 25 g is sufficient to be efficient. Even if a block of 20 g exists, the potential risks is covered by those calculated for rats as only 2 blocks of 20 g would be efficient to control mice.

**Secondary exposure**

Based on a reverse scenario, more than 0.3 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 (corresponding to about 0.0015 % of a 20 g piece of SORKIL BLOC). Therefore, even if SORKIL BLOC contains a bittering agent which reduces the likelihood of ingestion, the baits should be placed in bait boxes which do not allow access to children in secured areas. Product label (“do not open the sachet”) and good practice must advise users preventing access to bait by children and infants.

#### Risk for consumers via residues

Since no contamination is expected for feeding stuffs, the risk for consumers via residues was not assessed.

#### Summary of risks characterisation for SORKIL BLOC

**Treatment against rats:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL  (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% AEL** | **Conclusion** |
| **bulk formulation (exposure during decanting, loading and cleaning phases)** | | | | |
| Professional (without gloves) | 1.1 x 10-6 | 1.34x10-6 | 122 | Unacceptable |
| Professional (with gloves ; penetration factor of 10 %) | 1.1 x 10-6 | 1.34x10-7 | 12 | **Acceptable** |
| Non professional | 1.1 x 10-6 | 1.20x10-7 | 11 | **Acceptable** |
| **sachet formulation (exposure during cleaning phase)** | | | | |
| Professional (without gloves) | 1.1 x 10-6 | 3.35x10-8 | 3 | **Acceptable** |
| Non professional | 1.1 x 10-6 | 1.12x10-8 | 1 | **Acceptable** |

* **Major change application - 2018**

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600  (safety factor of 300 and a safety factor of 2 due to extrapolation from LOAEL to NOAEL) | Yes, 68% | 0.0000011 mg/kg bw/day |
| AELmedium-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600  (safety factor of 300 and a safety factor of 2 due to extrapolation from LOAEL to NOAEL) | Yes, 68% | 0.0000011 mg/kg bw/day |
| AELlong-term | Teratogenicity in rabbit | LOAEL = 0.001 mg/kg bw/day | 600  (safety factor of 300 and a safety factor of 2 due to extrapolation from LOAEL to NOAEL) | Yes, 68% | 0.0000011 mg/kg bw/day |
| ARfD | Not applicable |  |  |  |  |
| ADI | Not applicable |  |  |  |  |

*[Please insert rows for additional reference values if necessary, e.g. for local effects.]*

***Risk for industrial users***

Not applicable.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1 | Tier 1 (No PPE) | 1.1 x 10-6 | 6.7 x 10-7 | 61 | Yes |

**Conclusion**

The risk for professional users is considered acceptable with no PPE.

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

* **Renewal application for TANTALE C – 2019**

The conclusions are not changed for the risk assessement for the professional.

***Risk for non-professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 2 | Tier 1 (No PPE) | 1.1 x 10-6 | 6.0 x 10-8 | 5.5% | Yes |

**Conclusion**

The risk for non professional users is considered acceptable with no PPE.

* **Renewal application for TANTALE C – 2019**

The conclusion is not changed for the risk assessement for the non professional.

***Risk for the general public***

**Systemic effects**

The risk for the general public is considered covered by the initial assessment.

Therefore, please refer to the product assessment report related to SORKIL BLOC product authorisation under Regulation UE n° 528/2012*.*

* **Renewal application for TANTALE C – 2019**

The conclusion is not changed for the risk assessement ofor the general public.

## Risk assessment for the environment – PAR 2012

### Fate and distribution of the active substance, difenacoum, in the environment

The summary of information about the active substance is carried out with the data from the CAR of difenacoum owned by the Activa/Pelgar difenacoum & brodifacoum Task Force. No new ecotoxicological information on the active substance Difenacoum has been submitted in the product dossier.

#### Biodegradation of difenacoum

According to the OECD tests 301B and 302D, Difenacoum is not readily or inherently biodegradable. No studies on degradation in soil is available, but using the calculated value of Kp of 1.34 and considering the absence of biodegradation of difenacoum, it can be assumed that half life in soil is over 300 days. It was assumed during technical meeting (TMII-04) that no further degradation studies are needed for intended uses in sewers and in and around building.

So the risk assessment is based on the assumption that Difenacoum is not readily biodegradable and that the half life in soil is over 300 days.

#### Hydrolysis as a function of pH

According to the test OECD 111, the half-life (DT50) of difenacoum is over 1 year at pH 4, 7 and 9 at 25°C. The active substance is hydrolytically stable.

#### Photolysis in water

The active substance undergoes rapid photodegradation. Half-life varied from 0.6 hours to 3.8 hours. Greater than 80% photolysis was noted to have occurred by around five hours. Two breakdown products above 10% of the initial difenacoum concentration were detected and the proposal for the identification of structures was made. The photodegradation is regarded as a minor removal process for difenacoum and the exposure to water is low, therefore it was stated that no further characterisation of metabolites was requested.

#### Photodegradation in air

Photodegradation characteristics of the active substance have been estimated using the EPIWIN v. 3.12 models in the CAR of the Task Force Difenacoum dossier. Difenacoum has an estimated half-life of approximately 2 hours, therefore it is predicted to have a negligible effect on stratospheric ozone. It is predicted not to be a potential greenhouse gas. Finally, difenacoum has a low volatility (Henry’s law constant< 0.046 Pa.m3.mol-1) and emissions to the air compartment are expected to be low.

#### Distribution

##### Adsorption/desorption

The experimentally derived Koc value is not supported by the physical and chemical properties of difenacoum. Difenacoum is a large aromatic molecule with two polar groups which can potentially ionise at environmental relevant pH. Difenacoum has also a low water solubility and a high log Kow.

According to the Technical Guidance Document (TGD)[[14]](#footnote-15) (Part 3, Table 4) the QSAR equation used to calculate log Koc from log Kow (7.62, QSAR estimation) is:

**log Koc = 0.81 log Kow + 0.1**  (chemical class: Predominantly hydrophobics)

The properties of difenacoum may hamper the estimation of log Kow that is why it should be considered with some caution. The calculated log Koc is 6.27 and Koc = 1 871 544.

In the difenacoum dossier it has been stated that, according to its behaviour, the active substance would not be mobile and would be expected to absorb irreversibly to soil particles. Significant leaching could be expected to occur only in recently contaminated soil under alkaline conditions. Under other conditions, binding to the inorganic component of soil would be largely irreversible. The rate of binding is likely to be limited by steric hindrance of reaction in forming the cation bridge from the organic material.

##### Accumulation

The aquatic BCF has been estimated with calculation method because the fish bioconcentration test was invalid. In the absence of valid measured log Kow, the estimated value of log Kow used is 7.6. This value allows to calculate an estimated BCF for fish: 9010 (according to EPIWIN v 3.12) and 35 645 (Equation 75, TGD).

In order to remain coherent with the Annex I inclusion dossier, BCF for fish value of 9010 is used to perform secondary poisoning evaluation via aquatic trophic chain.

This log Kow is also entered the equation 82d of the TGD to get a BCFearthworm equal to 477 729.

The calculations show that difenacoum has a considerable bioaccumulation potential in aquatic and terrestrial organisms.

### Effects of the active substance on environmental organisms

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

Difenacoum is very toxic to aquatic organisms. Difenacoum was equally toxic to fish (LC50= 0.33 mg a.s/L, OECD 203), daphnia (EC50= 0.91 mg a.s/L, OECD 202) and algae (EbC50 =0.14 mg a.s/L, OECD 201). Nevertheless, a lower fish test result (LC50=0.064 mg/L) is available in the difenacoum dossier of Sorex Limited. Therefore, it is used for the derivation of PNECwater in the Difenacoum Task force Annex I inclusion dossier as recommended in the CAR.

In the absence of any ecotoxicological data for sediment-dwelling organisms, the PNECsediment was calculated using the equilibrium partitioning method.

Difenacoum has shown to degrade photolytically in water in laboratory conditions and it may form degradation products exceeding 10% of the parent compound. The metabolites are not considered to have ecotoxicological significance, because photolysis is considered to be a minor transformation path for difenacoum and the exposure to water via the STP is expected to be low.

Difenacoum did not cause any effects on the activated sludge respiration inhibition up to the nominal concentration of 999.7 mg/L (OECD 209). Because all test concentrations exceeded the water solubility of Difenacoum, the water solubility of 0.48 mg/L will be used as PNECSTP.

#### Atmosphere

No data are available on the biotic effects in the atmosphere. Difenacoum is not expected to con-tribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

#### Terrestrial compartment

Difenacoum caused no toxic effects on earthworms up to the nominal concentration of 994 mg/kg dry weight (OECD 207). Difenacoum may not be bioavailable to earthworms in soil which would explain the low toxicity. No studies on soil microorganisms or plants were submitted.

The photolysis degradation products are not considered ecotoxicologically relevant because the direct exposure of difenacoum to soil is expected to be low.

Toxicity of difenacoum in birds increased with exposure time. Difenacoum was considered as moderately toxic in acute oral exposure (LD50= 153 mg/Kg bw), toxic in 5-day dietary test (LC50=1.4 mg/Kg feed) and very toxic in the reproduction test (NOEC= 0.31 mg/Kg water, exposure via drinking water). Several dose related effects were detected in the reproduction test: increased adult mortality, increased mortality of 14-day old hatchlings, increased liver and spleen weights in adult females, a declining trend in number of eggs laid/hen/day, declining trend in viability of eggs. Due to methodological deficiencies the reproduction test is not considered to represent the worst case, and therefore the PNECoral of birds was derived from the dietary test. Difenacoum is very toxic to mammals, and rats seem to be particularly susceptible. The PNECoral for birds and mammals has been used for the risk characterization of primary and secondary poisoning.

#### PBT Assessment

Due to the properties of persistence, accumulation and toxicity of difenacoum, this substance fulfills the PBT criteria.

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

As already stated in the previous sections, difenacoum is concern for bioaccumulation with a calculated log Kow of 7.62, a high predicted aquatic BCF of 9 010 (US EPA EPIWIN) or 35 645 (TGD) and a high predicted terrestrial BCF of 477 729 (TGD). The active substance is not readily biodegradable and is of low solubility (0.5 mg/L pH7). Therefore, difenacoum has a considerable bioaccumulation potential in aquatic and terrestrial organisms.

The primary concern is from predators eating the rodent carcasses and earthworms which have ingested the active substance absorbed to soil. In guidance document for TP14, the active substance is considered to be placed in protected bait point. Therefore, a risk should be taken into account for primary poisoning mainly for birds and mammals of equal or smaller size than the target rodents. Also when target animals carry bait away from e.g. bait stations, non-target animals may be exposed. For the risk characterization of primary poisoning, the PNECoral described in section 2.8.2.6 will be used.

Also requiring consideration are predators eating fish or earthworms which have accumulated difenacoum from water and soil. The secondary exposure should be taken in consideration. The applicant has submitted, in the Annex I inclusion dossier, one acceptable study report where effects of difenacoum are studied in Barn Owls which have been exposed to poisoned mice. However, the PNECoral for birds and mammals are derived from a bird 5-day dietary test and a 90-day subchronic test in rat provided in the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier as described below (part 2.8.2.6).

