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 MAJOR CHANGE AND RENEWAL OF NATIONAL AUTHORISATIONAUTHORIZATION APPLICATIONS**



ULTIMA PASTE

Product type 14

Brodifacoum as included in the Union list of approved active substances

Case Number in R4BP: BC-RF030815-40 and BC-UH027374-34

Evaluating Competent Authority: France

Date: 13th April 2018

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Note to the reader:

**Disclaimer regarding general information**

This consolidated PAR for the renewal of the product authorisation ULTIMA PASTE is based on the PAR of the first authorisation SAPHIR PASTE granted by IE on 2011, in which all addenda have been included.

In part 1 and 2 of this consolidated PAR:

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

⁻ the assessments related to the renewal and last major change (assessed concomitantly with the renewal) of the product,are indicated at the end of each section and are highlighted in grey.

In part 3 of the consolidated PAR “proposal for decision”: the summary of product characteristics is pointed out and corresponds to the decision for the renewal, including the major change.

**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 renewal in Part 4, uses for “professionals” are mentioned according to the agreed standard SPC, but they not relevant in France. In case of mutual recognitions, it is proposed that each cMS adapts the conditions of authorization of the product according to its own legislation.

1. **History of the dossier (updated PAR -2017 )**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *IE* | na | 30/06/2011 | SAPHIR PASTE, initial assessment |
| NA-MRS | *FR* | na | 9/08/2012 | SAPHIR PASTE |
| NA-BBS | *FR* | n.a. | 08/01/2013 | same product ULTIMA PASTE |
| NA-MIC | *IE* |  |  | *SAPHIR PASTA*  *Addition of a trade name and packaging* |
| NA-MAC | *FR* | BC-RF030815-40 | 16.03.2018 | *Reduction of the concentration of Brodifacoum (from 0.004 % to 0.0025 %)*  *Addition of a trade name* |
| NA-RNL | *FR* | BC-UH027374-34 | 16.03.2018 | *Renewal of the authorisation* |

na: not applicable

**Authorised uses (0.005 % of brodifacoum)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionnals | Rats (*Rattus rattus* and *Rattus norvegicus*) | High infestation : 60 g of product/ bait station separated by 5 meters  Low infestation: 60 g of product / bait station separated by 10 meters | In and around buildings  Open areas and waste dumps | Individual sachets in paper tea  and cartridge in PP  Minimum pack size :5kg |
| Mice (*Mus musculus*) | High infestation : 10 g of product/ bait station separated by 3 meters  Low infestation: 10 g of product / bait station separated by 5 meters |
| Non professionnals | Rats (*Rattus rattus* and *Rattus norvegicus*) | High infestation : 60 g of product / bait station separated by 5 meters  Low infestation: 60 g of product / bait station separated by 10 meters | In and around buildings | Individual sachets in paper tea  and cartridge in PP  Maximum pack size :1,5 kg |
| Mice (*Mus musculus*) | High infestation : 10 g of product / bait station separated by 3 meters  Low infestation: 10 g of product / bait station separated by 5 meters |

**Intended uses for the major change and renewal (0.0025 % of brodifacoum)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Users** | **Target organisms** | **Application rate** | **Field of use** | **Packagings** |
| Professionals  and trained professional | Rat (*Rattus norvegicus*) | High infestation : 60 g of product / bait station separated by 5 meters  Low infestation: 60 g of product / bait station separated by 10 meters | In and around buildings | Individual sachets in paper tea  and cartridge in PP |
| Mice (*Mus musculus*) | High infestation : 10 g of product / bait station separated by 3 meters  Low infestation: 10 g of product / bait station separated by 5 meters |
| Trained professional | Rat (*Rattus norvegicus*) | High infestation : 60g of product / bait station separated by 5 meters  Low infestation: 60 g of product / bait station separated by 10 meters | Open areas waste dumps and landfills | Individual sachets in paper tea  and cartridge in PP |
| Non professionnals | Rat (*R*attus *norvegicus*) | High infestation : 60 g of product / bait station separated by 5 meters  Low infestation: 60 g of product / bait station separated by 10 meters | In and around buildings | For rats and mice  The bait is supplied in 10g sachets (tea paper sachet).  \* If the product is intended to be used against mice, 5 sachets can be removed. |
| Mice (*Mus musculus*) | High infestation : 10 g of product / bait station separated by 3 meters  Low infestation: 10 g of product / bait station separated by 5 meters | Indoor | The bait is supplied in 10g sachets (tea paper sachet). |

# General information about the product application(initial PAR 2011)

This application for product authorisation is for:

|  |  |
| --- | --- |
| **Trade name:** | Saphir Paste |
| **Authorisation No.:** | IE/BPA 70286 (Professional and Trained Professional)  IE/BPA 70287 (General public / Non-professional) |

Saphir Paste trade names in other Member States (based on R4BP data):

|  |  |
| --- | --- |
| **Trade name** | **Member State** |
| Brodipesce Pate | Estonia, France, Latvia |
| Raco Force Paste | Ireland, UK |
| Saphir (Pasta) | Italy |
| Rodistar | Italy |
| Biosnap Rat and Mouse Killer | UK |
| Doff Prebaited Mouse Station | UK |
| Ratta Extra Brodifacoum Paste | UK |

## Applicant/ Authorization Holder

|  |  |
| --- | --- |
| **Company Name:** | Lodi S.A.S. |
| **Address:** | Parc d'Activités des 4 Routes  F-35390 Grand Fougeray,  France |
| Tel: | +33 299 084 859 |
| **E-mail:** | [regulatory@lodi.fr](mailto:regulatory@lodi.fr) |
| **Contact:** | Ms Agnes Doyen |

## Marketing/Distributing Company (where applicable)

|  |  |
| --- | --- |
| **Company Name:** | LODI (UK) |
| **Address:** | Pensnett Trading Estate, Building 69, 3rd Avenue, Kingswinford, West Midlands, DY6 7FD  UK |
| **Tel:** | +44 (0)1384 404242 |
| **E-mail:** | N/A |
| **Contact:** | N/A |

## General Information on the Biocidal Product

|  |  |
| --- | --- |
| **Trade name:** | Saphir Paste |
| **Manufacturer’s development code number(s):** | N/A |
| **Active substance content:** | 0.004% w/w Brodifacoum |
| **Main group:** | MG03 Pest Control |
| **Product type:** | PT14 (Rodenticides) |
| **Product Specification:** | See Confidential Annex |
| **Site of product formulation:** | See Confidential Annex |
| **Frame formulation (yes/no):** | No |
| **Formulation type:** | Paste Bait |
| **Ready to use product (yes/no):** | Yes |
| **Chemical/micro-organism:** | Chemical Substance |
| **Contain or consist of GMOs[[1]](#footnote-1) (yes/no):** | N/A |
| **Is the product already notified/authorised (Directive 98/8/EC) (yes/no);**  **If yes:**  **product name:** | No  N/A |
| **Is the biocidal product equivalent to the product assessed for the purpose of Annex I inclusion to 98/8/EC (yes/no):** | No. |

|  |  |
| --- | --- |
| **Manufacturer of Formulated Product** | |
| **Company Name:** | Company CGB (Compagnie Générale des Biocides) |
| **Address:** | Parc d'Activités des 4 Routes –  F-35390 Grand Fougeray,  France |
| **Tel:** | +33 299 084 859 |
| **E-mail:** | [regulatory@cgbiocides.fr](mailto:regulatory@cgbiocides.fr) |
| **Contact:** | Ms Agnes Doyen |

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

|  |  |
| --- | --- |
| **Active substance chemical name:** | Brodifacoum |
| **IUPAC name:** | *3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin* |
| **CAS No:** | 56073-10-0 |
| **EC No:** | 259-980-5 |
| **Purity (minimum, g/kg or g/l):** | 950 g/kg |
| **Molecular formula:** | C31H23BrO3 |
| **Structural Formula:** |  |
| **Manufacturing site:** | See Confidential Annex |
| **Specification of pure active substance:** | See Confidential Annex |
| **Is a new active substance data package (source) supplied (yes/no):** | No |
| **If yes, Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):** | N/A |
| **If no, does the applicant have a LoA to the active substance data packaged used to support Annex I inclusion (yes/no):** | Yes (Pelgar International Ltd.) |

|  |  |
| --- | --- |
| **Manufacturer of active substance(s)** | |
| **Company Name:** | Pelgar International Ltd. |
| **Address:** | Unit 13  Newman Lane Industrial Estate  Alton.  Hants. GU34 2 QR  UK |
| **Tel:** | +44 (0)1420 80744 |
| **E-mail:** | anne@pelgar.co.uk |
| **Contact:** | Ms Anne Withall |

## Information on the intended use(s) of the biocidal product

|  |  |
| --- | --- |
| **Main Group:** | MG03 (Pest control) |
| **Product-type:** | PT14 (Rodenticide) |
| **Intended use:** | Brodifacoum paste bait to control rodents indoors, outdoors around buildings (amateur use) and outdoors in open areas and waste dumps (professionals only) for the protection of public health, stored products and materials. |
| **Target organisms:** | (I.1) Rodents  (I.1.1) Murids  (I.1.1.1) Brown rats (*Rattus Norvegicus*)  (I.1.1.3) House mouse (*Mus musculus*) |
| **Development stage:** | (II.1) Juveniles  (II.2) Adults |
| **Function:** | Rodenticide |
| **Mode of action:** | Anticoagulant  III.2 long-term action  III.2.1 anticoagulant  III.2.1.1 ingestion toxin  III.2.1.1.1 ingestion by eating |
| **Application aim:** | VII.1 Stored product protection/food protection  VII.2 Health protection  VII.3 Material protection (e.g. historical buildings, technical objects) |
| **Category of users:** | V.1 Non Professional/General public  V.2 Professional  V.3 Trained/specialised professional |
| **Area of use (indoors/outdoors):** | IV.1 Indoors (warehouses, houses, outbuildings)  IV.2 Outdoors (in and around buildings),  IV.2 Outdoors (open areas and waste dumps) IE/BPA 70286 only |
| **Application method:** | VI.2 Covered applications  VI.2.1 In bait stations(product can only be applied in bait stations for waste dump and open area applications)  VI.2.2 Other coverings (this does not include application down rat holes) |
| **Directions for use including minimum and maximum application rates, typical size of application area:** | **IE/BPA 70286, IE/BPA 70287**  Indoors and outdoors (in and around buildings)  Rats (Adult and Juvenile):  Secure 60g of bait in covered, tamper resistant baiting stations spaced 10m apart (3m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).  Mice (Adult and Juvenile):  Secure 10g of bait, in covered, tamper resistant baiting stations spaced 5m apart (3m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).  **IE/BPA 70286 (Professional Use Only)**  Outdoors (open areas and waste dumps)  Rats:  Secure 60g of baits in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings).  Mice:  Secure 10g bait in covered tamper resistant baiting stations or covered bait points spaced 5m apart (3m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). |
| **Potential for release into the environment (yes/no):** | Yes |
| **Potential for contamination of food/feedingstuff (yes/no):** | No |

* **Major change and renewal applications for ULTIMA PASTE - 2017**

**COMPARATIVE ASSESSMENT**

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

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

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

## Documentation

## Data submitted in relation to product application

A full new product dossier was submitted by Lodi S.A.S in support of the product Saphir Paste containing brodifacoum.

* **Major change and renewal applications for ULTIMA PASTE - 2017**

For the major change, please refer to the reference list in Annex1

For the renewal no new efficacy data was submitted.

## Access to documentation

Lodi S.A.S. has a letter of access to data held by PelGar International Ltd which was used to support the Annex I listing of the active substance brodifacoum in Directive 98/8/EC. Lodi S.A.S. does not have access to the Annex III product data package held by PelGar International Ltd.

Lodi S.A. has a letter of access to product data held by Belgagri S.A. relating to brodifacoum choice feeding trial for rats and mice in fresh and aged bait.

Lodi S.A. has a letter of access to product data held by BIO 6 S.A. relating to brodifacoum choice deeding trial against rats and albino house mice on aged product.

Lodi S.A.S has a letter of access to formulation toxicological data for the product Vertox Pasta Bait held by Pelgar International Limited.

* **Major change and renewal applications for ULTIMA PASTA - 2017**

For the major change, additional LOA has been submitted

## Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

## Harmonised classification of the active substance

Brodifacoum is not currently classified in Annex I of Council Directive 67/548/EEC or according to Annex VI of Regulation (EC) no 1907/2006 (REACH). The following classification and labelling is proposed on the basis of available data resulting from the review programme for brodifacoum and is provided in the table below according to Directive 67/548/EEC/Regulation (EC) 1272/2008. Additionally, the extrapolation of these proposals using the BG RCI converter tool (http://www.gischem.de/ghs/konverter) is also provided in the table below in accordance with Regulation (EC) 1272/2008.