#### Effects assessment of metabolites formed in target organisms

A metabolism study presented in the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier (doc IIIA-6.4 of the CAR) shows that total excreted radioactivity in rat faeces and urine (7 days after single dosing, low and high dose) was 41-71% of the dose administered. Two major faecal metabolites F7 and F8 (max 11.3% and 7.3%, respectively) were identified as isomers of hydroxylated difenacoum. Two other major metabolites, F5 and F6 (max 12.2% and 8.0 %, respectively) were characterised as isomers of difenacoum-based structure which formed glucuronide conjugates. Unchanged difenacoum was present at maximum at 2.9 %. The excretion and retention of radioactivity was also investigated after the final dose following administration of seven consecutive daily oral doses, no substantial differences in excretion patterns between single and repeated level oral doses was observed.

No information on toxicity of these four major metabolites is available. Considering that the metabolites could be potent as anticoagulants, the sum of these four metabolites and unchanged difenacoum in faeces will be taken into account in PEC calculation with assumption that the toxicity of metabolites is comparable to parent (data from the validated CAR of the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier). Therefore in the environmental exposure calculations, it is assumed that 40% of excreted amount in urine and faeces is metabolised and that 40 % of administered total amount is unchanged difenacoum in faeces (data from the validated CAR of the Activa/Pelgar Difenacoum Task Force Annex I inclusion dossier). These assumptions represent a worse case for release.

#### Summary of PNEC

##### PNEC for aquatic organisms:

The PNECwater is derived from the lowest available LC50 value 0.064 mg/L (fish test) with an assessment factor of 1000 as only data on acute toxicity is available. Therefore,

**PNECwater = 0.06 μg/L**

##### PNEC for sediment-dwelling organisms:

In the absence of data on sediment-dwelling organisms, the PNECsediment is derived from the equilibrium partitioning method.

**PNECsediment = 2.51 mg/kg wet weight.**

##### PNEC for STP micro-organisms:

As described in section 2.8.2.1, the water solubility of 0.48 mg/L will be used as the PNECSTP.

**PNECSTP = 0.48 mg/L**

##### PNEC for terrestrial organisms:

The PNECsoil is derived from the experimental data. An assessment factor of 1000 was applied to the LC50 > 994 mg/kg issued from an earthworms study to derive the PNECsoil.

PNECsoil = 0.994 mg/kg dry weight (0.877 mg/kg wet weight)

Nevertheless, as only one experimental test result is available, the PNECsoil derived with the equilibrium partitioning method (EPM) from the aquatic PNEC has also been taken into account:

PNECsoil = 2.04 mg/kg wet weight

Because the PNECsoil derived from the earthworms test is lower, it will be used for the risk characterization. So,

**PNECsoil = 0.994 mg/kg dry weight (0.877 mg/kg wet weight)**

##### PNEC for birds and mammals

PNECoral for birds is derived from the LC50 of 1.4 mg/kg food origin from the 5-day dietary test. The appropriate assessment factor according to the TGD is 3000. In order to transform the LC50 to LD50, LC50 is multiplied with average food consumption (13.5 g) and divided by average body weight 71.3 g. The food consumption and body weight are averaged for all treatment groups and over the 5-day exposure period. The resulting LD50 is 0.3 mg/kg bw/d. The PNECoral value kept for the risk assessment is:

**PNECoral for birds = 0.5 μg/kg food** equivalent to

**PNECoral for birds = 0.1 μg/kg bw/d**

PNECoral for mammals is derived from the NOAEL of 0.03 mg/kg bw/d origin from the 90-day subchronic test in rat (A6.4.1). The NOAEL is transformed to NOEC (concentration in food) by multiplying with the conversion factor of 20 (TGD, Table 22). The appropriate assessment factor according to the TGD is 90. The PNECoral value kept for the risk assessment is:

**PNECoral for mammals = 7 μg/kg food** equivalent to

**PNECoral for mammals = 0.3 μg/kg bw/d**

The PNECoral for birds and mammals have been used for the risk characterization of primary and secondary poisoning.

**Table 2.8.2.7: summary of the difenacoum PNECs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Compartment** | | **Test Value** | **AF** | **PNEC Unit** |
| Aquatic | PNECwater | LC50 =0.064 mg/l | 1000 | 0.064 µg/L |
| PNECsediment | PNECwater in eq. 70 (TGD) | | 2.51 mg/kg wet weight |
| PNECSTP | Water solubility= 0.48 mg/l | | 0.48 mg/L |
| Terrestre | PNECsoil | LC50 >994 mg/kg | 1000 | 0.994 mg/kg dry weight  0.877 mg/kg wet weight |
| PNECoral for birds | LC50 =1.4 mg/kg food  LD50= 0.3 mg/kg bw/d | 3000 | 0.5 μg/kg food eq. to  0.1 μg/kg bw/d |
| PNECoral for mammals | NOEC= 0.6 mg/kg food  NOAEL=0.03 mg/kg bw/d | 90 | 7 μg/kg food eq. to  0.3 μg/kg bw/d |

### Effects on environmental organisms for biocidal product

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product SORKIL BLOC. There is no substance of concern in the formulated product. Therefore the whole environment risk assessment of SORKIL BLOC is based on data obtained from the Competent Authority report of the active substance difenacoum as agreed at the Annex I inclusion stage

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

The product SORKIL BLOC is a ready to use wax block bait that contains difenacoum as active substance and denatonium benzoate as an aversive compound. Since difenacoum is the only substance of concern, the ecotoxicological effects can be derived from the effect studies conducted with the active substance.

#### Terrestrial compartment

According to the TNsG on data requirements (Ch. 2.5, Part B) additional data are required from rodenticidal products if they are used outside buildings in the form of baits, granulates and powder. In order to assess the risk for secondary poisoning, acute oral toxicity study and study by acceptance by ingestion of the biocidal product by any non-target organisms should be investigated. Nevertheless, it can be noted that in the active substance dossier for annex I inscription, the applicant has submitted two reports, with the representative products (wax block bait product) which deal with the UK national monitoring scheme of pesticide poisoning cases.

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

In the SORKIL BLOC Wax Blocks bait no substance of concern has been identified, and hence the secondary poisoning is caused entirely by the active substance difenacoum.

#### Summary of PNECs

In the product SORKIL BLOC Wax Blocks bait no substance of concern has been identified. Therefore the whole environment risk assessment is based on data obtained from the active substance, difenacoum, with PNECs values presented in section 2.8.2.7.

### ENVIRONMENTAL EXPOSURE ASSESSMENT

The product SORKIL BLOC is made up of wax blocks with 0.005% of difenacoum, provided either in individual package (PP or PE bags) or in bulk. The wax blocks are placed in secured bait stations (except when used in sewer systems). According to the applicant, the product is intended to be used in sewer systems, in waste water treatment plants and in and around industrial, commercial and residential buildings (in bait boxes).

The applicant considers the following application rates:

* For rat control in sewers, the recommended dose is 100 g per manhole (about 100 m) up to 200 g every 3 manholes.
* For rat control in waste water treatment plants, the recommended dose is 100 g up to 200 g product/secured bait point at intervals of 15 m apart.
* In and around buildings :
* Rat: from 80 g up to 200 g of product / bait station at distances of 15 meters apart.
* Mouse: from 25 g to 30 g of product / bait station at distances of 3 meters apart.

Bait points are inspected frequently and replenished when bait take is observed. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. Although a professional will eventually for practical reasons synchronise the inspection frequency with a work week so keeping inspections twice or once a week, so have 3.5 to 7 days inspection interval.

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

|  |  |  |
| --- | --- | --- |
| **PHYSICO-CHEMICAL PROPERTIES** | **Value** | **Unit** |
| Molecular weight | 444.5 | [g.mol-1] |
| Melting point | 216.3 | [°C] |
| Vapour pressure at test temperature | 5.00E-05 | [Pa] |
| Temperature at which vapour pressure was measured | 45 | [°C] |
| Octanol-water partition coefficient | 7.62 | [log10] |
| Water solubility at test temperature | 0.43 | [mg.L-1] |
| Temperature at which solubility was measured | 20 | [°C] |
| Organic carbon-water partition coefficient | 1 871 544 | [L.kg-1] |
| Half-life in soil | Not biodegradable\* | [d] |
| BCF | 9010 | L.kg-1 |

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

#### Sewer system – Wax block

The product SORKIL BLOC is made up of wax blocks with 0.005% of difenacoum, provided either in individual package (PP or PE bags) or in bulk. In the case of application in sewers, wax blocks are not placed in secured bait stations.

In sewers, the application dose is 100 g per manhole (*i.e.* every 100 m as the distance between two manholes may vary between 50 m to 300 m, but is generally 100 m) or 200 g every 3 manholes. The product is applied preferably in large main sewers (diameter > 30 cm). In larger sewers which can be walked in, baits can be placed along their length on available anchors or on specially installed bait trays each 100 meters or other distance interval.

It was considered that the use in waste water treatment plant was covered by the sewer scenario from the EUBEES ESD PT14 (2003)[[15]](#footnote-16).

From sewer use, the exposed compartments are:

* the sewage treatment plant (primary compartment)
* the aquatic compartment (surface water and sediment)
* the terrestrial compartment (agricultural soil after STP sludge spreading, groundwater)

The release to sewage water for the realistic worst case scenario is:

*Qprod*  = amount of product used in control operation after one week (kg),

*Fcprod* = fraction of active substance in product (-),

*Temission* = number of emission days (d),

*Freleased* = fraction of active ingredient released (-).

Emission calculations are carried out considering the default parameters of the ESD PT14 (Default values) as well as specific information on the product provided by the applicant (Normal case) concerning the fraction of the active ingredient released (Table 2.8.4.1‑1).

In the worst case approach (Default values), no metabolisation of the active substance is considered (*Freleased* = 0.9). For the normal case approach, according to the metabolism and toxicokinetics study (cf. section 2.8.2.6), it is assumed that 40% of excreted amount in faeces and urine is metabolised. Therefore, the metabolised fraction of the total amount applied (*Fmetab*) is 0.6 x 0.4 = 0.24 considering an ingested fraction of 0.6.

According to the ESD PT14, the refined *Freleased* is 0.3 + (0.6-0.24) = 0.66.

Elimination processes in STP are calculated using a Koc calculated from the Kow, the Henry's law constant and the results of biodegradation tests according to TGD by EUSES 2.1. Due to the low vapour pressure and Henry's law constant and because difenacoum is not readily biodegradable, only relevant elimination process is partitioning to suspended matters. EUSES calculations predict that 8.37 % is directed to water, 91.6 % to sludge and 0 % to air.

From the sewer use also an exposure to soil via the sludge application is possible. PECsoil and subsequent concentration in groundwater (porewater) calculated by EUSES are presented in the table below.

According to the ESD PT14, the default amount of product used in the control operation in sewer is 30 kg during the first 7 days of the control operation which corresponds to the realistic worst case situation.

Table 2.8.4.1‑1: Input values, emission and concentration in sewage water calculated according to the ESD PT14 for sewer system and the TGD - Worst case scenario with the default values from the ESD PT14 and normal case scenario.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | ***Local emission of active substance to waste water during episode:*** | | | **Default values** | | **Normal case** | | | **unit** | |
|  | |  | | |
| INPUTS | Q*prod:* | Amount of product used in control operation after one week | | 30 | | 30 | | | kg | |
| Fc*product*: | Fraction of active substance in product | | 0.005 | | 0.005 | | | % | |
| T*emission:* | Number of emission days (realistic worst case during the control operation) | | 7 | | 7 | | | d | |
| F*metabolised:* | Fraction of active ingredient metabolised | | 0 | | 0.24 | | | - | |
| F*released:* | Fraction of product released | | 0.9 | | 0.66 | | | - | |
|  |  |  |  | |  | |  |  | |  | |
| OUTPUTS | Elocal*water* | Mean local emission of active substance to waste water during episode | | 1.93E-04 | | 1.41E-04 | | | kg/d | |
| Cinfl *(default STP)* | Concentration in sewage water to default STP | | 9.64E-05 | | 7.07E-05 | | | mg/L | |
| **PEC calculated according to the TGD, part II (2003)** | | | | | | | | | | |
| PEC STP (eq. 33) | | PEC for microorganisms in the STP | | 8.07E-06 | | 5.92E-06 | | | mg/L | |
| PEC local water  (eq. 45) | | PEC in surface water during emission episode | | 2.18E-07 | | 1.60E-07 | | | mg/L | |
| PEC local sed  (eq. 50) | | PEC in sediment during emission episode | | 8.55E-03 | | 6.27E-03 | | | mg/kg wwt | |
| PIEC local soil  (eq. 66) | | PEC initial in soil | | 3.29E-04 | | 2.41E-04 | | | mg/kg wwt | |
| PEC local soil 10 years (eq. 62) | | PEC in soil after 10 years of application | | 3.29E-03 | | 2.41E-03 | | | mg/kg wwt | |
| PEC local soil porewater (eq. 67) | | PEC in porewater (based on PEC local soil after 10 years) | | 1.03E-04 | | 7.57E-05 | | | µg/L | |
| PEC fish (eq. 76) | | PEC in food via aquatic food chain | | 9.83E-03 | | 7.21E-03 | | | mg/kg wet fish | |
| PEC earthworm  (eq. 82c) | | PEC in food via terrestrial food chain | | 2.24E-02 | | 1.64E-02 | | | mg/kg wet earthworm | |

##### PEC in surface water and sediment

PEC values in the aquatic compartment and the STP from EUSES calculation are reported in the table 2.8.4.1-2 below.

Table 2.8.4.1‑2: PEC values for the aquatic compartment and the STP

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Default values** | **Normal case** | **Unit** |
| PEC in surface water during emission episode | 2.18E-07 | 1.60E-07 | mg/L |
| PEC in sediment during emission episode | 8.55E-03 | 6.27E-03 | mg/kg wwt |
| PEC for microorganisms in the STP | 8.07E-06 | 5.92E-06 | mg/L |

##### PEC in air

Difenacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Difenacoum has a potential for rapid photo-oxidative degradation in the air (half-life about two hours). The exposure of air is therefore considered negligible for the application of SORKIL BLOC biocidal product.

##### PEC in soil and groundwater

PEC values in terrestrial compartment and groundwater from EUSES calculation are reported in the table 2.8.4.1-3 below.

Table 2.8.4.1‑3: PEC values in terrestrial compartment and groundwater

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Default values** | **Normal case** | **Unit** |
| PEC initial in soil | 3.29E-04 | 2.41E-04 | mg/kg wwt |
| PEC in soil after 10 years of application | 3.29E-03 | 2.41E-03 | mg/kg wwt |
| PEC in porewater (based on PEC local soil after 10 years) | 1.03E-04 | 7.57E-05 | µg/L |

##### Non-compartment specific effects relevant to the food chain (primary and secondary poisoning)

###### Primary poisoning

According to the ESD PT14, no primary poisoning hazard to mammals or birds is relevant for the sewer scenario because no other mammals (or birds) are living or occurring in sewers.

###### Secondary poisoning

According to the ESD PT14, the secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In the case of rats the risk is covered by the ‘in and around buildings’ scenario performed in section 2.8.4.2. According to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.

Nevertheless, for the sewer scenario, the contamination of the food chain (via the contaminated terrestrial and aquatic compartment) is possible after the STP according to EUSES 2.1.0. These PEC values are therefore reported in table 2.8.4.1-4 below.

Table 2.8.4.1‑4: PEC in food via aquatic chain and terrestrial chain

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Default values** | **Normal case** | **Unit** |
| PEC in food via aquatic food chain | 9.83E-03 | 7.21E-03 | mg/kg wet fish |
| PEC in food via terrestrial food chain | 2.24E-02 | 1.64E-02 | mg/kg wet earthworm |

#### In and around building – Wax block

The product SORKIL BLOC is made up of wax blocks with 0.005% of difenacoum provided either in individual package (PP or PE bags) or in bulk. The wax blocks are always placed in secured bait stations when used in and around buildings.

According to the product instructions:

* The product SORKIL BLOC is made up of wax blocks with 0.005% of difenacoum provided either in individual package (PP or PE bags) or in bulk but always placed in secured bait stations.
* The application types “wax block” or “bait-box” of the ESD PT14 are applied for the following calculations in the exposure scenarios.
* According to the product instructions, the SORKIL BLOC baits are placed in bait stations only.
* Number of bait stations: 30 (20 inside and 10 outside, 15 meters apart for rats, 3 meters apart for mouse)
* Day 1: Treatment with 200 g product per box for rat, 30 g product per box for mouse
* Day 7, 14 and 21: bait refilling.

The only primary compartment to be exposed during ‘in and around use’ is the soil.

Emission calculations are carried out considering the default parameters of the ESD PT14 (Default values) as well as specific information on the product provided by the applicant (Normal case ; Table 2.8.4.2‑1).

For the normal case approach, as a worst case assumption, 40% of ingested active substance is released via urine and faeces as unchanged difenacoum and difenacoum-based metabolites according to metabolism and toxicokinetics study (section 2.8.2.6).

The scenario in the ESD PT14 is primarily based on grains and wax blocks. The formulation for difenacoum supported is a formulation/delivery type which does not strictly fit any of the product types for which emissions scenarios have been detailed in the ESD PT14. In fact, SORKIL BLOC is not handled in a loose form during application; it is enclosed in a PP or PE bags which is not removed. Due to the special formulation of this product, an estimated direct release during application and use is estimated to be at least 10 times lower compared to the 1% stated in the ESD PT14. Therefore the estimated direct release (*Frelease-D-soil*)during application and use is set to 0.1% (this refinement was agreed during TMI06). Moreover, according to the product instructions, bait stations are placed 15 m apart, which gives an exposed soil area of 1650 m² (instead of 550 m² calculated with the distance of 5 m from the ESD PT14).

According to the ESD PT14 and the applicant’s usage, the normal campaign baiting is:

* Day 1: Treatment with one normal bait per box ,
* Day 3: 100 % replenishment,
* Day 7: 25-50 % replenishment,
* Day 14: 10 % replenishment,
* Day 21: 0% replenishment

The normal campaign baiting is roughly equivalent to 1.5 replenishments corresponding to a total direct release over 28 days.

Table 2.8.4.2‑1: In and around buildings - Rat and mouse control campaign – Scenarios considering the default values from the ESD PT14 and the Normal cases according to the product instructions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **IN AND AROUND BUILDING (Bait boxes)** | | | **Default values**  **Rat** | **Normal case**  **Rat** | **Normal case**  **Mouse** | **Unit** |
|  |  |  |
| INPUTS | Q*prod:* | Amount of product used in control operation for each bait box | 250 | 200 | 30 | g |
| Fc*product*: | Fraction of active substance in product | 0.005 | 0.005 | 0.005 | % |
| Nsites: | Number of outsite application sites | 10 | 10 | 10 | - |
| N*refil*: | Number of refilling times | 5 | 1.5 | 1.5 | - |
| F*release-D, soil*: | Fraction of product released directly to soil | 0.01 | 0.001 | 0.001 | - |
| F*release-ID, soil*: | Fraction released indirectly to soil | 0.9 | 0.4 | 0.4 | - |
| F*metabolised:* | Fraction of active ingredient metabolised | 0 | 0.6 | 0.6 | - |
| AREA*exposed*: | Area directly exposed to rodenticide originating from bait box | 0.09 | 0.09 | 0.09 | m2 |
| DEPTH*soil*: | Depth of exposed soil | 0.1 | 0.1 | 0.1 | m |
| RHO*soil*: | Density of exposed soil | 1700 | 1700 | 1700 | kg/m3 |
| OUTPUTS | Elocal*soil-campaign, direct*: | Direct emission to soil from a campaign | 6.25E-03 | 1.50E-04 | 2.25E-05 | g/camp |
| Elocal*soil-campaign, indirect*: | Indirect emission to soil from a campaign | 5.57E-01 | 5.99E-02 | 8.99E-03 | g/camp |
| Elocal*soil-campaign*: | Total emission to soil from a campaign | 5.63E-01 | 6.01E-02 | 9.01E-03 | g/camp |
| AREA*exposed-ID* | Area indirectly exposed to rodenticide | 550 | 1650 | 330 | m2 |
| Clocal*soil-D* | Local concentration in soil due to direct release after a campaign: | 4.08E-02 | 9.80E-04 | 1.47E-04 | mg/kgwwt |
| Clocal*soil-ID* | Concentration in soil due to indirect (disperse) release after a campaign: | 5.96E-03 | 2.14E-04 | 1.60E-04 | mg/kgwwt |
| Clocal*soil* | Total concentration in soil | 4.68E-02 | 1.19E-03 | 3.07E-04 | mg/kgwwt |
| **PEC are calculated according to the TGD, part II (2003)** | | | | | | |
| PEC local soil | | PEC in soil | 4.68E-02 | 1.19E-03 | 3.07E-04 | mg/kgwwt |
| PEC local soil porewater = Cporewater | | PEC in porewater | 1.42E-06 | 3.62E-08 | 9.31E-09 | mg/L |

##### PEC in surface water and sediment

Exposure of surface water and sediment after the treatment with rodenticides in and around buildings is only relevant for indoor application of liquid poisons, residues from mixing and cleaning (ESD PT14) when a release is foreseen via the STP. Therefore the exposure of surface water and sediment is considered negligible for the application of SORKIL BLOC.

##### PEC in air

Difenacoum is not expected to partition to the atmosphere to any significant extent due to low vapour pressure and Henry's Law constant. Difenacoum has a potential for rapid photo-oxidative degradation in the air (half-life about two hours). The exposure of air is therefore considered negligible for the application of SORKIL BLOC product.

##### PEC in soil and groundwater

The PEC values for the terrestrial compartment and groundwater are reported in the table 2.8.4.2-2 below.

Table 2.8.4.2‑2: PEC values in terrestrial compartment and groundwater

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Default values** | **Normal case for Rat** | **Normal case for Mouse** | **Unit** |
| PEC in soil | 4.68E-02 | 1.19E-03 | 3.07E-04 | mg/kg wwt |
| PEC in porewater | 1.42E-06 | 3.62E-08 | 9.31E-09 | mg/L |

##### Non-compartment specific effects relevant to the food chain (primary and secondary poisoning)

###### Primary poisoning

The risk assessment for the primary poisoning presented below was extracted from the Annex I inclusion dossier for the active substance considering that difenacoum concentration is identical in the product SORKIL BLOC and in the representative product presented in the Annex I inclusion dossier for the active substance.