**Classification of the active substance, brodifacoum, according to Directive 67/548/EEC and CLP Regulation (EC) 1272/2008- (PAR 2011):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Symbol(s):** |  | **Pictogram(s):** |  |
| **Indication(s) of danger:** | T+ Very Toxic  N Dangerous for the Environment | **Signal word(s):** | Danger |
| **Risk phrases:** | R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.  R43: May cause sensitisation by skin contact R48/23/24/25: Toxic: Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61: May cause harm to the unborn child. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. | **Hazard statements:** | H300: Fatal if swallowed.  H310: Fatal in contact with skin.  H317: May cause an allergic skin reaction  H330: Fatal if inhaled.  H360D: May damage the unborn child.  H372: Causes damage to organs through prolonged or repeated exposure through inhalation. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects. |
| **Safety phrases:** | S20/21: When eating do not eat, drink or smoke  S35: The material and its container must be disposed of in a safe way  S36/37: Wear suitable protective clothing and gloves  S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)  S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheet. | **Precautionary statements:** | P101: If medical advice ist needed, have product container or label at hand.  P103: Read label before use.  P270: Do not eat, drink or smoke when using this product.  P273: Avoid release to the environment.  P280: Wear protective gloves and clothing  P281: Use personal protective equipment as required.  P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.  P308 + P313: IF exposed or concerned: Get medical advice/attention.  P314: Get medical advice/attention if you feel unwell.  P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations. |

Specific concentration limits for brodifacoum are proved below in accordance with Directive 67/548/EEC:

|  |  |  |
| --- | --- | --- |
| **Specific concentration limits:** | C≥2.5%  1%≤C<2.5% 0.5%≤C<1%  0.25%≤C<0.5%  0.025%≤C<0.25% 0.0025%≤C<0.025% | T+, N; R26/27/28-48/23/24/25-43-61-50/53 T+, N; R26/27/28-48/23/24/25-43-61-51/53 T+, N; R26/27/28-48/23/24/25-61-51/53  T+, N; R26/27/28-48/23/24/25-51/53  T ; R23/24/25-48/20/21/22-52/53  Xn; R20/21/22 |

Additionally, brodifacoum does not exhibit hazardous physical-chemical properties. Brodifacoum is thermally stable at 52°C. It is not classified as highly flammable and does not undergo self ignition below its melting point. It is not considered to be explosive or to have oxidising properties. There is no record that it has reacted with any storage container during many years of industrial production. It is concluded therefore, that there are no hazards associated with its physico-chemical properties under normal conditions of use.

* **Major change and renewal applications for ULTIMA GRAIN - 2017**

Classification of the active substance, brodifacoum, according to CLP Regulation (EC) 1272/2008 (ATP9):

|  |  |
| --- | --- |
| **Pictograms:** | GHS09 GHS08 GHS06 |
| **Signal word:** | Danger |
| **Hazard category** | Acute Tox 1  STOT RE 1  Repr 1A  Aquatic Acute 1  Aquatic Chronic 1 |
| **Hazard statements:** | H300: Fatal if swallowed.  H310: Fatal in contact with skin.  H330: Fatal if inhaled.  H360D: May damage the unborn child.  H372: Causes damage to organs (blood) through prolonged or repeated exposure.  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects. |
| STOT RE 2; H373: 0.002 % ≤ C < 0.02 %  STOT RE 1; H372: C ≥ 0.02 %  Repr. 1A; H360D: C ≥ 0.003 %  M-Factors:  M = 10  M(Chronic) = 10 | |

## Harmonised classification and labelling of the biocidal product

The current classification and labelling, based on the biocidal product evaluation for Saphir Paste, is provided in the tables below according to Directive 99/45/EC and Regulation (EC) 1272/2008, Annex VI, Part 3.

**Classification and Labelling of the biocidal product according to Directive 99/45/EC –(PAR 2011):**

|  |  |
| --- | --- |
| **Symbol(s):** | Not applicable |
| **Indication(s) of danger:** | Not applicable |
| **Risk phrases:** | Not applicable |
| **Safety phrases:** | S1+S2: Keep locked up and out of reach of children  S13: Keep away from food, drink and animal feeding stuffs.  S20 + S21: When using do not eat, drink or smoke.  S24: Avoid contact with skin  S35: This material and its container must be disposed of in a safe way.  S37: Wear suitable gloves (Professional only)  S46: If swallowed, seek medical advice immediately and show this container or label.  S49: Keep only in the original container  S61: Avoid release to the environment. Refer to special instructions/safety data sheet |

Classification and Labelling of the biocidal product according to the CLP Regulation (EC) 1272/2008 (PAR 2011):

|  |  |
| --- | --- |
| **Pictogram(s):** | Not applicable |
| **Signal word(s):** | Not applicable |
| **Hazard statements:** | Not applicable |
| **Precautionary statements** | P102: Keep out of reach of children.  P103: Read label before use.  P220: Keep/Store away from food, drink and animal feedingstuffs.  P262: Do not get on skin  P270: Do not eat, drink or smoke when using this product.  P273: Avoid release to the environment  P280: Wear protective gloves (Professional only)  P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician.  P404+405: Store locked up in a closed container.  P501: Dispose of contents/container in accordance with national regulations. |

**Physical-chemical properties:**

Not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view.

**Toxicology:**

There is no toxicology classification for the product under the Directive 99/45.

There is no toxicology classification for the product under the CLP Regulation 1272/2008.

**Environment:**

There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

**Other:**

Further, the content of the label should be updated to comply with the labelling requirements established (for biocidal products) where the labelling requirements in Article 20(3) of Directive 98/8/EC has been implemented. The safety data sheet should comply with the requirements in Regulation (EC) 1907/2006.

**Additional Labelling Requirements:**

|  |  |
| --- | --- |
| Addition safety Information: | To avoid risks to human health and the environment, comply with the instructions for use.  Harmful to wildlife  Use bait containers clearly marked “poison” at all surface baiting points.  Remove all remains of bait, dead rodents during and after treatment and dispose of safely.  Apply only in positions inaccessible to children and pets. |
| Special labelling provisions for Ireland: | Use Biocides Safely and Sustainably  (IE/BPA 70286) Not For Amateur Sale  It is illegal to use this product for uses or in a manner other than that prescribed on this label. |
| If a separate leaflet is attached to or supplied with the product, add the following information to the front label: | Read attached instructions before use |

* **Major change and renewal applications - 2017**

Classification and Labelling of the biocidal product according to the CLP Regulation (EC) 1272/2008:

|  |  |
| --- | --- |
| **Pictogram(s):** |  |
| **Signal word(s):** | Warning |
| **Hazard statements:** | H373 : May cause damage to organs (blood) through prolonged or repeated exposure |
| **Precautionary statements** | P260: Do not breathe dust/fumes/gas/mist/vapours/spray  P314: Get medical advice/attention if you feel unwell  P501: Dispose of contents/container in accordance with local regulation |

## Packaging

The packaging details for the biocidal product, Saphir Paste, as presented by the applicant, are outlined below for amateur and professional users (initial PAR 2011).

**Nomenclature:** PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride, AL = Aluminium

**Amateur product packaging:**

On the basis of the packaging details presented, it is considered appropriate to limit aspects of the packaging for amateur users as a risk mitigation measure. Packaging restrictions are to be limited to pre-baited bait stations and refill packs with a **maximum pack-size of 500g**. Additionally, the pasta bait should be supplied to the amateur market in sachets/wrapped in order to reduce exposure risks to amateur operators during application to bait stations.

**Amateur product packaging:**

**Amateur product packaging: cardboard case**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Container description:** | Cardboard case | | | |
| **Pack size(s):** | 50g | 100g | 120g | 200g |
| **Baits per pack:** | 5x  10g | 10x  10g | 12x  10g | 20x  10g |
| **Pack dimensions (LxWxH):** | 50 x 24 x 80 | 100 x 48 x 160 | 100 x 48 x 160 | 140 x 55 x 180 |
| **Inner packaging materials:** | PE or PP sachet | | | |
| **Outer packaging materials:** | Cardboard + PE liner | | | |
| **Ready-to-use (yes/no)** | Yes | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | |
| N/A | | | |
| **Shelf-life:** | 3 years | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | |

**Amateur product packaging: cardboard case**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Container description:** | Cardboard case | | | |
| **Pack size(s):** | 240g | 250g | 480g | 500g |
| **Baits per pack:** | 24x  10g | 25x  10g | 48x  10g | 50x  10g |
| **Pack dimensions (LxWxH):** | 140 x 55 x 180 | 140 x 55 x 180 | 140 x 70 x 210 | 140 x 70 x 210 |
| **Inner packaging materials:** | PE or PP sachet | | | |
| **Outer packaging materials:** | Cardboard + PE liner | | | |
| **Ready-to-use (yes/no)** | Yes | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | |
| N/A | | | |
| **Shelf-life:** | 3 years | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | |

**Amateur product packaging: SACHETS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Container description:** | Sachets | | | |
| **Pack size(s):** | 200 g | 250 g | 480 g | 500 g |
| **Baits per pack:** | 20\*10g | 25\*10g | 48\*10g | 50\*10g |
| **Pack dimensions (LxWxH):** | 180 x 50 x 190 | 190 x 50 x 190 | 190 x 50 x 250 | 190 x 50 x 250 |
| **Inner packaging materials:** | PE or PP sachet | | | |
| **Outer packaging materials** | PE | PE sachet (zip pouch) | PE | PE |
| **Ready-to-use (yes/no)** | Yes | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | |
| N/A | | | |
| **Shelf-life:** | 3 years | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | |

**Amateur product packaging: PREBAITED BAIT STATIONS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Container description:** | Pre-baited bait stations in cardboard outer | | |
| **Pack size(s):** | 10 g | 20 g | 60 g |
| **Baits per pack:** | 1\*10g | 2\*10g | 6\*10g |
| **Pack dimensions (LxWxH):** | 135 x 43 x 80 | 135 x 43 x 80 | 240 x 105x x190 |
| **Packaging materials:** | PP pre-baited station into Cardboard case | | |
| **Ready-to-use (yes/no)** | Yes | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | |
| N/A | | |
| **Shelf-life:** | 3 years | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | |

**Professional product packaging**

**Professional Product packaging: Buckets**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Container description:** | Buckets | | | | |
| **Pack size(s):** | 1 kg | 2 kg | 2.5 kg | 3 kg | 4 kg |
| **Baits per pack:** | 100\*10g | 200\*10g | 250\*10g | 300\*10g | 400\*10g |
| **Pack dimensions (LxWxH):** | 250 x 170 x 120 | 290 x 205 x 215 | 290 x 205 x 215 | 290 x 205 x 215 | 290 x 200 x 270 |
| **Inner Packaging materials:** | PE or PP sachet or loose bait | | | | |
| **Outer Packaging materials:** | PE or PP bucket | | | | |
| **Ready-to-use (yes/no)** | Yes | | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | | |
| N/A | | | | |
| **Shelf-life:** | 3 years | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | |

**Professional Product packaging: Buckets**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Container description:** | Buckets | | | | |
| **Pack size(s):** | 5 kg | 10 kg | 15 kg | 20 kg | 25 kg |
| **Baits per pack:** | 500\*10g | 1000\*10g | 1500\*10g | 2000\*10g | 2500\*10g |
| **Pack dimensions (LxWxH):** | 290 x 200 x 270 | 390 x 300 x 350 | 380 x 285 x 450 | 380 x 285 x 450 | 380 x 285 x 450 |
| **Inner Packaging materials:** | PE or PP sachet or loose bait | | | | |
| **Outer Packaging materials:** | PE or PP bucket | | | | |
| **Ready-to-use (yes/no)** | Yes | | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | | |
| N/A | | | | |
| **Shelf-life:** | 3 years | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | |

**Professional product packaging: cardboard boxes**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Container description:** | Cardboard boxes | | | | | |
| **Pack size(s):** | 3 kg | 5 kg | 10 kg | 15 kg | 20 kg | 25 kg |
| **Baits per pack:** | 300\*10g | 500\*10g | 1000\*10g | 1500\*10g | 2000\*10g | 2500\*10g |
| **Pack dimensions (LxWxH):** | 150 x 100 x 150 | 290 x 200 x 270 | 390 x 290 x 240 | 390 x 390 x 245 | 400 x 400 x 370 | 400 x 400 x 370 |
| **Inner Packaging materials:** | PE or PP sachet or loose bait | | | | | |
| **Outer Packaging materials:** | Cardboard + PE liner | | | | | |
| **Ready-to-use (yes/no)** | Yes | | | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | | | |
| N/A | | | | | |
| **Shelf-life:** | 3 years | | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | | |