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According to the ESD PT14, primary poisoning hazard to mammals and birds (both wild and domestic) can be considered small in the scenario “In and around buildings”. In scenarios where difenacoum is placed in protected bait point, there is the risk for primary poisoning mainly for birds and mammals of equal size or smaller as the target rodents, which may be able to enter the bait stations. Also when target animals carry bait away from e.g. bait stations, non-target animals may be exposed.

Worst case exposure estimations are based on the equations and default values proposed by the ESD PT14. Some defaults may be replaced by product-specific properties. The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area. **The worst case Tier 1 PECoral is 50 mg/kg** (difenacoum present at 0.005% w/w in SORKIL BLOC) and is used in quantitative risk assessment for the long-term situation.

According to ESD PT14, a Tier 2 evaluation assessment can be done estimating the daily uptake of a compound (ETE) by non-target animals according to the equation 19 of the ESD PT14

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

FIR: food intake rate of the indicator species,

BW: indicator species body weight,

C: concentration of the active substance in fresh diet,

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) these AV and PT are refined to 0.9 and 0.8, respectively.

When the elimination of the active substance is taken into account the expected concentration of active substance (EC) in animal is calculated with the following equation:

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

where El is the fraction of daily uptake eliminated (number between 0 and 1, default 0.3).

According to the toxico-kinetic study (section 2.8.2.6), the total daily elimination in rats taking into account excretion through faeces and metabolism of difenacoum in rat liver, is approximately 40% (elimination factor 0.4), which is also used in calculations for non-target animals as there is no other data available. Calculations of ETE and EC values for worst case and realistic worst case situations are presented in the Table below. According to the guidance agreed at 23rd Competent Authority meeting these values are used for qualitative risk assessment of primary poisoning in acute situation.

**Table 2.8.4.2‑3: Expected concentrations of difenacoum in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations with and without elimination**

|  |
| --- |
|  |

Calculations of the expected concentrations (EC) for 5 days exposure considering elimination are calculated according to the ESD PT14 equation 21 as a worst case i.e. AV, PT and PD are set to 1.

According to the guidance agreed at 23rd CA meeting EC5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

**Table 2.8.4.2‑4: Expected concentrations of difenacoum (EC5) in non-target animals for the long-term situations (worst case).**

|  |
| --- |
|  |
| Among the anticoagulant poisoning incidents, dogs are common victims. The intoxication of dogs is easily detected as they live together with man. Intoxication incidents of wild animals may often remain unobserved. Small non-target rodents, such as voles, and small, granivorous birds can feed on rodenticidal baits because they can pass through the entrance hole of a bait station. Exposure may also arise if target animals carry bait away from the bait station. The domestic animals at risk are dog, pig and hen. Birds eating cereal and weed seeds like sparrows, pigeons and pheasants are possible wild species that may be at risk of primary poisoning. |

###### Secondary poisoning

* Secondary poisoning via the aquatic food chain

As no exposure of the aquatic compartment is foreseen with the use of SORKIL BLOC in and around buildings, no risk assessment for secondary poisoning through the aquatic food chain is required.

* Secondary poisoning via the terrestrial food chain

***The earthworm-eating mammal or bird***

According to the TGD secondary poisoning through the terrestrial route is soil → terrestrial organisms (earthworm) → earthworm-eating mammal or bird. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in the soil.

PECoralpredator is calculated for rat application for the refined scenario as:

**PEC oral,predator = Cearthworm** (eq 80, TGD, 2003)

**Cearthworm = (BCFearthworm\*Cporewater+ Clocalsoil\*Fgut\*CONVsoil)/ (1+Fgut kgdwt/kgwwt\*CONVsoil kgwwt/kgdwt)** (eq 82c, TGD 2003).

No measured BCF for earthworm is available and the calculated **BCF** **of 477 729** **L/kgwet earthworm** (section 2.8.1.5.2) is used in the calculations.

**Cearthworm** = (477 729 L/kgwet earthworm x 3.62E-08 mg/L + 1.19E-03 mg/kgwwt x 0.1 kgdwt/kgwwt x 1.13 kgwwt/kgdwt)/(1+0.1 \*1.13) = **1.57E-02 mg/kgwet earthworm.**

According to the TGD, the most appropriate scenario is that 50% of the diet comes from a local area and 50% comes from the regional area, thus when the PEClocal,soil is used in calculation, the **PECoral,predator** to be used in risk assessment is 0.0162 mg/kgwet earthwom x 0.5 = **7.85E-03 mg/kgwet earthworm.**

***The rodent-eating mammal or the rodent-eating bird***

As secondary poisoning assessment according to the TGD considers the oral intake of a chemical only via fish or worms, another food chain rodenticide (bait) →rodent → rodent-eating mammal or rodent-eating bird is assessed in the ESD PT14.

The risk assessment for the secondary poisoning presented below was extracted from the Annex I dossier for the active substance inclusion considering that difenacoum concentration is identical in the product SORKIL BLOC and in the representative product presented in the Annex I inclusion dossier for the active substance.

According to the ESD PT14 for secondary poisoning hazard, in 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); also scavengers may search for food close to buildings and thus secondary poisoning through poisoned rats exists.

For estimation of secondary poisoning risk through poisoned rats, tiered approach is presented in the ESD PT14:

* The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food i.e. poisoned rodents (concentration in food); the predator is assumed to catch the rodent after last meal on day 5 or day 14.
* The Tier 2 assessment of long-term secondary poisoning is based on the expected concentration in predators compared to PNECoral expressed as a daily dose; the predators accumulate difenacoum by feeding on poisoned target rodents during one day (rodents ate baits every day during 5 and 14 days).

Therefore, the amount of difenacoum in rats is estimated according to equations 19 and 21 in ESD PT14:

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

In calculations AV and PT for rodent are set to 1 and PD values to 1, 0.5 and 0.2.

The daily elimination is assumed to be 40%, see details in section 2.8.2.6**.** Results are presented in the following Table.

|  |
| --- |
| **Table 2.8.4.2‑5: Estimated concentration (EC) of difenacoum in target rodents (rats) in mg a.s./kg bw at different times during a control operation** |

* Tier 1 PECoral for short term situation is calculated according to the equation 22 in the ESD PT14;

**PEC oral, predator = (ECn +ETE) x F rodent)**

using value 1 for Frodent (non-target animal consume 100% of their daily intake on poisoned rodents).

where

Frodent : fraction of poisoned rodents in predator's diet

ECn: expected concentration of a.s. in the rodent on day 'n' before the last meal

N: the number of days the rodent is eating rodenticide until caught, default 5.

These values, presented in the table 2.8.4.2-6 below, are used for qualitative risk assessment of secondary poisoning in acute situation.

* Tier 1 PECoral for long term situation is calculated in a similar way, but the Frodent is set to 0.5, which means that it is assumed that non-target animal consume 50 % of their daily intake on poisoned rodents. These values, presented in the table below, are used for Tier 1 quantitative risk assessment of secondary poisoning in the long-term situation.

**Table 2.8.4.2‑6: Predicted environmental concentrations of difenacoum in food of predator (PEC oral) for acute and long-term situations.**

|  |
| --- |
|  |

* Tier 2 for long-term exposure: According to guidance agreed by the CA the PECoral is the concentration of active substance in non-target animals after a single day of exposure (mg/kg bw) using values PD of 1 (100% bait consumption by rodent) and Frodent of 0.5. PECoral values presented in the table below are used for Tier 2 quantitative risk assessment of secondary poisoning in the long-term situation.

**Table 2.8.4.2‑7: Expected concentrations of difenacoum in non-target animals due to secondary poisoning after a single day exposure (concentration of difenacoum in rodenticide bait 0.005 %); rodents caught by predators on day 5 and 14 (after feeding), PD 1, Frodent 0.5.**

|  |
| --- |
|  |

### RISK CHARACTERISATION FOR THE ENVIRONMENT

#### Sewer system – Wax block

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

PNEC values for the water compartment were calculated in the section 2.8.2.7. While PEC values for the sewer system were presented in section 2.8.4.1.

Table 2.8.5.1-1 below presents PEC/ PNEC ratios for surface water, sediment and STP:

Table 2.8.5.1-1: PEC/PNEC ratios for the aquatic compartment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **PEC** | | **PNEC** | **PEC/PNEC** | |
| **Default values** | **Normal case** | **Default values** | **Normal case** |
| Surface water (mg/L) | 2.18E-07 | 1.60E-07 | 6.40E-05 | 3.41E-03 | 2.50E-03 |
| Sediment (mg/kg wwt) | 8.55E-03 | 6.27E-03 | 2.51 | 3.41E-03 | 2.50E-03 |
| STP (mg/L) | 8.07E-06 | 5.92E-06 | 0.48 | 1.68E-05 | 1.23E-05 |

No unacceptable risk is identified for the aquatic compartment including surface water, sediment and STP when the product SORKIL BLOC is used in sewer system against rats.

##### Terrestrial compartment

PNEC values for the terrestrial compartment were calculated in the section 2.8.2.7. While PEC values for the sewer system were presented in section 2.8.4.1.

Table 2.8.5.1-2 below presents PEC/ PNEC ratios for terrestrial compartment including groundwater.

Table 2.8.5.1-2: PEC/PNEC ratios for the terrestrial compartment (incl. Groundwater)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **PEC** | | **PNEC** | **PEC/PNEC** | |
| **Default values** | **Normal case** | **Default values** | **Normal case** |
| Agricultural soil  (mg/kg wwt) | 3.29E-03 | 2.41E-03 | 0.877 | 3.76E-03 | 2.75E-03 |
| Groundwater (µg/L) | 1.03E-04 | 7.57E-05 | 0.01\* | 1.03E-03 | 7.57E-04 |

\*0.01µg/L corresponds on the threshold value for the toxicity in drinking water issued from the human health section.

No unacceptable risk is identified in terrestrial compartment (including the groundwater) when the product SORKIL BLOC is used in sewer system against rats.

##### Primary poisoning

According to the ESD PT14, no primary poisoning hazard to mammals or birds is relevant for the sewer scenario because no other mammals (or birds) are living or occurring in sewers. Moreover, the risk assessment is covered by the assessment of the “in and around building” uses presented in section 2.8.5.2.2.

##### Secondary poisoning

According to the ESD PT14, the secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In the case of rat control in sewer the risk is covered by the ‘in and around buildings’ scenario. According to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. *Blatta orientalis* will remain underground and are not significant prey items for birds.

Nevertheless, for the sewer scenario, the contamination of the food chain (via the terrestrial and the aquatic compartment) is possible after the STP according to EUSES 2.1.0.

The PEC/PNEC ratios are reported below.

**Table 2.8.5.1-3: Secondary poisoning via aquatic and terrestrial food chain in sewer system.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Aquatic PECoral,predator  mg/kg wet | | Terrestrial PECoral, predator  mg/kg wet | | PNEC oral  µg/kg food | Aquatic  PEC/PNEC | | Terrestrial PEC/PNEC | | | Default values | Normal case | Default values | Normal case | Default values | Normal case | Default values | Normal case | | Birds | 9.83E-03 | 7.21E-03 | 2.24E-02 | 1.64E-02 | 0.5 | 19.7 | 14.4 | 44.80 | 32.80 | | Mammals | 7 | 1.4 | 1.0 | 3.20 | 2.34 | | |

In any case, the risk assessments for secondary poisoning are unacceptable via the terrestrial or aquatic food chain in sewer system.