**Professional product packaging: cardboard cases**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Container description:** | Cardboard cases | | | | |
| **Pack size(s):** | 50 g | 100 g | 120 g | 200 g | 240 g |
| **Baits per pack:** | 5\*10g | 10\*10g | 12\*10g | 20\*10g | 24\*10g |
| **Pack dimensions (LxWxH):** | 70 x 50 x 105 | 100 x 48 x 160 | 100 x 48 x 160 | 140 x 55 x 190 | 140 x 55 x 190 |
| **Inner Packaging materials:** | PE or PP sachet or loose bait | | | | |
| **Packaging materials:** | Cardboard + PE liner | | | | |
| **Ready-to-use (yes/no)** | Yes | | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | | |
| N/A | | | | |
| **Shelf-life:** | 3 years | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | |

**Professional product packaging: cardboard cases**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Container description:** | Cardboard cases | | | | |
| **Pack size(s):** | 250g | 480g | 500g | 520g | 720g |
| **Baits per pack:** | 25\*10g | 48\*10g | 50\*10g | 52\*10g | 72\*10g |
| **Pack dimensions (LxWxH):** | 140 x 55 x 190 | 140 x 70 x 210 | 140 x 70 x 210 | 140 x 70 x 210 | 183 x 72 x 263 |
| **Inner Packaging materials:** | PE + PP sachet or loose bait | | | | |
| **Packaging materials:** | Cardboard + PE liner | | | | |
| **Ready-to-use (yes/no)** | Yes | | | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | | | |
| N/A | | | | |
| **Shelf-life:** | 3 years | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | |

**Professional product packaging: cardboard cases**

|  |  |  |  |
| --- | --- | --- | --- |
| **Container description:** | Cardboard cases | | |
| **Pack size(s):** | 750 g | 1 kg | 2 kg |
| **Baits per pack:** | 75\*10g | 100\*10g | 200\*10g |
| **Pack dimensions (LxWxH):** | 183 x 72 x 263 | 183 x 72 x 263 | 320 x 210 x 170 |
| **Inner Packaging materials:** | PE + PP sachet or loose bait | | |
| **Packaging materials:** | Cardboard + PE liner | | |
| **Ready-to-use (yes/no)** | Yes | | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | | |
| N/A | | |
| **Shelf-life:** | 3 years | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | |

**Professional product packaging: Zip pouch**

|  |  |
| --- | --- |
| **Container description:** | Zip pouch |
| **Pack size(s):** | 250 g |
| **Baits per pack:** | 25\*10g |
| **Pack dimensions (LxWxH):** | 195 x 150 x 40 |
| **Outer packaging materials:** | PE + PP sachet or loose bait |
| **Inner packaging materials:** | PE sachet (zip pouch) |
| **Ready-to-use (yes/no)** | Yes |
| **Child safety features (yes/no):**  **If yes, please specify:** | No |
| N/A |
| **Shelf-life:** | 3 years |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. |

**Professional product packaging: Prebaited bait stations**

|  |  |  |
| --- | --- | --- |
| **Container description:** | Prebaited bait stations | |
| **Pack size(s):** | 240 g | 480 g |
| **Baits per pack:** | 24\*10g | 48\*10g |
| **Pack dimensions (LxWxH):** | 240 x 115 x 190 | 240 x 115 x 190 |
| **Outer packaging materials:** | cardboard case | |
| **Inner packaging materials:** | PP + PP pre-baited station | |
| **Ready-to-use (yes/no)** | Yes | |
| **Child safety features (yes/no):**  **If yes, please specify:** | No | |
| N/A | |
| **Shelf-life:** | 3 years | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | |

**Professional product packaging: Cartridge (for use with caulking gun)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Container description:** | Cartridge | | | |  |  |
| **Pack size(s):** | 80g | 150g | 280g | 310g | 400g | 500g |
| **Baits per pack:** | N/A | N/A | N/A | N/A | N/A | N/A |
| **Pack dimensions (LxWxH):** | 145\*Ø28 ; | 124,5\* 46,2 | 216\*Ø46,2 | 256\*Ø46,8 | 216\*Ø58.2 |  |
| **Packaging materials:** | PP | PP | PP | PP | PP | PP |
| **Ready-to-use (yes/no)** | Yes | | | |  |  |
| **Shelf-life:** | 3 years | | | | | |
| **Conditions of storage:** | Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children. | | | | | |

|  |  |
| --- | --- |
|  |  |
| Container materials[[3]](#footnote-3): | Case – cardboard with PE liner  Bag – PE  Sachets – PE + PP  Pre-baited bait stations – PP  Bucket – PP or PE  Box – Cardboard with PE liner  Cartridge: PP |
| Safety features: | Covered bait stations (tamper resistant)  Wrapped bait (sachets) |

* **Packagings authorized by FR CA for the product SAPHIR PASTA in the frame work of the mutual recognition:**

**For professional users:**

SAPHIR PASTA is supplied in individual tea paper sachet (10 g).

Tea paper sachets are packed in:

- PP bucket (5-10 kg)

- Cardboard box with PE liner (5-10-15-20 kg)

**For non professional users:**

SAPHIR PASTA is only supplied in tea paper sachet (10 g).

Tea paper sachets are packed in:

* Cardboard box with PE liner (50-100-120-150-200-240-250-300-400-480-500 g)
* Tamper resistant pre-filled bait station (PVC, PE or PP)

**Packagings claimed and accepted by FR CA for the major technical modification of the product ULTIMA PASTE:**

**For professional and users**

ULTIMA PASTE is packed in individual tea sachet paper (10 g) and cartridges in PE (50-500 g)

Individual sachets are packed in

* Bucket (PP, PE) :3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10 kg
* Cardboard box with inner PE liner :3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10 kg
* Pre-baited station (PP, PS, PVC): 10g, in cardboard box with inner PE liner of, 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg.

Cartridge in PE contain: 50 g, 100g, 150g, 200g, 250g, 260g, 270g, 280g, 310g, 500 g.

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

**For non professional users:**

**Rats and Mice**

ULTIMA PASTE is packed in individual tea sachet paper (10 g)

* in prefilled bait station (PVC, PP, or PS) - secondary packaging: carton sleeve of 20, 30, 40, 50, 60, 70, 80, 90, 100, 110 120, 130, 140 et 150.g
* in cardboard box: 2 x 10g sachets (20g), 3x 10g sachets (30g), 4 x 10g sachets (40g), 5 x 10g sachets (50g), 6 x 10g sachets (60g), 7 x 10g sachets (70g), 8 x 10g sachets (80g), 9 x 10g sachets (90g), 10 x 10g sachets (100g), 11 x 10g sachets (110g), 12 x 10g sachets (120g), 13 x 10g sachets (130g), 14 x 10g sachets (140g), 15 x 10g sachets (150g).
* in plastic can (PE or PP) : 2 x 10g sachets (20g), 3x 10g sachets (30g), 4 x 10g sachets (40g), 5 x 10g sachets (50g), 6 x 10g sachets (60g), 7 x 10g sachets (70g), 8 x 10g sachets (80g), 9 x 10g sachets (90g), 10 x 10g sachets (100g), 11 x 10g sachets (110g), 12 x 10g sachets (120g), 13 x 10g sachets (130g), 14 x 10g sachets (140g), 15 x 10g sachets (150g).
* in metal box : 2 x 10g sachets (20g), 3x 10g sachets (30g), 4 x 10g sachets (40g), 5 x 10g sachets (50g), 6 x 10g sachets (60g), 7 x 10g sachets (70g), 8 x 10g sachets (80g), 9 x 10g sachets (90g), 10 x 10g sachets (100g), 11 x 10g sachets (110g), 12 x 10g sachets (120g), 13 x 10g sachets (130g), 14 x 10g sachets (140g), 15 x 10g sachets (150g).

Maximum pack size: 150 g

# Summary of the product assessment

## Physico/chemical properties and analytical methods

Active substance (taken from the Activa/PelGar Brodifacoum and Difenacoum Task Force CAR):

Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C. Brodifacoum is non-volatile, with a Henry’s Law Constant value of 2.35E-18 Pa.m3.mol-1. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4*-hydroxycoumarin* group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log Pow was found to be 4.92 at pH 7 and 20°C. As expected, Log Pow decreased with higher temperature and pH. Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

Biocidal product:

Saphir Paste is not explosive, oxidising or highly flammable and therefore does not classify from a physical and chemical point of view. The paste bait is stable when stored for 2 weeks at 54oC and when stored at ambient temperatures (20oC) for 3 years. The paste bait is stable when stored in various different packaging materials (with the exception of the coextruded bag with cardboard box) for 3 years at ambient temperature (20oC). The test item is a ready-to-use paste bait and is not intended to be added or mixed with any other product.

## Identity related issues

An equivalence check was carried out by Italy that showed that the PelGar source of Brodifacoum active substance was equivalent to the source of Brodifacoum active substance listed in Annex I of 98/8/EC (see Annex I: Confidential Information and Data).

**Composition of the biocidal product Saphir Paste (intial PAR 2011)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Component** | **% w/w** | **g/kg** | **Chemical name** | **CAS no** | **Function** |
| Brodifacoum | 0.005 | 0.05 | 3-[3-(4’-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin | 56073-10-0 | Active substance |
| Co-formulants | See Confidential Data and Information (Annex I) | | | | |

**Note:** The biocidal product Saphir Paste is not the same as the representative biocidal product accompanying the Annex I inclusion. See confidential information and data for details of the composition of Saphir Paste.

* **Major Change for the biocidal product ULTIMA PASTE - 2017**

For the major change dossier, there is a reduction of the active substance concentration from 40 ppm to 25 ppm according to the CLP regulation.

See details of the change of composition in the confidential annex submitted in a separated document.

## Physico-chemical properties

LODI S.A.S. have a letter of access from PelGar International Limited which covers the all the data for the Annex I listing of the active ingredient Brodifacoum. PelGar International Limited is a member of the Activa/PelGar Difenacoum and Brodifacoum Task Force and as such has access to the complete Annex I listing documentation submitted by this group. LODI do not have access to any of PelGar’s product studies (Annex III) data for the purpose of product authorisation at the Member State level.

## Physical, Chemical and Technical Properties of the Biocidal Product

**Summary of the Physical and Chemical Properties of the Biocidal Product Saphir Paste (initial PAR 2011)**

| **Section** | **Study** | **Method** | **Results** | **Comment** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 1.1 | Appearance | Observation. | Aspect: Malleable blue paste in individual sachet  Colour: 2.5PB5/6  Odour: No characteristic odour | Carried out to GLP. The results are acceptable. | “Chemical stability of Brodifacoum paste bait after accelerated storage”. Study no. LODI.59/2011. 15th November 2011. Richerioux, Sandra. |
| 1.2.1 | Explosive properties | Justification  (examination of the components of the formulation) | “Based on the structural formula of the components, Brodifacoum paste bait has no potential of explosivity and the test according to OECD A14 method is not required.” | Carried out to GLP. The components do not contain any group that might act as an explosive agent. The RefMS accepts the Applicant’s justification.  Saphir Paste is not explosive. | “Explosive properties of Brodifacoum paste bait”. Study no. LODI.66/2011. 25th September 2011. Richerioux, Sandra. |
| 1.2.2 | Oxidising properties | Justification  (examination of the components of the formulation) | “Based on the structural formula of the components, the product have no potential for oxidising properties and the test according to OECD A17 method is not required.” | Carried out to GLP. The components do not contain any group that might act as an oxidising agent. The RefMS accepts the Applicant’s justification.  Saphir Paste is not oxidising. | “Oxidising properties of Brodifacoum paste bait”. Study no. LODI.65/2011. 8th November 2011. Richerioux, Sandra. |
| 1.3.1 | Flash point |  |  | Not required. The test item is not a liquid. |  |
| 1.3.2 | Flammability | EEC method A 10 | Preliminary test:  The flame of a gas burner ignited the test substance pile. The test substance glowed, burned with a little flame and turned into a charred residue. A light white smoke was observed.  After removal of the ignition source, the flame doesn’t spread and extinguished immediately. No more propagation of combustion was observed. | Carried out to GLP. Propagation of combustion of the test item is less than 200mm length of the pile within 4 minutes. Therefore, the main test is not required.  The test item is not highly flammable. | “Flammability of Brodifacoum paste bait”. Study no. LODI.58/2011. 27th June 2011. Meriadec, Elodie. |
| 1.3.3 | Auto-flammability | EEC method A 16. | No self ignition temperature of the test item was recorded up to 400oC (corrected value). | Carried out to GLP. The result is acceptable.  The test item is not auto-flammable. | “Self ignition temperature of solids on Brodifacoum paste bait”. Report no. 11-912011-010. 23rd January 2012. Demangel, Benjamin. |
| 1.4.1 | Free acidity/ Alkalinity |  | Determination is not required because pH of a 1% (m/v) aqueous dilution of Brodifacoum Paste Bait is >4 and < 10 (FAO guideline). | Not required. |  |
| 1.4.2 | pH (1 %) | CIPAC MT 75.3 | The pH in distilled water is 6.3 after 10 minutes. | Carried out to GLP. The result is acceptable. | “pH of Brodifacoum paste bait”. Study no. LODI.64/2011. 7th October 2011. Richerioux, Sandra. |
| 1.5.1 | Viscosity |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.5.2 | Surface tension |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.6 | Relative density | OECD 109 and NF T20-053 method. | 1.142 | Carried out to GLP. A pycnometer was used to determine the relative density. The result is acceptable. | “Relative density of Brodifacoum paste bait”. Study no. LODI.52/2011. 9th September 2011. Richerioux, Sandra. |
| 1.7.1 | Storage stability  (accelerated storage) | CIPAC MT 46.  GIFAP Monograph no.17 | **Aspect:**   |  |  |  |  | | --- | --- | --- | --- | |  | **Aspect** | **Colour** | **Odour** | | **T0** | Malleable blue paste in individual sachet | 2.5PB5/6 | No characteristic odour | | **T14days** | Still malleable blue paste but slightly friable, in individual sachet | 10B4/4 | No characteristic odour | | **T21days** | Still malleable blue paste but slightly friable, in individual sachet | 10B4/4 | No characteristic odour |     **Active substance content:**   |  |  |  |  | | --- | --- | --- | --- | |  | **Concentration (ppm)** | **Deviation with declared value (%)** | **Deviation between T0 and T14 and T21 (%)** | | **T0** | 45.12 | +12.80 | - | | **T14days** | 43.62 | +9.05 | -3.32 | | **T21days** | 42.64 | +6.60 | -5.50 |   The declared active substance content was 40 ppm. | Carried out to GLP. The test item is stable for 2 and 3 weeks at 54oC. The results indicate that the test item will be stable for 2 and 3 years at ambient temperatures. The results are acceptable. | “Chemical stability of Brodifacoum paste bait after accelerated storage”. Study no. LODI.59/2011. 15th November 2011. Richerioux, Sandra. |
| 1.7.2 | Shelf life (storage ambient temperatures) | GIFAP Monograph no.17. | **Aspect:**  T0 = Malleable blue paste in individual bag  T6months = Malleable blue paste in individual bag  T1year = Malleable blue paste in individual bag  T17months = Malleable blue paste in individual bag  T2 years = Malleable blue paste in individual bag  **Colour:**  T0 = 2.5PB5/6  T6months = 2.5PB5/6  T1year = 2.5PB5/6  T17months = 2.5PB5/6  T2years = 2.5PB5/6  **Odour:**  T0 = No characteristic odour  T6months = No characteristic odour  T1year = No characteristic odour  T17months = No characteristic odour  T2years = No characteristic odour  **Active substance content:**   |  |  |  |  | | --- | --- | --- | --- | |  | **Conc. (ppm)** | **Deviation with declared value (%)** | **Deviation between T0 and Tx (%)** | | **T0** | 45.1 | +12.75 | - | | **T6month** | 41.7 | +4.25 | -7.54 | | **T1year** | 41.6 | +4.00 | -7.76 | | **T17months** | 43.9 | +9.75 | -2.66 | | **T2years** | 42.4 | +6.00 | -5.99 |   The declared value is 40 ppm. | Carried out to GLP. Carried out at 20oC ± 2oC. The paste bait is stable for 2 years storage at ambient temperatures. The results are acceptable. | “Chemical stability of Brodifacoum Paste Bait after 1 year storage at 20oC.” Study no. LODI.60/2011. 26th October 2012. Richerioux, Sandra.  &  “Chemical stability of Brodifacoum Paste Bait after 2 years storage at 20oC.” Study no. LODI.61/2011. 19th November 2013. Richerioux, Sandra. |
| 1.7.3 | Packaging stability  (20oC) |  | **Chemical stability:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Colour** | **Odour** | **Aspect** | **Analysis** | | **T0** | 2,5PB5/6 | Slight odour of hazelnut | Malleable blue paste in individual bag. Presence of grease on individual bag. | 45.1 ppm | | **T3years** | 2,5PB5/6 | Fat odour | Malleable blue paste in individual bag. Presence of grease on individual bag. | 43.4 ppm | | **Deviation between T0 and T3years** | | | | **-3.77%** |   **Physical properties (for all types of packaging):**  T0 = Blue and malleable paste in individual bag. Presence of grease on individual bag.  T6months = Blue and malleable paste in individual bag. Presence of grease on individual bag.  T1year = Blue and malleable paste in individual bag. Presence of grease on individual bag.  T2years = Blue and malleable paste in individual bag. Presence of grease on individual bag.  T3years = Blue and malleable paste in individual bag. Presence of grease on individual bag.  **PP Bucket:**   |  |  |  |  | | --- | --- | --- | --- | |  | **Weight** | | | | **Bucket (g)** | **Test item (g)** | **Total (g)** | | T0 | 44.134 | 293.21 | 337.35 | | T6months | 44.428 | 292.67 | 337.11 | | Deviation | 0.67% | -0.18% | -0.07% | | T1year | 44.436 | 291.58 | 336.01 | | Deviation | 0.68% | -0.56% | -0.40% | | T2years | 44.430 | 290.19 | 334.63 | | Deviation | 0.67% | -1.03% | -0.81% | | T3years | 44.435 | 289.89 | 334.33 | | Deviation | 0.68% | -1.13% | -0.90% |   T0 = Bucket with white and non-porous internal wall  T6months = Bucket with white and non-porous internal wall. Presence of grease on internal wall of the bucket  T1year = Bucket with white and non-porous internal wall. Presence of grease on internal wall of the bucket  T2years = Bucket with white and non-porous internal wall. Presence of grease on internal wall of the bucket  T3years = Bucket with white and non-porous internal wall. Presence of grease on internal wall of the bucket  **PE bag with cardboard box:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Weight** | | | | | **PE bag (g)** | **Cardboard box (g)** | **Test item (g)** | **Total (g)** | | T0 | 3.420 | 23.410 | 122.75 | 149.57 | | T6months | 3.512 | 23.690 | 120.47 | 147.64 | | Deviation | 2.69% | 1.20% | -1.86% | -1.29% | | T1year | 3.484 | 23.998 | 121.18 | 148.66 | | Deviation | 1.87% | 2.51% | -1.28% | -0.61% | | T2years | 3.485 | 23.931 | 120.70 | 148.12 | | Deviation | 1.90% | 2.23% | -1.67% | -0.97% | | T3years | 3.508 | 23.797 | 120.76 | 148.04 | | Deviation | 2.57% | 1.65% | -1.62% | -1.02% |   T0 = Transparent bag without hole – cardboard box with grey and dry internal wall  T6months = Transparent bag, without hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T1year = Transparent bag, without hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T2years = Transparent bag, without hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T3years = Transparent bag, without hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  **PP bag with cardboard box:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Weight** | | | | | **PP bag (g)** | **Cardboard box (g)** | **Test item (g)** | **Total (g)** | | T0 | 6.972 | 23.503 | 111.36 | 141.83 | | T6months | 7.042 | 23.776 | 110.18 | 141.01 | | Deviation | 1.00% | 1.16% | -1.06% | -0.58% | | T1year | 7.037 | 24.094 | 110.22 | 141.36 | | Deviation | 0.93% | 2.51% | -1.02% | -0.33% | | T2years | 7.053 | 24.005 | 109.55 | 140.61 | | Deviation | 1.16% | 2.14% | -1.63% | -0.86% | | T3years | 7.089 | 23.872 | 109.50 | 140.46 | | Deviation | 1.68% | 1.57% | -1.67% | -0.97% |   T0 = Transparent bag with one hole – cardboard box with grey and dry internal wall  T6months = Transparent bag with one hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T1year = Transparent bag with one hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T2years = Transparent bag with one hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T3years = Transparent bag with one hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  **Coextruded bag with cardboard box:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Weight** | | | | | **Coextruded bag (g)** | **Cardboard box (g)** | **Test item (g)** | **Total (g)** | | T0 | 5.016 | 23.386 | 82.638 | 111.04 | | T6months | 4.600 | 23.950 | 79.887 | 108.91 | | Deviation | -8.29% | 2.41% | -3.33% | -1.92% | | T1year | 4.652 | 24.269 | 80.954 | 110.20 | | Deviation | -7.76% | 3.78% | -2.04% | -0.76% | | T2years | 4.942 | 24.479 | 80.534 | 109.96 | | Deviation | -1.48% | 4.67% | -2.55% | -0.97% | | T3years | 4.968 | 24.354 | 80.539 | 109.83 | | Deviation | -0.96% | 4.14% | -2.54% | -1.09% |   T0 = Transparent and non-porous bag without hole – cardboard box with grey and dry internal wall  T6months = Transparent and non-porous bag without hole. Presence of grease within bag – cardboard box with grey internal wall. Presence of grease at the bottom of the box.  T1year = Transparent and non-porous bag without hole. Presence of grease within bag – cardboard box with grey and dry internal wall.  T2years = Transparent and non-porous bag. Holes in the weld. Presence of grease within bag – presence of grease on the wall of the box.  T3years = Transparent bag. Holes in the weld. Presence of grease within bag – presence of grease on the wall of the box.  **Doypack:**   |  |  |  |  | | --- | --- | --- | --- | |  | **Weight** | | | | **Doypack (g)** | **Test item (g)** | **Total (g)** | | T0 | 11.803 | 154.86 | 166.66 | | T6months | 12.118 | 154.21 | 166.33 | | Deviation | 2.67% | -0.42% | -0.20% | | T1year | 12.126 | 154.15 | 166.27 | | Deviation | 2.74% | -0.46% | -0.23% | | T2years | 12.131 | 153.61 | 165.74 | | Deviation | 2.78% | -0.81% | -0.55% | | T3years | 12.146 | 153.30 | 165.45 | | Deviation | -2.91% | -1.01% | -0.73% |   T0 = Internal wall in aluminium, without porosity and hole  T6months = Internal wall in aluminium, without porosity and hole. Presence of grease on internal wall of the doypack  T1year = Internal wall in aluminium, without porosity and hole. Presence of grease on internal wall of the doypack  T2years = Internal wall in aluminium, without porosity and hole. Presence of grease on internal wall of the doypack  T3years = Internal wall in aluminium, without porosity and hole. Presence of grease on internal wall of the doypack  **PP prebaited baitbox:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Weight (g)** | | | | |  | **Bait station** | **Sample 1** | **Sample 2** | **Total** | | T0 | 47.465 | 10.942 | 10.177 | 68.583 | | T6months | 47.725 | 10.616 | 9.849 | 68.191 | | Deviation | 0.55% | -2.98% | -3.22% | -0.57% | | T1year | 47.735 | 10.770 | 9.980 | 68.487 | | Deviation | 0.57% | -1.57% | -1.94% | -0.14% | | T2years | 47.738 | 10.742 | 10.001 | 68.484 | | Deviation | 0.58% | -1.83% | -1.73% | -0.14% | | T3years | 47.740 | 10.671 | 9.963 | 68.372 | | Deviation | 0.58% | -2.48% | -2.10% | -0.31% |   T0 = Black box with smooth internal wall, without porosity.  T6months = Black box with smooth internal wall, without porosity. Presence of grease at the location of the paste.  T1year = Black box with smooth internal wall, without porosity. Presence of grease at the location of the paste.  T2years = Black box with smooth internal wall, without porosity. Presence of grease at the location of the paste.  T3years = Black box with smooth internal wall. Presence of grease at the location of the paste.  **PS prebaited baitbox:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Weight (g)** | | | | | **Bait station** | **Sample 1** | **Sample 2** | **Total** | | T0 | 11.992 | 10.258 | 10.374 | 32.625 | | T6months | 12.259 | 9.955 | 10.047 | 32.263 | | Deviation | 2.23% | -2.95% | -3.15% | -1.11% | | T1year | 12.268 | 10.072 | 10.215 | 32.559 | | Deviation | 2.30% | -1.81% | -1.53% | -0.20% | | T2years | 12.265 | 10.101 | 10.189 | 32.556 | | Deviation | 2.28% | -1.53% | -1.78% | -0.21% | | T3years | 12.266 | 10.030 | 10.141 | 32.436 | | Deviation | 2.28% | -2.22% | -2.25% | -0.58% |   T0 = Black box with smooth internal wall at the location of the paste  T6months = Black box with smooth internal wall at the location of the paste. Presence of grease at location of the paste.  T1year = Black box with smooth internal wall at the location of the paste. Presence of grease at location of the paste.  T2years = Black box with smooth internal wall at the location of the paste. Presence of grease at location of the paste.  T3years = Black box with smooth internal wall. Presence of grease at location of the paste. | Carried out to GLP. The results are acceptable.  The deviation weights (packaging weights and test item weights) after 3 years at 20 ± 2oC are lower than 5% for the following packaging: PP bucket, PP and PE bag with cardboard box, Doypack, PS and PP prebaited baitbox. Moreover, no significant changes were observed on these packaging and on the test item.  For the coextruded bag with cardboard box, the deviation weight is higher than 5% (-8.29%) and grease was observed at the bottom of the box.  The packaging is stable for 3 years at ambient temperature with the exception of the coextruded bag with cardboard box. | “Chemical and packagings stability of Brodifacoum paste bait after 3 years storage at 20oC (Analysis at T = 1year)”. Study no. LODI.62/2011.B. 30th October 2012. Richerioux, Sandra.  &  “Chemical and packagings stability of Brodifacoum paste bait after 3 years storage at 20oC (Analysis at T = 2years)”. Study no. LODI.62/2011.C. 6th November 2013. Richerioux, Sandra.  &  “Chemical and packagings stability of Brodifacoum paste bait after 3 years storage at 20oC”. Study no. LODI.62/2011. 12th November 2014. Richerioux, Sandra. |
| 1.8.1 | Wettability |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.2 | Persistent foaming |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.3.1 | Suspensibility |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.3.2 | Dispersibility |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.4 | Wet/dry sieving test |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.5 | Particle size distribution |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.6 | Water content |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.7 | Emulsion stability |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.8.8 | Flowability, pourability and dustability |  |  | Not applicable as the product is a ready to use paste. |  |
| 1.9 | Physical compatibility |  |  | Not applicable. The product is ready-to-use. It is not intended to be mixed with any other product. |  |