However, as conclude in the CAR, the risk of secondary poisoning via the aquatic food chain is considered insignificant due to low water solubility and high adsorption tendency of difenacoum. It is also assumed that mechanical screening of sewage water reduces the concentration in the recipient water, although this reduction cannot be quantified.

The risk for secondary poisoning via the terrestrial food chain is higher compared to the aquatic environment. Despite of the calculated risk, the RMS considers the secondary poisoning via earthworms less important than secondary poisoning via the food chain bait → rodent → rodent-eating birds or mammals. The secondary poisoning risk assessment via the food chain bait→ rodent → rodent-eating birds or mammals is performed under the scenario “In and around buildings – wax block (section 2.8.5.2).

The application in sewer systems should be authorised only if the specific use restrictions can be applied to reduce the risk for primary and secondary poisoning, including the application of bait blocks in zone not liable to flooding.

#### In and around buildings – Wax block

##### Terrestrial compartment

PNEC values for the terrestrial compartment were calculated in the section 2.8.2.7. While PEC values for the in and around buildings were presented in section 2.8.4.2.3.

The Table 2.8.5.2-1 below presents PEC/ PNEC ratios for terrestrial compartment including groundwater.

Table 2.8.5.2-1: PEC/PNEC ratios for the terrestrial compartment (incl. groundwater)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PEC** | | | **PNEC** | **PEC/PNEC** | | |
| **Default values** | **Normal case** | | **Default values** | **Normal case** | |
| **rat** | **mouse** | **rat** | **mouse** |
| Terrestrial  (mg/kg wwt) | 4.68E-02 | 1.19E-03 | 3.07E-04 | 0.877 | 5.34E-02 | 1.36E-03 | 3.50E-04 |
| Groundwater (µg/L) | 1.42E-03 | 3.62E-05 | 9.31E-06 | 0.01\* | 1.42E-02 | 3.62E-04 | 9.31E-05 |

\*0.01µg/L corresponds on the threshold value for the toxicity in drinking water issued from the human health section.

No unacceptable risk is identified in the terrestrial compartment (including groundwater) when the product SORKIL BLOC is used in and around building against rats and mice.

##### Primary poisoning

Concentration of the bait is compared to the PNECoral expressed as the concentration in food.

**Table 2.8.5.2-2: Tier 1 risk characterisation of primary poisoning.**

|  |
| --- |
|  |
| |  |  |  |  | | --- | --- | --- | --- | |  | PEC mg/kg food | PNEC µg/kg food | PEC/PNEC | | Birds | 50 | 0.5 | 100000 | | Mammals | 50 | 7 | 7143 | |

With a Tier 1 Approach, the risk for primary poisoning in birds and mammals is not acceptable.

The expected concentrations (EC) in the non-target animals after five days exposure have been calculated with the tier 2 assumptions, i.e, PT=0.8 and AV=0.9. The PNECoral is expressed as the daily dose.

**Table 2.8.5.2-3: Tier 2 risk characterisation of primary poisoning.**

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With a Tier 2 Approach, the risk for primary poisoning is not acceptable in the non-target animals.

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 PT14 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.

##### Secondary poisoning

###### Secondary poisoning via aquatic food chains

As no exposure of the aquatic environment is foreseen with the use of SORKIL BLOC in and around buildings, no risk assessment for secondary poisoning through the aquatic food chain is needed.

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

***The earthworm-eating mammal or bird***

In the terrestrial environment birds and mammals may be at risk for secondary poisoning if they feed on contaminated soil organisms. The risk characterization is done separately for birds and mammals to be consequent with the calculations done according to the ESD PT14.

Table 2.8.5.2-4: Secondary poisoning via aquatic and terrestrial food chain in ”in and around buildings”.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Terrestrial PECoral,predator  mg/kg wet earthworm | PNEC oral  µg/kg food | Terrestrial PEC/PNEC |
| Birds | 7.85E-03 | 0.5 | 15.70 |
| Mammals | 7 | 1.12 |

The PEC/PNEC ratio exceeds 1 for both earthworm eating birds and mammals (

Table 2.8.5.2-4).

The risk is due to feeding on contaminated soil invertebrates in a soil volume of 0.009 m3. Despite of the calculated risk, the RMS considers the secondary poisoning via earthworms less important than secondary poisoning via the food chain bait → rodent → rodent-eating birds or mammals.

***The rodent-eating mammal or bird***

A qualitative assessment of the acute secondary poisoning is made by comparing the concentration in the rodents to LD50 values from acute oral studies. Rodents are assumed to eat entirely on bait containing difenacoum and the non-target animals are assumed to consume entirely poisoned rodents. The qualitative assessment indicates that birds are likely to survive and mammals are likely to die if they eat poisoned rats (**Erreur ! Source du renvoi introuvable.**). The species specific sensitivity differences or other aspects normally covered by the assessment factors are not taken into account in the qualitative assessment.

**Table 2.8.5.2-5: Qualitative assessment of acute secondary poisoning.**

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* **Tier 1 assessment of long term secondary poisoning**

The Tier 1 assessment of secondary poisoning is based on the concentration in the predator's or scavenger's food, i.e. poisoned rodents. The rodents are assumed to consume entirely the bait (PD = 1), while half of the predator's or scavenger's daily food intake is poisoned rodents (Frodent = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days, whereas the predator or the scavenger is assumed to eat the poisoned rodents during one day. The predator is assumed to catch the rodent after last meal on day 5 or day 14. Only resistant rodents are assumed to eat bait 14 day. The calculation of concentrations in rodents is explained in detail in Section 2.8.4.2.4.2. The PNECoral is based on the highest concentration causing no effects in the test with long-term exposure. The derivations of PNECs are explained in Section 2.8.3.3.

**Table 2.8.5.2-6: Tier 1 risk characterisation of secondary poisoning. Expected concentration in target rodents is compared to the PNECoral expressed as concentration in food. Rodents are assumed to consume entirely bait (PD=1). Half of the predator's diet is poisoned rodents (Frodent=0.5).**

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The Tier 1 risk characterisation shows that there is an unacceptable risk for secondary poisoning of mammals and birds (Table 2.8.5.2-6).

Resistant rodents can feed on the poisoned baits longer and accumulate higher difenacoum residues than non-resistant rodents. Resistant rodents can continue to feed difenacoum up to two weeks, while the non-resistant rodents stop feeding after 5 days. Based on the calculations, the resistant rodents cause about 1.5 times higher risk for secondary poisoning of birds and mammals than non-resistant rodents.

* **Tier 2 assessment of long term secondary poisoning**

In the Tier 2 assessment of long-term secondary poisoning the expected concentration in predators is compared to PNECoral expressed as a daily dose. The predators accumulate difenacoum by feeding on poisoned target rodents during one day. The rodents are assumed to eat entirely the bait (PD = 1), whereas half of the predator's or scavenger's daily food intake is poisoned rodents (Frodent = 0.5). The rodents are assumed to eat the baits in five or fourteen successive days. The susceptible rodents are assumed to stop feeding after 5 days, but resistant rodents are assumed to continue feeding until day 14. The calculation of expected concentrations is explained in detail in Section .

**Table 2.8.5.2-7:: Tier 2 risk characterisation of long term secondary poisoning. The expected concentrations in predatory birds and mammals are compared to the PNECoral expressed as daily dose.**

|  |
| --- |
|  |

Also the Tier 2 risk characterisation shows a high risk for secondary poisoning (Table 2.8.5.2-7). The PNECoral expressed as a dose is approximately equal for birds and mammals, and the sensitivity of the species used in calculations is determined predominantly by the ratio of daily food consumption to body weight so that the higher ratio results in the higher risk. No data are available on the sensitivity of the example species (the species listed in Table 12 of the ESD PT14) to difenacoum. Only one day exposure of predators is assumed in the ESD PT14, but it is mentioned that predators could be exposed over several days. This would mean higher accumulation in predators, because daily elimination of difenacoum from the predators is assumed to be less than the ingested amount. On the other hand, it is unlikely that all worst case assumptions would materialize simultaneously in nature. It is likely that in the long-term exposure, the prey rodents do not eat only the bait and also the fraction of poisoned rodents in the predator's diet can be lower than 50%. The resistant rodents cause somewhat higher risk for predators than non-resistant rodents, but the difference is smaller than in the Tier 1 assessment.

The applicant has submitted two experimental studies on the secondary poisoning in Barn Owls. Tier 1 and Tier 2 risk characterisation are recalculated for the Barn Owl on the basis of the measured concentrations in rats and mice with the experimental data provided in the difenacoum Task Force Annex I inclusion dossier. The risks are significantly lower than with the ESD PT14 calculations however they are still considerably higher than 1 indicating risk for secondary poisoning of the Barn Owls.

A review of the available monitoring data was provided in the difenacoum Task Force Annex I inclusion dossier to characterize the risk of secondary poisoning. Most of the incidents were due to misuse, abuse or unspecified use. Only few incidents resulted from approved use of difenacoum. However, like theoretical calculations and experimental results, the monitoring data clearly show that difenacoum poses an inacceptable risk for secondary poisoning. While all available information indicates risk, it does not tell the frequency of secondary poisoning incidents among wildlife.

In order to reduce the risk of primary and secondary poisoning, it is mandatory to follow the use instructions of rodenticidal baits. It is considered that these instructions will be respected by trained professional users.

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

* **Major change application - 2018**

The product TANTALE C is based on the assessment of the product SORKIL BLOC performed by FR CA, the active substance content assessed was 0.005% w/w of difenacoum.

For the major change, the applicant claimed an active substance content of 0.0025% w/w of difenacoum. Regarding this new information, the assessment of the product TANTALE C is cover by the authorization of the product SORKIL BLOC. Therefore, the conclusion of the environmental risk assessment remains unchanged.

* **Renewal application - 2019**

No new ecotoxicological information has been submitted at the renewal of the approval of the active substance difenacoum and in the product dossier. No studies were conducted with the product TANTALE C for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of Difenacoum.

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

## Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC).*

# Proposal for the decision – renewal 2019

**Summary of product characteristics for a biocidal product**

**1. Administrative information**

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

| **Trade name(s)** | TANTALE C |
| --- | --- |
|  |  |

**1.2. Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Edialux |
| **Address** | ZA Macon Est  01750 Replonges  France |
| **Authorisation number** |  | |
| *Suffixes to the authorisation number linked to trade names* |  | |
| *R4BP asset reference number* | BC-PW049464-02 | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | EDIALUX |
| **Address of manufacturer** | ZA Macon Est  01750 Replonges  France |
| **Location of manufacturing sites** | ZA Macon Est  01750 Replonges  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | LARC |
| **Address of manufacturer** | ZA Kerampaou  29140 Melgven  France |
| **Location of manufacturing sites** | ZA Kerampaou  29140 Melgven  France |

|  |  |
| --- | --- |
| **Name of manufacturer** | EDIALUX N.V. |
| **Address of manufacturer** | Riksweg 28  2880 Bornem  Belgium |
| **Location of manufacturing sites** | Riksweg 28  2880 Bornem  Belgium |

|  |  |
| --- | --- |
| **Name of manufacturer** | EDIALUX N.V. |
| **Address of manufacturer** | Industrieweg 3  2880 Bornem  Belgium |
| **Location of manufacturing sites** | Industrieweg 3  2880 Bornem  Belgium |

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

|  |  |
| --- | --- |
| **Active substance** | Difenacoum |
| **Name of manufacturer** | Pelgar International Ltd |
| **Address of manufacturer** | Unit 13, Newman Lane  Alton, Hampshire  GU34 2QR  Great Britain |
| **Location of manufacturing sites** | Unit 13, Newman Lane  Alton, Hampshire  GU34 2QR  Great Britain |

**2. Product composition and formulation**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Difenacoum | 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-  hydroxycoumarin | Active substance | 56073-07-5 | 259-978-4 | 0.0026 (technical) |

**2.2. Type of formulation**

|  |
| --- |
| Ready-to-use bait: block |

**3. Hazard and precautionary statements**

| **Classification** | |
| --- | --- |
| Hazard category | STOT RE 2 |
| Hazard statement | H373 |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H373 (blood): May cause damage to organs through prolonged or repeated exposure |
| Precautionary statements | P314: Get medical advice/attention if you feel unwell.  P501: Dispose of contents/container in accordance to... [*… in accordance with local/regional/national/international regulation]* |
|  | |
| Note |  |

**4. Authorised use(s)**

**4.1. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations[[16]](#footnote-17)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Mice: 40 g of bait per bait station/bait point. If more than one bait station/point is needed, the distance between each should be of 3 meters.  Rats: 200 g of bait per bait station/bait point. If more than one bait station/point is needed, the distance between each should be of 15 meters.  The amount of product per bait station/point must be adapted to the effective rate.  The number of bait stations/points is function of the area of treatment and infestation rate. |
| **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)*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations: for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g; for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

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

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

|  |
| --- |
| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.  *-* Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use the product in pulsed baiting treatments. |

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

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

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

|  |
| --- |
|  |

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

|  |
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|  |

**4.2. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Bait formulations:  - Ready-to-use bait to be used in tamper-resistant bait stations.  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Mice: 40 g of bait per bait station/bait point. If more than one bait station/point is needed, the distance between each should be of 3 meters.  Rats: 200 g of bait per bait station/bait point. If more than one bait station/point is needed, the distance between each should be of 15 meters.  The amount of product per bait station/point must be adapted to the effective rate.  The number of bait stations/points is function of the area of treatment and infestation rate. |
| **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)*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations: for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g; for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

|  |
| --- |
| - Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.  - Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.  - Remove the remaining product at the end of treatment period.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice.  *- [For outdoor use, baiting points must be covered and placed in strategic sites to minimise the exposure to non-target species].* |

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

|  |
| --- |
| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice*.*  - Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - Do not use this product in pulsed baiting treatments.  - Do not apply this product directly in the burrows. |

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

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

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

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

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**4.3. Use description**

**Table 3. Use # 3 – Rats – trained professionals – sewers**

|  |  |
| --- | --- |
| **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) |
| **Field(s) of use** | Sewers |
| **Application method(s)** | - Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Sewers: 100 g of bait every 100 m or 200 g of bait every 300 m. |
| **Category(ies) of users** | Trained professionals only |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  *(****In France only*** *: minimum pack size of 5 kg)*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

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

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

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

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

|  |
| --- |
|  |

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

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|  |

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

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| --- |
|  |

**4.4. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations[[17]](#footnote-18) |
| **Application rate(s) and frequency** | 40 g of bait per bait station.  If more than one bait station is needed, the distance between bait stations should be of 3 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations: for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g. |

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

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

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

|  |
| --- |
|  |

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

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

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

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|  |

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

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|  |

**4.5. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | 200 g of bait per bait station.  If more than one bait station is needed, the distance between bait stations should be of 15 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations: for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

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

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

|  |
| --- |
|  |

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

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

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

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| --- |
|  |

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

|  |
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|  |

**4.6. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice)  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Rats: 200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 15 meters.  Mice: 40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 3 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Minimum pack size of 3 kg*.*  - Bait formulations:  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g) or in bulk without being packed in individual sachet.  They are then packed in PP buckets or in cardboards with PE liner (3-5-10 kg).  Blocks can also be supplied in PE pre-filled bait stations: for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g; for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

|  |
| --- |
| - Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.  - The bait stations should be visited *[for mice -* at least every 2 to 3 days at*]* *[for rats -* only 5 to 7 days after*]* the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - *[When available]* Follow any additional instructions provided by the relevant code of best practice. |

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

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

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

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.7. Use description**

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

*[Other target organisms may be added[[18]](#footnote-19) to this use or presented in another table]*

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations[[19]](#footnote-20). |
| **Application rate(s) and frequency** | Bait products:  - 40 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 3 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 100 g for mice and 300 g for mice and rats  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g).  They are then packed in PP buckets or in cardboards with PE liner (up to 300 g).  Blocks can also be supplied in PE pre-filled bait stations: for mice, 2\*20 g, 1\*25 g, 1\*28 g or 1\*30 g. |

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

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

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| --- |
|  |

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

|  |
| --- |
|  |

**4.8. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Indoor. |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  200 g of bait per bait station. If more than one bait station is needed, the distance between bait stations should be of 15 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 300 kg  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g).  They are then packed in PP buckets or in cardboards with PE liner (up to 300 g).  Blocks can also be supplied in PE pre-filled bait stations: for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.9. Use description**

**Table 9. Use # 9 – Rats – general public – outdoor around buildings**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor around buildings |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations2. |
| **Application rate(s) and frequency** | Bait products:  200 g of bait per bait station.  If more than one bait station is needed, the distance between bait stations should be of 15 meters.  The number of sachets per bait station must be adapted to the effective rate.  The number of bait stations is function of the area of treatment and infestation rate. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | Maximum pack size of 300 kg  TANTALE C is supplied in blocks. Blocks are packed in individual PE or PP sachet (20-200 g).  They are then packed in PP buckets or in cardboards with PE liner (up to 300 g).  Blocks can also be supplied in PE pre-filled bait stations: for rats, 5\*20 g, 4\*25 g, 4\*28 g, 4\*30 g, 3\*40 g, 2\*50 g, 2\*70 g, 2\*80 g, 1\*100 g, 1\*150 g or 1\*200 g. |

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

|  |
| --- |
| - Place the bait stations in areas not liable to flooding.  - Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.  - The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. |

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

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

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

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

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|  |

**5. General directions for use**

**5.1. Instructions for use**

|  |
| --- |
| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.  - The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.  - *[If national policy or legislation requires it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.  - Bait should be secured so that it cannot be dragged away from the bait station.  - Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.  - Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  ***FOR TRAINED PROFESSIONAL ONLY****- The* frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.  - If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.  - If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.  ***FOR PROFESSIONNALS ONLY*** Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  ***FOR PROFESSIONNALS ONLY*** Remove the remaining bait or the bait stations at the end of the treatment period.  *- Instructions for use that are "bait-specific":*   * *Do not open the sachets containing the bait*.   **FOR NON PROFESSIONAL USERS**  - Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.  - Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.  - Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.  - Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).  - Where possible, bait stations must be fixed to the ground or other structures.  - *[*Do not open the sachets containing the bait *- where relevant for the bait formulation in the product].*  - Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.  - Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.  - Do not place bait stations near water drainage systems where they can come into contact with water.  - When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  - Remove the remaining bait or the bait stations at the end of the treatment period. |

**5.2. Risk mitigation measures**

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| --- |
| **FOR PROFESSIONAL AND TRAINED PROFESSIONAL USERS**  - Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".  - The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".  - ***FOR TRAINED PROFESSIONAL ONLY*** Do not use in areas where resistance to the active substance can be suspected.  - Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.  - ***FOR TRAINED PROFESSIONAL ONLY*** Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.  - Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.  - ***FOR PROFESSIONAL ONLY*** To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required].*  - ***FOR PROFESSIONAL ONLY*** Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.  - ***FOR PROFESSIONAL ONLY.*** The product information (i.e. label and/or leaflet) shall clearly show that:   * the product shall not be supplied to the general public (e.g. "for professionals only"). * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations").   - ***FOR PROFESSIONAL ONLY*** Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  **FOR NON PROFESSIONAL USERS**  - Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.  - Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).  - The product information (i.e. label and/or leaflet) shall clearly show that:   * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").   - Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.  - Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.  - Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

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

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| - This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.  - Antidote: Vitamin K1 administered by medical/veterinary personnel only.  - In case of:  - Dermal exposure, wash skin with water and then with water and soap.  - Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.  - Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*  - Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"  - Hazardous to wildlife. |

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

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

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

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| - Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.  - Do not store at temperatures above 40 ° C.  - Store in places prevented from the access of children, birds, pets and farm animals.  - Shelf life: 12 month. |

**6. Other information**

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| - (**in France only** : The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance difenacoum. Results of the resistance monitoring must be submitted at the renewal of the product.)  - Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait.  - Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.  - This product contains a bittering agent and a dye. |

Annex 1: List of studies reviewed

***List of new data******[[20]](#footnote-21) submitted in support of the evaluation of the active substance – PAR 2012***

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| A3.3 | Report No. 2109/0005 | Walker JA and Mullee, DM | 2007 | Difenacoum: Determination of General Physico-chemical Properties  SafePharm Laboratories | Pelgar |  |  |  |  |
| A4.2 (c) | CEMR-4470 | Marshall L. | 2009 | Validation of a method for the determination of Difenacoum residues in sediment | Activa / PelGar Brodifacoum and Difenacoum Task Force |  |  |  |  |
| A4.2 (c) | CEMR-4469 | Marshall L. | 2009 | Validation of a method for the determination of Difenacoum residues in animal Matrices (Liver and Muscle) and Crop matrix | Activa / PelGar Brodifacoum and Difenacoum Task Force |  |  |  |  |
| A4.2 (e) | CEMR-4469 | Marshall L. | 2009 | Validation of a method for the determination of Difenacoum residues in animal Matrices (Liver and Muscle) and Crop matrix | Activa / PelGar Brodifacoum and Difenacoum Task Force |  |  |  |  |
|  | | | | | | | | | |