**Conclusions:**

Saphir Paste is not explosive, oxidising or highly flammable and therefore does not classify from a physical and chemical point of view. The paste bait is stable when stored for 2 weeks at 54oC and when stored at ambient temperatures (20oC) for 3 years. The paste bait is stable when stored in various different packaging materials (with the exception of the coextruded bag with cardboard box) for 3 years at ambient temperature (20oC). The test item is a ready-to-use paste bait and is not intended to be added or mixed with any other product.

**Data requirements:**

None.

**The paste bait is compatible with the following packaging:**

PP bucket, PP and PE bag with cardboard box, Doypack, PS and PP prebaited baitbox.

**Professional product amendment to packaging:**

An application to include an additional pack type, a PP cartridge for use with a caulking gun was submitted for the Saphir paste formulation. Based on a justification by the applicant and the previous information provided under the original application it was considered that the brodifacoum formulation would be compatible with the PP cartridge and would hold up to long term storage in a mastic tube.

Previous information (see point 1.7.3 in the table above) indicated that the deviation weights (packaging weights and test item weights) after 3 years at 20 ± 2oC are lower than 5% for the following packaging: PP bucket, PP and PE bag with cardboard box, Doypack, PS and PP prebaited baitbox. Moreover, no significant changes were observed on these packaging and on the test item.

On the basis of the proposed amendment for Saphir Paste to be contained in a cartridge for use with a caulking gun; since we know that Brodifacoum containing products do not have any negative interaction with packaging made from PP and since we know that a Brodifacoum containing product has held up to long term storage in a mastic tube, it is considered that the inclusion of the “cartridge” packaging type is acceptable for Saphir Paste.

**The paste bait is incompatible with the following packaging:**

Coextruded bag with cardboard box.

**Proposed shelf life for the paste bait:**

3-years.

* **Major Change and renewal applications ULTIMA PASTE - 2017**

For the major change dossier, new data below have been submitted to support of the Physical, chemical and technical properties.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| Storage stability test – **accelerated storage** | CIPAC 46.3  14 days storage stability at 54°C | ULTIMA PASTE  (0.0025% w/w of brodifacoum)  Batch N° RB2017316 | Determination of physico-chemical properties and storage stability test at 54°C for 14 days packed in individual paper sachet packed in a Cardboard box:   |  |  |  | | --- | --- | --- | |  | Initial | After 14 days at 54°C | | Appearance | Malleable blue paste in individual tea paper sachet. Presence of grease on sachet. | Malleable blue paste in individual tea paper sachet. Presence of grease on sachet. | | Appearance of packaging | Clean and dry internal wall | Clean and dry internal wall | | Content of AS | 0.00236% | 0.00238% | | Variation of AS (%) | - | +0.85% |   Quantification of AS has been done by HPLC UV detection with the method evaluated in the part 2.2.4.  Determination of physico-chemical properties and storage stability test at 54°C for 14 days packed in individual paper sachet packed in a PP bag:   |  |  |  | | --- | --- | --- | |  | Initial | After 14 days at 54°C | | Appearance | Malleable blue paste in individual tea paper sachet. Presence of grease on sachet. | Malleable blue paste in individual tea paper sachet. Presence of grease on sachet. | | Appearance of packaging | Traransparent bag, without hole. Presence of grease inside the bag. | Traransparent bag, without hole. Presence of grease inside the bag. | | Content of AS | 0.00236% | 0.00238% | | Variation of AS (%) | - | +0.85% |   Quantification of AS has been done by HPLC UV detection with the method evaluated in the part 2.2.4. | The variation of AS content after 14 days at 54 °C storage is acceptable in both commercial packagings. | PICARDAT, T. (2017), Study N° LODI.13/2017 |
| Storage stability test – **long term storage at ambient temperature** | CIPAC 46.3  2 years storage stability  GIFAP n°17 | ULTIMA PASTE  (0.0025% w/w of brodifacoum) | Determination of physico-chemical properties and storage stability test packed in commercial packaging:   |  |  |  | | --- | --- | --- | |  | Initial | After 2 years at rt | | Appearance | The study is currently on going. | | | Appearance of packaging | | Variation of weight (%) | | Content of AS | | Variation of AS (%) |   Quantification of AS will be done by HPLC UV detection with the method evaluated in the part 2.2.4. |  |  |

|  |
| --- |
| Based on the differences and the co-formulants the new composition can be considered as similar as the old composition. Therefore the previous conclusion made by the RMS (IE) on physical, chemical and technical properties for the product SAPHIR PASTE in section 3.1.2 are acceptable for the product ULTIMA PASTE  Based on the accelerated storage stability test, the shelf life of the product is 2 years. |

**General conclusion on the physical, chemical and technical properties ofthe product for renewal applications**

The product ULTIMA PASTE is an RB ready to use bait formulation.. It is not explosive and has no oxidising properties. The product is not flammable.

The biocidal product is stable 14 days at 54°C in individual tea paper sachet in cardboard box and PP bag. Considering the product is a solid and it is compatible with tea paper sachet in cardboard box and PP bag, compatibility with other claimed packagings is considered acceptable. The accelerated storage of the productand the read across with the product SAPHIR PASTA indicate, that the biocidal product is expected to be stable 2 years at ambient temperature. Results of long term storage stability test are currently on progress and results are needed to confirm the stability of the product in post-authorization.

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

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

## Analytical methods

Saphir Paste was not assessed as part of the Annex I inclusion process therefore the Applicant has submitted the following method of analysis to cover the outstanding data gap (initial PAR 2011).

|  |  |
| --- | --- |
| Report: | LODI.51/2011 |
| Title: | “Brodifacoum paste bait, Brodifacoum grain bait” |
| Author(s): | Richerioux, Sandra. |
| Date: | 23rd January 2012 |
| GLP: Yes/No | Yes |
| **Principle of the Method:** | Brodifacoum was quantified by liquid chromatography using a reverse phase column and a UV detector at 310 nm. |
| **Linearity:** | The operator prepared five solutions containing 80%, 90%, 100%, 110% and 120% of the concentration of the test item. Three injections were carried out for each solution. The concentrations used were 1.61, 1.81, 2.01, 2.21 and 2.41 mg/L.  For Brodifacoum peak 1 the r2 was 0.9949. A calibration curve was provided and was linear.  For Brodifacoum peak 2 the r2 was 0.9923. A calibration curve was provided and was linear. |
| **Precision/repeatability:** | Three solutions were prepared of a concentration C (~ 2.00586 mg/l) of the product. Three injections of each solution were carried out and the RSD was calculated.  Intermediary fidelity (mg/l):   |  |  |  |  | | --- | --- | --- | --- | |  | **1st Injection** | **2nd Injection** | **3rd Injection** | | **Solution a** | 2.23 | 2.21 | 2.25 | | **Solution b** | 2.25 | 2.19 | 2.25 | | **Solution c** | 2.26 | 2.21 | 2.22 |   % RSD = 0.949  Intralaboratory fidelity (mg/l):   |  |  |  |  | | --- | --- | --- | --- | |  | **1st Injection** | **2nd Injection** | **3rd Injection** | | **Solution a** | 2.21 | 2.28 | 2.23 | | **Solution b** | 2.25 | 2.19 | 2.25 | | **Solution c** | 2.26 | 2.21 | 2.22 |   % RSD = 1.188 |
| **Accuracy:** | **Recovery results:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Paste bait | **50% doped placebo** | **100% doped placebo** | **150% doped placebo** | **Overall MR** | | Theoretical content (ppm) | 22.38 | 41.12 | 59.06 | **99.28%** | | Experimental content (ppm) – mean of 3 injections | 23.98 | 40.68 | 54.20 | | Mean recovery (MR) | 107.15% | 98.93% | 91.77% |   The operator doped a placebo with 50, 100 and 150% of the theoretical concentration of test item. Three injections were carried out per solution. The mean recovery (MR) was calculated for each solution. |
| **Specificity:** | The operator injected a placebo. If an adjacent peak appeared, the resolution must be higher than 2. The operator then stresses the sample by adding 5 ml of acetic acid and injects the solution. If a peak appeared, the resolution must be higher than 2.  No peak other than internal standard was found for the placebo paste.  No peak appeared for the paste bait that was stressed with acetic acid.  Chromatograms were provided and were acceptable. |
| **Limit of detection:** | The operator injected a solution containing 10 ppm of active substance and calculated the ratio S/N between the intensity of the peak and the intensity of the background noise. The operator divided by 10 then by 2 the concentration of the active substance until obtaining a ratio lower than 3. The LOD is the last concentration for which S/N is higher than 3.  LOD = 0.1254 ppm |
| **Limit of quantification:** | The operator injected a solution containing 50 ppm of active substance and calculated the ratio S/N between the intensity of the peak and the intensity of the background noise. The operator divided by 10 then by 2 the concentration of the active substance to obtain a ratio lower than 10. The LOQ is the last concentration for which S/N is higher than 10.  LOQ = 0.6270 ppm |

**Conclusion:**

The method is acceptable for the determination of Brodifacoum in the paste bait.

**Data requirements:**

None.

* **Major change and renewal applications ULTIMA PASTE - 2017**

For the major change dossier submitted respectively in 2017, new data below have been submitted to support of the methods for detection and identification.

**Report:** Validation of the analytical method for the quantification of brodifacoum in brodifacoum paste bait 25ppm, PICARDAT, T. 2017

**Study GLP N°:** LODI.10/2017

**Test facility:** LODI SAS

PA des Quatre Routes

35390 GRAND FOUGERAY

FRANCE

Principle of the method:

A method to determine brodifacoum in the biocidal product brodifacoum paste bait 25 ppm (ULTIMA PASTE) by HPLC – UV was submitted. The test item is quantified by HPLC method (Column: reversed phase) using UV detection (310 nm) after solid-liquid 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:   * Formulation blank * Stressed test item (with acetic acid)   No interference was found: no peak appears in the formulation blank at the retention time of brodifacoum.  There are two different peaks for brodifacoum. | |
| Linearity | Linearity was studied by carrying out 5 levels concentrations, analysed twice between 50% and 150% of the concentration in the test item. (= between 2.62 mg.L-1 and 7.87 mg.L-1).  Linearity has been determined for each peak of brodifacoum.  Calibration curve has been provided with an r higher than 0.99. | |
| Compound | Linearity % |
| Brodifacoum  Peak 1 | 2.62 mg.L-1 to 7.87 mg.L-1 Y = 11.27156 X – 1.80044.10-1 r = 0.99992 |
| Brodifacoum  Peak 2 | 2.62 mg.L-1 to 7.87 mg.L-1  Y = 11.81000 X + 3.06683.10-1  r = 0.99992 |
| Extraction efficiency | Due to the solid/liquid extraction, extraction yield has been determined:  Five samples of known concentration are prepared and analysed twice. The extraction yield is determined for each sample and the mean extraction yield is calculated from these five solutions.  Result: Mean extraction yield 90.33% | |
| Accuracy | Accuracy was determined by analysis 3 samples solutions containing 80%, 100% and 120% of theoretical concentrations of 25 ppm. Two injections (n =2) of each preparation are made. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate (%) | RSD (%) | n | | 80%  0.00205% w/w | No data provided | 100.98 | - | 2 | | 100%  0.00264% w/w | No data provided | 106.45 | - | 2 | | 120%  0.0033475% w/w | No data provided | 111.21 | - | 2 | | |
| Precision | Repeatability was evaluated by analysing ten sample solutions.   |  |  |  | | --- | --- | --- | | Compound | Mean (% w/w) | Repeatability (RSD) | | Brodifacoum | 0.00246 | RSD = 2.17% |   The limit of quantification (LOQ) is 0.655 mg.L-1 for brodifacoum | |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The provided analytical method is fully validated for the determination of the active substance brodifacoum at 25 ppm in the product brodifacoum paste bait ULTIMA PASTE.  For the analytical methods for determining relevant components and/or residues in different matrices, the previous conclusion made by the RMS (IE) for the product SAPHIR PASTE in are still acceptable for the product ULTIMA PASTE |

## Analytical method for the relevant impurities, isomers and co-formulants in the biocidal product

Not applicable.

## 

## Efficacy of the Biocidal Product

## Function/Field of use

MG 03: Pest Control.

PT14: Rodenticide

First authorisation (intial PAR 2011)

## Organisms to be controlled (initial PAR 2011)

Saphir Paste (containing 40 mg/kg brodifacoum) is a ready-to-use paste bait (RB) intended to control the brown rat (*Rattus norvegicus*) and the house mouse mice (*Mus musculus*). Lodi has proposed the use area as indoors and outdoors (in and around buildings, waste disposal sites, open areas) for the protection of public health stored products and materials. The use scenario encompassing waste disposal sites and open areas is intended for professional users only.

For rats, each bait point will contain 60g of bait; a mouse bait point will contain 10g bait. Bait points are placed typically every 5-10m (rats) or 2-5 m (mice) with the distances adapted to the infestation level.

Advice concerning application frequency should be included on the draft label.

The label should contain wording to the effect that effective control should be expected from bait stored up to two years under suitable storage conditions.

## 

## Dose/Mode of action

Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K1 epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidoting therapy (vitamin K1).

## Effects on the target organisms (efficacy)

Data from trials using the paste formulation were provided in the form of laboratory and field studies to verify the proposed label claims.

Laboratory palatability and efficacy studies:

One laboratory palatability and efficacy (choice) test conducted on rats (lab reared and wild) and wild mice with fresh bait.

One laboratory palatability and efficacy (choice) test conducted on rats and mice with fresh and aged bait (6, 12 & 24 month storage).

One laboratory palatability and efficacy (choice) test conducted on rats with bait with aged bait (accelerated storage).

One laboratory palatability and efficacy (choice) test conducted on mice with with aged bait (accelerated storage).

Field efficacy studies:

One field studies conducted on rats (*Rattus norvegicus*).

One field studies conducted on mice (*Mus musculus*).

The applicant provided the study reports from four laboratory studies conducted on Brodipasta which is equivalent to Saphir paste. The experiments were all choice studies conducted to high standard according to relevant in-house methods, CEB methods, EPPO guideline or in accordance with the TNsG on Product Evaluation Appendices to Chapter 7 - Product Type 14 - Efficacy Evaluation of Rodenticidal Biocidal Products endorsed at the 32nd meeting of representatives of Members States Competent Authorities.

The results from the studies are summarised in **annex 8a** The results achieved demonstrated that Saphir paste is palatable to the house mouse and the brown rat according to the criteria given in TNsG on Product Evaluation as the bait intake was greater than 20% of the total food consumption in all the studies. The storage treatment (even up to 24 month storage) was found not to adversely affect the palatability or effectiveness of the product. The treated bait achieved 100% mortality across all the laboratory tests.

Results from two field studies using Saphir paste were also provided. The field trial programme demonstrated an overall efficacy based on post baiting consumption figures of 89.9% for the mouse field trial and efficacy of >95% for the brown rat field trial. The field trial programme demonstrated high effectiveness against wild populations of the brown rat (*Rattus norvegicus*) and for the mouse (*Mus musculus*) under normal use situations.

* **Major change and renewal applications for ULTIMA PASTE 2017**

According to the new uses claimed by the applicant in the frame of the major change application, ULTIMA PASTE is intended to be used to control rats in and around buildings, by professional and non-professional users, only indoor against mice for non-professional users and in open area, in waste dumps and landfills by professional users. The major change consist to the reduction of the active substance from 0.004 % to 0.0025 % w/w brodifacoum

The application rates recommended by the applicant are the following:

* Rats: 60 g per baiting point separated by 5 -10 m
* Mice: 10 g per baiting point separated by 3– 5 m

The products, organisms or objects to be protected are public and private buildings, and farms, open areas.

New laboratory and field tests on *Mus musculus*, *Rattus norvegicus and Rattus rattus* were submitted to assess the efficacy of the product ULTIMA PASTE containing 0.0025 % w/w brodifacoum.

Laboratories studies

* One laboratory palatability and efficacy (choice) tests conducted on mice with fresh bait;;
* One laboratory palatability and efficacy (choice) tests conducted on brown rat with fresh bait.

Field efficacy studies:

* One field study conducted on rats (*Rattus norvegicus*) with fresh bait ;
* One field study conducted on mice (*Mus musculus*) with fresh bait;
* One field study conducted on rats (*Rattus rattus*) with fresh bait

Regarding the claimed uses, efficacy data are compliant with the requirements of the TNsG PT14 / Guidance on the Biocidal Products Regulation - Volume II Efficacy (2016), and the results of these tests are respecting the criteria of the TNsG PT14 / Guidance on the Biocidal Products Regulation - Volume II Efficacy (2016).

Therefore, the product ULTIMA PASTE (0.0025 % w/w brodifacoum) has shown a sufficient efficacy and can be used for the control of mice at the application rate of 10 g and rats at the application rate of 100 g/point. The application rate of 60 g claimed for rats is not validated as field test has been performed with this dose againt only *R. rattus*

All efficacy studies are presented in Annex 8b

Consequently, the product ULTIMA PASTE (0.0025 % w/w brodifacoum) has shown a sufficient efficacy and can be used for the control of rats (*Rattus norvegicus* and *Rattus rattus*) and house mice (*Mus musculus*).

Uses and doses validated for the major change and the renewal are the following

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Target organisms** | **Application rate and intervals** | **Use area** |
| ULTIMA PASTE  Bait containing 0.0025% w/w of brodifacoum. | Rats (*Rattus norvegicus* and *Rattus rattus*) | 100 g / bait point separated by 5 - 10 meters | In and around building, open areas, waste dumps and landfills |
| Mice (*Mus musculus*) | 10 g / bait point separated by 3 - 5 meters | In and around building, open areas, waste dumps and landfills |

## 

## Known limitations (e.g. resistance)

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Resistance is exclusively related to the active substance Brodifacoum and is discussed in Doc. II-A (please see Brodifacoum Assessment Report – 17/09/2009, revised 16/12/2010 and refer to Letter of Access from Pelgar International Limited). The resistance to Brodifacoum is not regarded as unacceptable and only few events are referred as “suspected” resistance to Brodifacoum products. In conclusion there is no reason to suspect a lack of efficacy of Brodifacoum-based products and it is possible to state that Brodifacoum is fully active against rodents' populations that developed resistance to Warfarin.

Where resistance to Brodifacoum is suspected or has been shown, resistant management strategies should be employed and products containing an alternative active substance should be used or a professional pest control operator be consulted.

Moreover, the following measures from Codes of Good Practice in Rodent control[[4]](#footnote-4) (EPPO standards - Guidelines on Good Plant Protection Practice – Rodent control for crop protection and on farms- PP 2/5) are recommended and usually respected by the applicators:

- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the size of the infestation.

- A complete elimination of rodents in the infested area should be achieved.

- The use instruction of products should contain guidance on resistance management for rodenticides.

- Resistant management strategies should be developed, and Brodifacoum should not be used in an area where resistance to this substance is suspected.

- The authorisation holder shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

- When the product is being used in public areas, the areas treated must 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.

In addition, the IE CA recommends the following in relation to resistance management:

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

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003).

**Resistance management strategies**

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

To this extent the applicant suggests the following measures to aid in the prevention of resistance:

* Maximum use of non-chemical control techniques.
* Preferential use of rodenticides and formulations to which resistance rarely develops.
* Ensure the complete eradication of the target population whenever a rodenticide is used.
* Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.
* Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.

**It is recommended that the label states that any instances of resistance are referred to the manufacturer of the a.s.**

In order to prevent the development and spreading of resistance, some resistance management strategies measures such as those from the Codes of Good Practices in rodent control are recommended:

* The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the infestation level.
* A complete elimination of rodents in the infested area should be achieved.
* The use instruction of products should contain guidance on resistance management for rodenticides.
* The authorisation holder shall report any observed resistance incident to the Competent Authorities or other appointed bodies involved in resistance management.

**The proposed labels contain detailed instructions for use.**

* The population size of the target rodent should be evaluated before a control campaign.
* The number of baits and the timing of the control campaign must be in proportion to the infestation level.
* Baits must be placed in a safe manner inaccessible to children and non-target species and not be applied to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product.
* Bait consumption should be regularly checked and consumed or spoilt bait replaced until consumption has stopped. The remaining baits and material must be removed and disposed of safely at the end of the treatment according to local/national wastes disposal regulation.
* Water must not be contaminated with the product or its container.
* The rodents’ bodies all along the treatment must be disposed of according to local/national regulation.

**In addition to the above applicant and label recommendations the RMS advocates the adoption of the following advice to avoid the development of resistance in susceptible rodent populations.**

Details of treatment should be recorded.

* Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).
* Inspected baiting points weekly and replace old bait where necessary.
* Do not routinely use anticoagulant rodenticides as permanent baits. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas. (The RMS view is that routine use of anticoagulant baits should not be recommended in above described situations.) .
* Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting programme or apply alternative control techniques to eliminate the residual infestation (acute or sub-acute rodenticides, gassing or trapping).

**Treatment of rodent infestations containing resistant individuals**

* Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.
* Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.
* In both cases it is essential that complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.
* Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).

**Application of area or block rodent control to eliminate resistance**

* Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties.
* Where there are indications that resistance may be more extensive than a single infestation, apply area or block control rodent programmes.
* The area under such management should extend at least to the boundaries of the area known resistance and ideally beyond.

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

* **Major change and renewal applications of ULTIMA PASTE - 2017**

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 (xxx et al., 1982[[5]](#footnote-5); xx, 1984[[6]](#footnote-6); xxx et al. 1995[[7]](#footnote-7)). 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 (xxx and xxx 1988[[8]](#footnote-8)). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. xxx 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 (xxx and xxx, 1988; xx et al. 1992a,b[[9]](#footnote-9)).

Studies carried out in different European countries, in the UK more particularly (xxx 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 (xxx 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 (xxxx et al., 2009). The same mutation was also found in UK (xxx., 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

## Humaneness (initial PAR 2011)

The use of Brodifacoum as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. It is recognised that such substances do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 5.1 of Directive 98/8/EC ‘to avoid unnecessary pain and suffering of vertebrates’, as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

**Conclusion:**

The IE CA considers that the palatability and efficacy data provided is adequate to support the recommendation for the use of the product against rats and mice, even when stored for up to two years.

The treatment frequency is 2-4 applications per year, 3-6 months apart, when re-infestation occurs.

**Issues identified:**

Advice concerning application frequency should be included on the draft label.

The label should contain wording to the effect that effective control should be expected from bait stored up to two years under suitable storage conditions.

## Evaluation of the label claims

* **Major change and renewal applications 2017**

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

The validated application rates are the following:

* Mice (M*us musculus*): 10 g /secured bait point separated by 3-5 m.
* Rats (*R. norvegicus* and *R. rattus*): 100 g / secured bait point separated by 5-10 m.

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

The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance brodifacoum. Results of the resistance monitoring must be submitted at the renewal of the product.

## Biocidal Product Risk Assessment (Human Health and the Environment)

## 

## Description of the intended use(s)

The product is a paste rodenticide. It is a ready-to-use paste or pasta which contains 50 ppm (0.005% w/w) brodifacoum (56073-10-0) used by professional and amateur users. The bait is used in and around buildings and in sewer systems. The target organisms to be controlled are Brown rat, Roof rat or House rat, House mouse and Field mouse.