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

| **Section No** | **Reference No** | **Author** | | **Year** | | **Title** | | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | |  | |  | |  | **Yes** | **No** | **Yes** | **No** |
| Doc IIIB 3.2, 3.3 | Report No 10/03 | | Ambrosi, D. Vinot, D. | | 2010 | | Literature survey on flammability, auto-flammability, explosive properties, oxidizing properties of the ingredients of the product EDI-575 | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 3.4 | Report No 20100380.04 | | Dornhagen, J. | | 2010 | | EDI-575 [Wax Block Exotic Seed (block bait, BB)]  Flammability (solids) A.10 | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 3.4 | Report No 20100380.03 | | Dornhagen, J. | | 2010 | | EDI-575 [Wax Block Exotic Seed (block bait, BB)]  Auto-flammability (solids – determination of relative self-ignition temperature) A.16 | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 3.6 | Report No 20100380.02 | | Dornhagen, J. | | 2010 | | EDI-575 [Wax Block Exotic Seed (block bait, BB)]  Relative density A.3 (OCDE 109) | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 3.1, 3.7 | Report No Mo3931 | | Broda, J. | | 2010 | | Determination of physic-chemical properties and storage stability test for EDI-575 [Wax Block Exotic Seed packed in PP bucket | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 3 | Report No 20100380.01 | | Dornhagen, J. | | 2010 | | EDI-575 [Wax Block Exotic Seed (block bait, BB)]  Melting point A.1 (OCDE 102) | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 4 | Report No MV031 | | M.T. Garcia | | 2010 | | Determination of Difenacoum in Grain Baits and Block Baits | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 4 | Report No Mo3916 | | M.T. Garcia | | 2010 | | Supplement to method MV031-E01: EDX Determination of Difenacoum in Grain Baits and Block Baits, Biogenius | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 5.10.1 | XXX | XXX | | XXX | | Bait choice- EDI 575 BB-ROD fresh bait with difenacoum, Mice  (*Mus musculus*)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 5.10.2 | XXX | XXX | | XXX | | Bait choice- EDI 575 BB-ROD fresh bait with difenacoum, Rats  (*Rattus norvegicus*)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 5.10.3 | XXX | XXX | | XXX | | Bait choice- EDI 575 BB-ROD aged bait with difenacoum, Mice  (*Mus musculus*)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 5.10.4 | XXX | XXX | | XXX | | Bait choice- EDI 575 BB-ROD aged bait with difenacoum, Rats  (*Rattus norvegicus*)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 5.10.5 | XXX | XXX | | XXX | | Efficacy assessment for use in damp conditions of Wax Block Exotic Seed (EDI-575 BB-ROD) containing 50 mg.kg-1 difenacoum, using CD albino Norway rat,  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 6.1.2 | XXX | XXX | | XXX | | Sorkil rodenticide wax block – block bait (BB) EDI-550, Evaluation of acute dermal toxicity in rats (draft report)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 6.2 | XXX | XXX | | XXX | | Sorkil rodenticide wax block – block bait (BB) EDI-550, Assessment of acute dermal irritation (draft report)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 6.2 | XXX | XXX | | XXX | | Sorkil rodenticide wax block – block bait (BB) EDI550, Assessment of acute eye irritation (draft report)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIIB 6.3 | XXX | XXX | | XXX | | Sorkil rodenticide wax block – block bait (BB) EDI-550, Assessment of the skin sensitisation potential in the mouse using the local lymph node assay (LLNA) (draft report)  XXX | | Edialux Formulex NV |  |  |  |  |
| Doc IIC B6.6 (1) | - | Chambers JG and Snowdon PJ | | 2004 | | Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits  Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished. | | CEFIC |  |  |  |  |
| Doc IIC B6.6 (2) | - | Vetter D and Sendor T | | 2006 | | Estimation of the frequency of dermal exposure during the occupational use of rodenticides. Report of EBRC Consulting under contact to CEFIC Rodenticide Working Group. Unpublished. | | CEFIC |  |  |  |  |

* **Major change of the biocidal product TANTALE C:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| DEMANGEL, B. | 2017 | Chemical stability during and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on EDI-575\_25  Study n°17-904017-001  DEFITRACES  GLP Study | Y | EDIALUX | 2017 |
| DEMANGEL, B. | 2017 | Storage procedure for 6 months at 20±2 °C  Study n°17-904017-002  DEFITRACES  GLP Study | Y | EDIALUX | 2017 |
| RICAU, H. | 2017 | Validation of analytical method for the determination of difenacoum in the EDI-575\_25.  Study n°17-904017-004  DEFITRACES  GLP Study | Y | EDIALUX | 2017 |
| XXX | XXX | EDI-575\_24. Study on the palatability and efficacy of a 0.0024% w/w difenacoum block bait in house mouse (Mus musculus).  XXX | Y | Edialux |  |
| XXX | XXX | EDI-575\_24. Study on the palatability and efficacy of a 0.0024% w/w difenacoum block bait in brown rat (Rattus norvegicus).  XXX | Y | Edialux |  |
| XXX | XXX | Evaluation of the efficacy of the EDI-575\_24 (block rodenticide containing 0.0024% w/w difenacoum) for the control of house mouse infestations in and around agricultural buildings.  XXX | Y | Edialux |  |
| XXX | XXX | Evaluation of the efficacy of EDI-575\_24 (block rodenticide containing 0.0024% w/w difenacoum) for the control of brown rat infestations in and around agricultural buildings. XXX | Y | Edialux |  |
| XXX | XXX | EDI-575\_25. Palatability and efficacy study of a block bait containing 25 mg/kg difenacoum in black rat (Rattus rattus).  XXX | Y | Edialux |  |
| XXX | XXX | EDI-575\_25. Evaluation of the efficacy of a block rodenticide containing 25 mg/kg difenacoum for the control of black rat infestations in and around agricultural buildings.  XXX | Y | Edialux |  |
| XXX | XXX | EDI-575\_24. Palatability and efficacy study of a 26-monthsold difenacoum block bait in black rat (Rattus rattus).  XXX | Y | Edialux |  |

Annex 2: Analytical methods residues – active substance – PAR 2012

**Difenacoum**

Date: 12/2011

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

|  |  |  |  |
| --- | --- | --- | --- |
| matrix | limit | relevant residue | reference or comment |
| plant products | LOQ= 0.01mg/kg | Difenacoum |  |
| food of animal origin | LOQ= 0.01mg/kg | Difenacoum |  |
| soil | LOQ= 0.0214 μg/g | Difenacoum |  |
| drinking water | LOQ = 0.05 μg/L | Difenacoum |  |
| surface water | LOQ = 0.05 μg/L | Difenacoum |  |
| air | Unnecessary due to the low vapour pressure of difenacoum | | |
| body fluids / tissues | LOQ= 0.01mg/kg | Difenacoum |  |

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

**Methods for products of plant origin**

| reference | matrix | LOQ (mg/kg) | principle | comment | owner |
| --- | --- | --- | --- | --- | --- |
| Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469 | Oil-seed rape | LOQ= 0.01mg/kg | *LC-MS/MS* |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

**Methods for foodstuffs of animal origin**

| reference | matrix | LOQ (mg/kg) | principle | comment | owner |
| --- | --- | --- | --- | --- | --- |
| Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469 | Meat | LOQ= 0.01mg/kg | *LC-MS/MS* |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

**Methods for soil**

| reference | LOQ (mg/kg) | principle | comment | owner |
| --- | --- | --- | --- | --- |
| Morlacchini, M., 2006, Residues determination of Brodifacoum, Difenacoum and Bromadiolone in soil, CERZOO (Italy), Study CZ/05/002/Activa/Soil | LOQ= 0.0214 μg/g | *HPLC – UV-VIS* |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

**Methods for sediment**

| reference | LOQ (mg/kg) | principle | comment | owner |
| --- | --- | --- | --- | --- |
| Marshall, L., 2009, Validation of a Method for the Determination of Difenacoum Residues in Sediment, CEM Analytical Services Limited, Study CEMR-4470 | LOQ= 0.01mg/kg | LC-MS/MS |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

**Methods for drinking water and surface water**

| reference | matrix | LOQ (µg/l) | principle | comment | owner |
| --- | --- | --- | --- | --- | --- |
| Martinez M.P. 2005. Difenacoum Technical: Validation of the Analytical Method for the Determination of the Residues in Drinking, Ground and Surface waters, Test Laboratory of ChemService S.r.l. ChemService Study No. CH-288/2005 | Water | LOQ = 0.05 μg/l | *HPLC – MS/MS* |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

**Methods for air**

| reference | LOQ (µg/m3) | principle | comment | owner |
| --- | --- | --- | --- | --- |
| Unnecessary due to the low vapour pressure of difenacoum | | | | |

**Methods for body fluids/tissue**

| reference | matrix | LOQ (mg/kg) | principle | comment | owner |
| --- | --- | --- | --- | --- | --- |
| Marshall, L., 2009, Method Validation for the Determination of Difenacoum in Animal Matrices (Liver and Muscle) and Crop Matrix (Oilseed Rape), CEM Analytical Services Limited, Study CEMR-4469 | Liver | LOQ= 0.01mg/kg | *LC-MS/MS* |  | Activa / PelGar Brodifacoum and Difenacoum Task Force |

Annex 3: Efficacy of the Active Substance from its Use in the SORKIL BLOC – PAR 2012

| **Test product** | **Test organisms** | **Test system / Concentrations applied / exposure time** | **Test results: effects, mode of action, resistance** | **Reference** |
| --- | --- | --- | --- | --- |
| SORKIL BLOC | CD1 mice (*Mus musculus*)  10 mice (5 males, 5 females) | Laboratory test.  Choice feeding test: fresh baits.  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  4-day acclimatization period, 8-day pre-test control diet intake assessment, 4-day bait feeding period and 14-day control bait period. | Amount of intake of the treated baits:  - 85.25% for male  - 81.69% for female  100% mortality was observed in 14 days in both male and female. The times to death were 3 to 8 days after the first intake of treated baits. | XXX |
| SORKIL BLOC | CD rats (*Rattus norvegicus*)  10 rats (5 males, 5 females) | Laboratory test.  Choice feeding test: fresh bait.  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  4-day preconditioning, 8-day pre-test control diet intake, 4-day choice feeding period and at least 14-day post-treatment observations. | Amount of intake of the treated baits:  - 35.10% for male  - 44.08% for female  100% mortality was observed in both male and female. The times to death were 3 to 10 days after the first intake of treated baits. | XXX |
| SORKIL BLOC | CD1 mice (*Mus musculus*)  10 mice (5 males, 5 females) | Laboratory test.  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  Choice feeding test: aged baits.  4-day acclimatization period, 8-day pre-test control diet intake assessment, 4-day bait feeding period and 14-day control bait period. | Amount of intake of the treated baits:  - 80.28% for male  - 81.47% for female  100% mortality was observed in both male and female. The times to death were 5 to 7 days after the first intake of treated baits for male and 5 to 8 days for female. | XXX |
| SORKIL BLOC | CD rats (*Rattus norvegicus*)  10 rats (5 males, 5 females) | Choice feeding test: aged bait.  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  4-day preconditioning, 8-day pre-test control diet intake, 4-day choice feeding period and at least 14-day post-treatment observations. | Amount of intake of the treated baits:  - 37.57% for male  - 34.37% for female  The times to death were 3 to 6 days after the first intake of treated baits for male rats. Seven days after the bait application had commenced, 4 female rats were dead.  100% mortality was observed in male rats. Four of the 5 female rats died (80%) within the timeframe required (14 days).One female rat only consumed 1 g of the aged treated bait during the 4 days application, which seems to be too little to cause death.  Thus the required mortality of 90% in 14 days of all treated animals has been achieved. | XXX |
| SORKIL BLOC | CD Albino rats (*Rattus norvegicus*)  10 rats (5 males, 5 females) | Laboratory test.  Choice feeding test with fresh bait placed in damp conditions for 5 days (at 35ºC ± 2ºC, in a relative humidity greater than 96%).  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  4-day conditioning period, 4-day choice feeding period and at least 14-day post-treatment observations. | The mean acceptance of the test item was 30.0% (S.D. 17.3%):  Mortality was 100% in the test group, with a mean ‘days to death’ of 4.7 days (range 3 to 6 days) | XXX |
| SORKIL BLOC  EDI 575\_25  (25 ppm difenacoum) | Black Rats (*Rattus rattus*)  23 rats | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase (4 days)  Treatment census  Post-treatment lag phase (3 days)  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: 15 days (200 g of oat per station per day)  Treatment : 200 g of bait per day in each lockable bait station, every 2 to 15 meters (total 8 bait stations) during 18 days  Post-baiting: 5 days  (200 g of oat per station per day)  Mortality was observed from the first day of intoxication and noted about every 2 days until the end of the trial. | Estimated efficacy = 91.9 %.  Pre-baiting plateau = 463.3 g/day  Post-baiting = 37.7g/day  R.I = 1 | XXX |
| SORKIL BLOC  EDI 575\_25  (25 ppm difenacoum) | Wild Blackats (*Rattus rattus*)  10 rats (5 males, 5 females) | Choice feeding test: fresh bait.  The quantity of food placed in each pot was sufficient to meet each animal’s daily needs  4-day preconditioning, 4-day pre-test control diet intake, 4-day choice feeding period and at least 14-day post-treatment observations. | Amount of intake of the treated baits: 25 %  100% mortality was observed in 14 days. The times to death were 4 to 7 days after the first intake of treated baits.  R.I = 1 | XXX |