* **Major change and renewal applications for ULTIMA PASTE 2017**

ULTIMA PASTE is a ready-to-use rodenticide containing 0.0025% brodifacoum. The major change consists in a decrease of active substance concentration (from 40 ppm to 25 ppm) and small variations in the composition that have no impact on the classification and the risk assessment.

## Hazard Assessment for Human Health

No new exposure studies have been submitted for evaluation. Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. Non-target organisms are most at risk from secondary poisoning, i.e. consumption of rodent carcasses by predators such as raptors.

* **Major change and renewal applications for ULTIMA PASTE 2017**

No new study has been provided.

## 

## Toxicology of the active substance

Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Like all anticoagulant rodenticides, brodifacoum is structurally similar to vitamin K. Blood forms a clot at the site of injury by virtue of a complicated ‘clotting cascade’, involving numerous clotting factors. The clotting factors are made in the liver as inactive precursors, converted to active form and allowed to circulate in the bloodstream. Vitamin K is employed in the liver in the activation process, and is used in a continuous cyclic process involving several enzymes. The anticoagulant rodenticides block these enzymes, preventing regeneration of the vitamin K and preventing activation of the clotting factors.

Brodifacoum requires labelling with the symbol T+ and the risk phrases R 28 ‘Very toxic if swallowed’; R27 ‘Very toxic in contact with the skin’ and R26 ‘Very toxic by inhalation’. Brodifacoum is not classified as a skin irritant or eye irritant.

Repeated dosing studies show effects on blood coagulation and death at low doses (µg/kg bw/day), and therefore labelling with R48/23/24/25 is warranted.

Under the GHS scheme Acute tox. 1, H310, Acute tox. 2 H300 and STOT RE 1 H372.

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

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

As long as dermal absorption is concerned, on the basis of the available study and reading acroos from data on other 2nd generation anticoagulant rodenticides, twodifferent values could be used for risk characterisation depending on the type of formulation, that is 3% (pellets and grains) or 0.047% (wax block bait).

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

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

**Summary of brodifacoum subchronic, chronic, mutagenic and reproductive toxicity.**

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

**Genotoxicity and Carcinogenicity**

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

**Conclusion on Reproductive toxicity**

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

In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to *Warfarin*. None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of *Brodifacoum**.*

**Medical data**

Routine monitoring of workers (industrial users) producing *Brodifacoum* and formulating products has been carried out for the last forty years. Between June 1981 and September 1982, three poisoning incidents occurred with successful recovery. With the exception of these incidents, routine monitoring has shown no clinical effects in any workers. During this time there has been no evidence of allergenicity, sensitisation or any other abnormal effects induced by repeated and continual exposure to these anticoagulant rodenticides.

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

 Warfarin Brodifacoum

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

**Conclusions**:

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

* AELacute of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
* AELmedium term of 6.7 x 10-6 mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
* AELchr of 3.3 x 10-6  mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

**Data requirements:** (List if applicable)

None.

## Toxicology of the biocidal product

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

**Summary of acute toxicity data for the biocidal product Ruby Block**

| **Parameter** | **Test material** | **Species** | **Result** | **Classification** | **Ref.** |
| --- | --- | --- | --- | --- | --- |
| Acute Oral Toxicity | Brodifacoum Pasta Bait.  Batch: 61509601 | See comments below | See comments below | none. | xxx  . (2007a). study number: xxx |
| **Acceptable (Y/N): Yes** | | **Method:** OECD 420 (2001) | | **GLP (Y/N): Yes** |
| **Comments:** Please refer to the document ‘Saphir Paste PAR – MS addendum for Tox – 70286, 70287’. The applicant has a LoA to the study referenced above from Pelgar, see section 1.6.2 | | | | |
| Acute Dermal Toxicity | Brodifacoum Pasta Bait.  Batch: 61509601 | See comments below | See comments below | none. | xxx. (2007b). study number: xxx |
| **Acceptable (Y/N): Yes** | | **Method:** OECD 402 (1987) | | **GLP (Y/N): Yes** |
| **Comments:** Please refer to the document ‘Saphir Paste PAR – MS addendum for Tox – 70286, 70287’. The applicant has a LoA to the study referenced above from Pelgar, see section 1.6.2 | | | | |
| Acute Inhalation Toxicity | none | none | none | none | none |
| **Acceptable (Y/N):** | | **Method:** | | **GLP (Y/N):** |
| **Comments:** Inhalation exposure is not appropriate for Pasta Bait formulation. Active substance has very low volatility and is only present at 0.005% (w/w) in the semi solid, wax product. Company justification accepted. | | | | |
| Information on mixture of biocidal products | none | none | none | none | none |
| **Acceptable (Y/N): Yes** | | **Method:** | | **GLP (Y/N):** |
| Not applicable since following the proposed uses of Pasta Bait and the label claims, the rodenticide Pasta Bait is not intended to be used in a mix with other biocidal products. Company justification accepted. | | | | |
| Acute Skin Irritation | Brodifacoum Pasta Bait.  Batch: 61509601 | See comments below | See comments below | none | xxx (2007c). study number: xxx |
| **Acceptable (Y/N): Yes** | | **Method:** OECD 404 (2002) | | **GLP (Y/N): Yes** |
| **Comments:** Please refer to the document ‘Saphir Paste PAR – MS addendum for Tox – 70286, 70287’. The applicant has a LoA to the study referenced above from Pelgar, see section 1.6.2 | | | | |
| Acute Eye Irritation | Brodifacoum wax block bait.  Batch: 61509601 | See comments below | See comments below | none | xxx (2007d). study number: xxx |
| **Acceptable (Y/N): Yes** | | **Method:** OECD 405 (2002) | | **GLP (Y/N): Yes** |
| **Comments:** Please refer to the document ‘Saphir Paste PAR – MS addendum for Tox – 70286, 70287’. The applicant has a LoA to the study referenced above from Pelgar, see section 1.6.2 | | | | |
| Skin Sensitisation | none | none | none | none | none |
| **Acceptable (Y/N):** | | **Method:** | | **GLP (Y/N): Yes** |
| **Comments:** A skin sensitisation study is not available for the product so active substance data has been used to derive a classification. Brodifacoum showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer (CAR IT). However, based on the generic concentration limits for mixtures at a Brodifacoum concentration of 0.005% w/w classification is not required by Directive 1999/45/EC or Regulation (EC) No 1272/2008. | | | | |

**Conclusion:**

According to the results of the toxicological studies, Brodifacoum paste does not classify with respect to Directive 1999/45/EC or Regulation (EC) No 1272/2008. However, safety phrases and precautionary statements are proposed by the Rapporteur.

**Data requirements:**

None.

* **Major change change and renewal applications for ULTIMA PASTE 2017**

No new study has been provided. Based on the results of the studies, the concentration of the active substance and of other components contained in the product and according to the above classification, ULTIMA PASTE is classified as follows under Regulation (EC) No 1272/2008:

STOT RE 2, H373: May cause damage to organs (blood) through prolonged or repeated exposure.

## Toxicology of the co-formulants (substances of concern)

The biocidal product contains no other substances in quantities that would be of toxicological concern. The majority of these components are food grade materials and are not classified.

Please refer to consolidated Annexes (include. Confid Annex) for product specification and list of co-formulants.

* **Major change and renewal applications for ULTIMA PASTE 2017**

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

## Exposure Assessment for Human Health

The contact gel is used as a gel in plastic bait boxes or covered/protected gel points or contact gel can be placed on strips of insulation tape or paper tape fixed to, for example, overhead pipe-ways and ductwork. The product is applied by professional pest controllers, only.

Single-use pre-treated ‘gel tubes’ (plastic tube containing gel - analogous to single-use pre-treated bait boxes) are also sold. As the amount of gel in a single gel point is enclosed in a sealed tube and there is no exposure to the user, the standard risk assessment for professionals applying bait from other packs is protective of this use.

The application of Block bait is regarded as a suitable worst case scenario for Paste bait. In the Chambers study operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box this value was then doubled for 200g boxes) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks.

The most relevant route of exposure to the active substance is the dermal route. For exposure assessment only active substance from wax blocks has been modelled. The block product typically takes the form of a solid waxy block with a strong sweet smell containing 0.005% w/w Brodifacoum.

In the final CAR for brodifacoum dermal absorption values were derived from read across from data on Difenacoum. The values chosen were 0.047% for wax formulations and 3% for grain/pellet formulations. These values were deemed appropriate in the absence of product specific data.

* **Major change and renewal applications for ULTIMA PASTE 2017**

The value of 0.047% is retained for assessment.

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No impact of the decrease of the a.s content is expected at this very low concentration.

The active substance has a low vapour pressure, therefore the potential for evaporation is low, and hence the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. In the case of wax blocks, inhalation exposure is irrelevant. Inhalation exposure from handling grain bait during loading/application and cleaning is also proposed as negligible. The only relevant inhalation exposure is assumed to be that from the decanting of loose grain, pellets and granules due to the potential release of airborne dusts.

Any potential oral exposure will be indirect exposure via possible release to the environment. Other possible exposure scenarios include dermal contact with dead animals and accidental ingestion of poison baits by children.

*Key Endpoints for Exposure Assessment*

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

* AELacute of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
* AELmedium term of 6.7 x 10-6 mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
* AELchr of 3.3 x 10-6  mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

**Data requirements:**

None.

#### Exposure to professional users

|  |  |  |
| --- | --- | --- |
| MG/PT | Field of uses envisaged | Likely concentrations at which a.s. will be used |
| Main group 03;  PT 14 | **Professional uses** | |
| Rodenticide used in and around buildings  Use in sewerage (only against rats) | 0.005% w/w |
| **Non-professional uses** | |
| Rodenticide used in and around buildings | 0.005% w/w |

There are two groups of humans which may be potentially exposed to the rodenticide baits : those who handle, apply and dispose of the product or other residues such as carcasses or faeces (direct exposure) and those who may be incidentally exposed while the product is in use (incidental exposure).

## Method of application

Block bait is made of paraffinic blocks to which the active substance has been added. These Brodifacoum baits are used indoors and outdoors to kill mice and rats: they are placed at the appropriate places in bait stations or covered under a curved tile, a wooden board or in a piece of tube; the animals eat some of the product and die.

Baits must be 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. Preferably bait stations will be used where the bait can't be hidden, fixed or locked up.

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.

In sewers, the bait is eaten *in situ* by target rodents. The brown rat is the only mammal able to live in sewers.

For house and field mice control, the recommended dose is 20 to 30 g of bait every 2 to 5 meters.

For rat control, the recommended dose is 60 to 100 g of bait every 5 to 10 meters.

In sewers, place 200 to 300 g every 30-50m (never more than 300 g at each manhole).

There are three phases for the human exposure:

- Application phase: application of rodenticides by professionals and non-professionals.

In and around domestic, industrial and commercial buildings, the product is applied manually, at measured amounts in bait boxes or covered. Professional users are assumed to wear protective gloves when handling the product unlike amateur users.

In sewerage, the bait is applied only by professionals, typically hanged to a wire tied up to the wall a few centimetres above the bottom of manholes.

Bait points are controlled regularly. Any bait eaten or damaged has to be replaced. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. During the bait inspections, also a search in the zone will be done for dead rodents.

- Use phase: Post-application, *i.e.* from the use of rodenticide products and from contact with the product (*e.g*. residential exposure including indoor air contamination, contact with the product during use). The use phase is the period when the biocidal product is waiting to be consumed by the target organism. This means that no primary exposure of humans is intended and should not take place (please refer to point 3.2.4 Secondary exposure).

- Disposal phase: Disposal (including handling of surplus formulated product, burning/incineration, dumping, empty containers, dead rodents (carcasses) disposal).

When no further bait take is observed, bait stations must not be 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.

For sewer systems no specific removal disposal is instructed.

## Human exposure assessment

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use1)** | **Professional use2)** | **General public3)** | ***via* the environment4)** |
| Inhalation5) | Not appropriate | Yes | Yes | No |
| Dermal6) | Not appropriate | Yes | Yes | No |
| Oral | Not appropriate | No | Yes | No |

1) Industrial use (manufacture of active substance and formulation of products) is not covered by BPD. Workers in formulation manufacture are not exposed to levels of a.s. that would affect blood clotting.

2) Includes non-trained professionals.

3) Indirect exposure due to transient mouthing by infants is included in the scenarios for the general public.

4) According to the TNsG, indirect exposure *via* the environment is considered to be of minor importance as the release of rodenticides to the environment is limited.