Annex 4: Toxicology and metabolism –active substance – PAR 2012

**Difenacoum**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 12/2011

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.0000011 mg/kg bw/day | Teratogenicity in rabbit | 600 |
| AEL medium-term | 0.0000011 mg/kg bw/day | Teratogenicity in rabbit | 600 |
| AEL acute | 0.0000011 mg/kg bw/day | Teratogenicity in rabbit | 600 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption: not reported |  |
| Oral absorption: 68 % |  |
| Dermal absorption: 0.047 % for wax block bait and paste (Activa Pelgar study) – 3 % for pellet and grain baits (Sorex study) |  |

| **Major change – 2018**  **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 1 – H300 ; H310 ; H330  STOT RE 1 – H372 (blood)  Repr. 1B – H360D  Repr. 1B; H360D: C ≥ 0,003 % STOT RE 2; H373: 0,002 % ≤ C < 0,02 % STOT RE 1; H372: C ≥ 0,02 % |
|  |  |

Annex 5: Toxicology – biocidal product – PAR 2012

**SORKIL BLOC**

Date: 12/2011

|  |  |
| --- | --- |
| **General information** | |
| Formulation Type: wax block |  |
| Active substance(s) (incl. content): 0.005% difenacoum |  |
| Category |  |

| **Acute toxicity, irritancy and skin sensitisation of the preparation** | | | |
| --- | --- | --- | --- |
| The applicant had not submitted toxicological data on EDI-575. Both EDI-575 and EDI-550 are both block bait formulations containing 0.005% (w/w) difenacoum with the same use and user type. The comparison of the compositions of EDI-550 and EDI-575 shows that cereal flour, vegetable oil and sucrose were replaced in EDI-575 by two ingredients: seed mix and vanilla flavouring which have also non-toxic properties. Consequently, a read-across from EDI-550 data to EDI-575 dossier is acceptable.  Data of EDI-550 are the followings:  LD50 oral : not classified for acute oral toxicity based on CLP exemptions based on calculations |  |  |  | |  |
| Rat LD50 dermal (OECD 402) > 2000 mg/kg bw |  |  |  | |  |
| Rat LC50 inhalation: justification for non-submission of data |  |  |  | |  |
| Skin irritation (OECD 404) : non irritant |  |  |  | |  |
| Eye irritation (OECD 405): non irritant |  |  |  | |  |
| Skin sensitisation (OECD 429; modified LLNA): Study not acceptable – not sensitising based on CLP exemptions based on calculations |  |  |  | |  |

Acute toxicity tests:

| Route | Method Guideline | Species Strain Sex no/group | dose levels  duration of exposure | Value LD50/LC50 | Remarks | Reference |
| --- | --- | --- | --- | --- | --- | --- |
| Dermal | OECD 402 | Sprague Dawley rats  5/sex | 2000mg/kg bw | > 2000mg/kg bw | No effect | XXX |

Dermal irritation test:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Species | Method | Average score 24, 48 and 72 h | | Reversibility yes/no | Result | Remarks | Reference |
| Erythema | Oedema |
| Albinos NZ rabbit  3 females | OECD 404  Semi-occlusive, 4h | 0.11 | 0 | na | Not irritant |  | XXX |

Ocular irritation test:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species | Method | Average Score (24h, 48h, 72h) | | | | Result | Reversibility yes/no | Remarks | Reference |
| Cornea | Iris | Conjunctiva | |
| Redness | Chemosis |
| Albinos NZ rabbit  3 Males | OECD 405 | 0 | 0 | 0.78 | 0.22 | Not irritant | Redness reversible on day 3  Chemosis reversible on day 2 |  | XXX |

Sensitisation test:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Method** | **Result** | **Remark** | **Reference** |
| CBA/J mice  4 females/group | Non radioactive cell counting LLNA: 5, 10, 25% (w/w) in dimethylformamide on day 1, 2, 3. Sacrifice on Day 6 and determination of the proliferation of lymphocytes in the draining auricular lymph nodes by cell counting | SI < 1.4: not sensitiser | Not acceptable (method not currently validated) | XXX |

| **Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)** | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies |  |  |  |  |
| Toxicological data on active substance(s) (not tested with the preparation) |  |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) |  |  |  |  |
|  |  |  |  |  |
| Further toxicological information |  | | | |

|  |  |
| --- | --- |
| **Major change – 2018**  **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
| Regulation 1272/2008/EC | STOT RE 2 - H373 |

Annex 6: Safety for professional operators – PAR 2012

**SORKIL BLOC**

Date: 12/2011

**Exposure assessment**

| **Exposure scenarios for intended uses** |
| --- |

Primary exposure of professionals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Component | CAS | Actual  Dermal  Total  [mg/day] | Actual  Dermal  Total  [mg/kg/d] | Inhalation Exposure  [mg/m³] | Model |
| Sachet not considered: exposure during loading and cleaning (worst case) | | | | | | |
| Tier 1 (without gloves) | Difenacoum | 56073-07-5 | 8.04 x10-5 | 1.34x10-6 | negligible | Cefic study |
| Tier 2 (with gloves; penetration factor: 10%) | Difenacoum | 56073-07-5 | 8.04x10-6 | 1.34x10-7 | negligible | Cefic study |
| Sachet considered: exposure only during cleaning considered (reasonable case) | | | | | | |
| Tier 1 (without PPE) | Difenacoum | 56073-07-5 | 2.01x10-6 | 3.35x10-8 | negligible | Cefic study |

Risk assessment

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Scenario | Component | CAS | AEL [mg/kg/d] | Absorption  [%] | | Inhal ext [mg/m3] | Derm syst  [mg/kg bw/d] | %AEL | Risk |
| inh | derm |
| Sachet not considered: exposure during loading and cleaning (worst case) | | | | | | | | | |
| Tier 1 (without gloves) | Difenacoum | 56073-07-5 | 1.1x10-6 | 100 | 0.047 | negligible | 1.34x10-6 | 122 | Unacceptable |
| Tier 2 (with gloves; penetration factor: 10%) | Difenacoum | 56073-07-5 | 1.1x10-6 | 100 | 0.047 | negligible | 1.34x10-7 | 12 | Acceptable |
| Sachet considered: exposure only during cleaning considered (reasonable case) | | | | | | | | | |
| Tier 1 (without gloves) | Difenacoum | 56073-07-5 | 1.1x10-6 | 100 | 0.047 | negligible | 3.35x10-8 | 3 | Acceptable |

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

**SORKIL BLOC**

Date: 12/2011

| **General information** | |
| --- | --- |
| Formulation Type: wax block |  |
| Active substance(s) (incl. content): difenacoum 0.005% |  |
| Category |  |
| Authorisation number |  |

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

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

| **Exposure scenarios for intended uses** | |
| --- | --- |
| Primary exposure: non-professional use |
| Secondary exposure, acute: child ingesting bait |
| Secondary exposure, chronic: none |

Conclusion:

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

Details for the exposure estimates:

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 0.3 mg of product per day.

Details for the exposure estimates:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual  Dermal Total**  **[mg/day]** | **Actual  Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| Sachet not considered: exposure during loading and cleaning (worst case) | | | | | | |
| Non professional | Difenacoum | 56073-07-5 | 7.20x10-6 | 1.20x10-7 | negligeable | Cefic study |
| Sachet considered: exposure only during cleaning considered (reasonable case) | | | | | | |
| Non professional | Difenacoum | 56073-07-5 | 6.72 x10-7 | 1.12x10-8 | negligeable | Cefic study |

Risk assessment

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption**  **[%]** | | **Inhalation exposure [mg/m3]** | **Derm syst**  **[mg/kg bw/d]** | | **Expo**  **%AEL** | **Risk** |
| **inhalation** | **dermal** |
| Sachet not considered: exposure during loading and cleaning (worst case) | | | | | | | | | | |
| Non-professional | Difenacoum | 56073-07-5 | 1.1x10-6 | 100 | 0.047 | negligeable | | 1.20x10-7 | 11 | Acceptable |
| Sachet considered: exposure only during cleaning considered (reasonable case) | | | | | | | | | | |
| Non-professional | Difenacoum | 56073-07-5 | 1.1x10-6 | 100 | 0.047 | negligeable | | 1.12x10-8 | 1 | Acceptable |

Annex 8: Residue behaviour – PAR 2012

**SORKIL BLOC**

Date: 12/2011

The intended use descriptions of the SORKIL BLOC for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

1. 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-2)
2. 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-3)
3. 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-4)
4. 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-5)
5. 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-6)
6. Human exposure to biocidal products – TNsG June 2007 [↑](#footnote-ref-7)
7. Chambers JG and Snowdon PJ - Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits - Synergy Laboratories Ltd., Report No. SYN/1302. Unpublished. [↑](#footnote-ref-8)
8. HEEG (Human Exposure Expert Group) opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants); June 2010 [↑](#footnote-ref-9)
9. [↑](#footnote-ref-10)
10. "An evaluation of performance standards and non-radioactive endpoints for the LLNA – The report and recommendations of ECVAM Workshop 65" (2008) [↑](#footnote-ref-11)
11. Non-radioactive LLNA [↑](#footnote-ref-12)
12. It has to be noted that this dermal absorption study has not been re-assessed by FR taking into account the criteria laid in the EFSA guidance on dermal absorption of 2012. [↑](#footnote-ref-13)
13. Unlike the value for the loading phase, the number of blocks is not taken into account. [↑](#footnote-ref-14)
14. Technical Guidance Document on Risk Assessment, Part II, 2003 [↑](#footnote-ref-15)
15. ESD PT14: Emission scenario document (ESD) for biocides used as rodenticides (PT14) (EUBEES ESD, 2003) [↑](#footnote-ref-16)
16. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-17)
17. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-18)
18. Provided that the efficacy of the product for this species has been demonstrated. Where relevant, the application rate or the instructions for use should be adapted for this species accordingly. [↑](#footnote-ref-19)
19. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-20)
20. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-21)