5) The skin is the main exposure route with a small proportion of inhalation exposure to dust when grain-based baits are mechanically handled by professionals. The active substance is of low volatility and it is incorporated at very low concentrations into a solid, non-volatile matrix. Therefore inhalation exposure is considered as negligible.

6) Except for the grain block bait which is always packed in individual sachets for both professionals and general public and for grain bait only for the amateurs, dermal contact with the product is a realistic scenario.

The magnitude of human exposure to block bait can be assessed by applying standard exposure models of TNsG[[10]](#footnote-10) for human exposure (2007) or the Harmonised approach for the assessment of rodenticides (anticoagulants) endorsed at TM II 2011 for professionals and amateurs users. Moreover, CONSEXPO 4.1 model can be used to assess the exposure to the biocidal product used by non-professionals.

The following basic primary exposure pathways have to be considered for a risk assessment in order to sum up the exposure of humans to Brodifacoum. The main exposure path is direct skin contact during the use of the biocidal product.

Ingestion is a secondary pathway or an accidental primary exposure during the use of the biocidal product.

Inhalation is considered as negligible.

According to the various pathways, the following absorptions will be applied in the assessment:

- Inhalatory uptake fraction: 1 (default value of 100%);

Inhalation rate: 1.25 m3/h (default value)

- Dermal uptake: 0.047% for wax formulations and 3 % for and grain/pellet.

- Oral uptake fraction 100%

## 

## Professional exposure

For professional use, the operator is trained in the correct use of the bait, *i.e.* placement, number of bait points/boxes required based on the infestation rate area, the amount of bait or number of bait place packs per bait point/box and safe handling procedures.

The use of PPE - disposable gloves and a dust mask may be employed when decanting bait and disposable gloves may be employed when loading bait boxes and disposing of remaining bait and carcasses. However, when the bait is contained within a bait box there will be no exposure of the operator to the product.

PPE (coverall, boots and gloves) is required as standard when the bait is used in sewage systems.

**Exposure calculations – professionals**

The CEFIC/EBPF Rodenticides Data Development Group conducted an operator exposure study using flocoumafen (which may be considered a suitable surrogate for all other second generation anti-coagulants) to determine exposure during simulated use of rodenticide baits (*Chambers* 2004, unpublished, confidential). This study examined exposure to wax blocks (20g wax block baits, 5 blocks/bait box) and grain bait. Guidance is also taken from a confidential paper entitled “Harmonised Approach for Rodenticides” by the German Competent Authority, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA).

The daily exposure frequency and its division between different tasks are based on a survey organised by CEFIC (and based on a questionnaire answered by selected pest control companies in several EU countries), and on an agreement between Member States on the common approach for exposure assessment and ECB guidelines.

The application of Block bait is regarded as a suitable worst case scenario for Paste and Cluster Baits. In the Chambers study operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks.

The Chambers study determined exposure from the application phase from the following scenario: 5 operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks. Three trials were conducted with 1, 5 and 10 times securing of these wax blocks. Since the results of 1, 5 and 10 securing are similar all trials were included in the calculation of the 75th percentile by the RMS. The proposed value of **28mg (of wax bait) per manipulation** is valid for loading of one bait box with 100g of wax blocks (a single manipulation constitutes the placement of a single bait station). Since the recommended amount for rat control is up to 200g bait per bait point, this exposure value is multiplied by a factor of 2 because only 100g was used in the Chambers Study. The proposed value of **56mg (of wax bait) per manipulation** is valid for loading of one bait box with 200g of wax blocks.

For professional operators the potential total daily dermal exposure (assuming the previously agreed number of 60 manipulations from TM III/10 is applied) from the application-phase is **3360mg** wax block product (i.e. 56mg × 60 bait sites).

The Chambers study determined exposure from the disposal or post-application phase from the following scenario: 5 operators emptied a loaded bait station by sliding the wax block off the mounting pegs into a 10 L plastic bucket. This is done 1, 5 and 10 times. The proposed value of **5.75 mg per manipulation (determined by the RMS, Difenacoum CAR 2009)** is valid for cleaning of one bait box. For the resulting potential dermal exposure of post-application-phase the agreed number of 15 manipulations (TM III/10) should be taken into account. For the post-application phase the potential total daily dermal exposure is **86 mg** wax block product (i.e. 5.75mg x 15 disposal manipulations). The size of one bait block is ignored and the figure is valid for different sized blocks (e.g. 10g, 100 g).

The calculation of PCO (pest control operator) and amateur dermal exposure in placing and clean-up of rodenticidal wax blocks, taking into account measured values (75th percentiles), defaults according to ECB guidelines and the common agreement on daily exposure frequencies (TM III/10) is presented in the following table.

|  |  |
| --- | --- |
| ***Pest Control Operator, No PPE:*** | |
| Amount of exposure to product (75th percentile) during securing of 10 20g wax blocks (200g). Value is for placement of 1 bait station. | 56.0 mg |
| Amount of Brodifacoum on fingers/hands (0.005% in wax block, 20 x 10g blocks sewer maximum application worst case) | 112 mg × (0.005 / 100)  = 5.6×10-3 mg |
| Systemic dose per application at 1 bait station:  (dermal absorption 0.047%, bw 60kg) | (5.6×10-3 mg) × (0.047 / 100)) / 60kg  = 4.39×10-8 mg/kg |
| Amount of exposure to product (75th percentile) during clean-up and disposal per bait station | 5.75 mg |
| Systemic dose (Brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg) per clean-up of one bait station. | 2.25×10-9 mg/kg |
| Assuming ‘reasonable worst case’ scenario of 60 bait sites and 15 clean-ups, systemic dose per day | ((4.39×10-8 mg/kg × 60)  + (2.25×10-9 mg/kg × 15))  =  **2.6×10-6 mg/kg/day**  **0.0026 μg/kg/day** |
| Expressed as a % of the AEL: |  |
| AELmedium term of 6.7 x 10-6 mg/kg bw/day **(0.0067 μg/kg/d)** | **39% of the AEL** |
|  |  |
| ***Pest Control Operator, With PPE (gloves)*** | |
| Default 10-fold reduction of exposure. | **2.6×10-7 mg/kg/day**  **0.00026 μg/kg/day** |
| Expressed as a % of the AEL: |  |
| AELmedium term of 6.7 x 10-6 mg/kg bw/day **(0.0067 μg/kg/d)** | **3.9% of the AEL** |

|  |  |
| --- | --- |
| ***Non-Trained Professional (e.g. farmer), No PPE:*** | |
| Systemic dose resulting from application of product to five bait sites plus five bait sites cleaned per day, no PPE (difenacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg). | ((2.19×10-8 mg/kg × 5)  + (2.25×10-9 mg/kg × 5))  =  **1.2×10-7 mg/kg/day** |
| Expressed as a % of the AEL: | **0.0001 μg/kg/day** |
| AELmedium term of 6.7 x 10-6 mg/kg bw/day **(0.0067 μg/kg/d)** | **1.5%** |
|  |  |
| ***Non-Trained Professional (e.g. farmer), With PPE (gloves):*** | |
| Default 10-fold reduction of exposure. | **1.2×10-8 mg/kg/day** |
|  | **0.00001 μg/kg/day** |
| Expressed as a % of the AEL: |  |
| AELmedium term of 6.7 x 10-6 mg/kg bw/day **(0.0067 μg/kg/d)** | **0.15%** |
|  |  |

**Application by spatula and caulking gun**

This calculation covers the exposure of a professional user when applying rodenticide bait via a caulking gun or spatula. The calculation is based on the information from the worked examples database, based on bridging to the paste application of wood preservative using a trowel (reverse-reference approach).  The worked examples data are ADE values inside gloves so the calculation assumes that gloves are worn.

From the wood preservative example, which addresses application of pastes by brush, trowel, caulking gun and gloved hand, a good case for bridging can be made for the contact gel application by spatula (vs trowel) and by caulking gun.

The wood preservative example assumes that the application process leads to a maximum of 30 minutes’ exposure per day and we must assess whether this is a reasonable exposure time for a professional pest controller using contact gel.

Time Required to Apply and Clean up Contact Gel Points

In the case of contact gel applied by caulking gun, a case could be made that this is covered by the 14 manipulations listed for paste bait.  The text in the HEEG document states:

*For the handling of paste bait the following was agreed: The paste bait described in the report by Vetter and Sendor was paste bait deployed using prefilled cartridges. Dermal exposure was considered possible only at removal and re-attachment of the nozzle's protection cap and was assumed to occur only before the first and after the last bait placing on a given site. Hence, the number of sites visited per day (multiplied with 2) was considered to be the relevant exposure determinant.*

If a user were filling a number of gel points in a small area, the same would be true for use of our contact gel caulking gun product - the user may not find it necessary to put the cap on between filling each bait station on that site.

For spatula application, an alternative way of thinking of this is again to assume that, given the contact gel is applied by spatula in the same way as wax blocks are placed in bait points, the number of manipulations would be at a maximum the same as the number for a wax block.  ie. 60+15.

The applicants experts think that to apply bait, either by spatula or by caulking gun, a maximum time of 15 seconds per bait point would be plenty of time.  Clean up probably takes about half a minute per bait point at most. (this time estimate agrees with UK Toban pasta bait which is applied in the same manner)

For application by caulking gun using the figure of 11 loadings and 3 clean ups, exposure is far lower than the 30 minutes used in the model.

Loading: 11 bait stations x 15 seconds = 2.75 minutes

Clean up: 3 bait stations x 30 seconds = 1.5 minutes

This gives a total handling time of 4.25 minutes.

For application by spatula and assuming the number of bait stations is the same as for wax blocks, this would give a total handling time of :

Loading: 60 bait stations x 15 seconds = 15 minutes

Clean up: 15 bait stations x 30 seconds = 7.5 minutes

Total time = 22.5 minutes

Therefore in both cases, the figure used in the modelling of 30 minutes is sufficient to cover a professional user.

Acceptable Exposure Level

The maximum level of exposure to the active substance has already been calculated in the AS review and is listed in the Assessment Report List of End Points as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| AELacute | VALUE  0.0000033mg/kg/day | STUDY  Rat developmental tox | SAFETY FACTOR  300 |

Therefore maximum amount of AS = 0.0000033 mg/kg/day

Reverse-reference Calculation

For a non-volatile paste (such as this brodifacoum product), inhalation exposure is assumed to be negligible and so, using the dermal absorption data for this formulation (0.047%), to exceed the acceptable exposure level, active substance contamination to the skin would need to exceed:

0.0000033 x 2128

= 7.00 x 10-3 mg/kg/day

If the operator weights 60 kg then the AS contamination would have to exceed:

7.00 x 10-3 x 60 kg

= 0.42 mg/day

As the maximum concentration of AS in the ready-for-use paste formulation is 0.005%, then the weight of paste product containing 0.42 mg AS will be:

0.25/0.005 x 100

= 8400 mg

Assuming that dermal exposure will be predominantly to the hands and in this case, based on the worked examples database, gloves are assumed to be worn since professionals are expected to wear gloves, then the rate of actual hand exposure to the hands is required to exceed:

8400 mg / 30 min

= 280 mg/min

If it is considered that the penetration of brodifacoum through protective gloves is 10%, the operator would need to get about 84 g of product on the outside of the gloves and this would have to remain on the surface until the active had migrated through the paste and penetrated the glove.

Part 2 of the TNsG (2002) states that “in an HSE survey of pest controllers (1994) it was estimated that the median duration "using pesticides" was 120 minutes.” It expands to say that treatment time is up to 100 minutes for pastes. If the 100 minutes is applied rather than 30 as suggested by the company

84g / 100 min

= 0.84 g/min

To put this exposure in context. To recieve an exposure of paste product in excess of the AEL the operator would be required to have almost the same quanity of gel on his protective glove as would load a 100g bait station. This level of exposure is considered very unlikely.

## Exposure to non-professional users

Contact gels applied by gun or syringe are professional use only and are not modelled for armature use. Block baits are considered a suitable worst case for paste bait delivered in a closed sachet.

Bait boxes for use by the general public may be supplied as sealed units or as lockable, tamper-proof units that may be refilled by the user. Bait may be used in covered/protected bait points, rather than bait boxes, where appropriate.

Calculations for non-professional exposure are presented below; the first scenario assumes no exposure during application phase while the second scenario assumes that the bait boxes would have to be loaded by the user. As for the non-trained professionals, it is assumed that a non-professional user places ten bait blocks per site (200g) on five bait sites and cleans five bait sites per day.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product type** | **Exposure scenario** | **PPE** | **Inhalation uptake** | **Dermal uptake** |
| 14 | Non-professional (amateur) | None | Not relevant | 1.12×10-8 mg/kg/day1) |
| 14 | Non- professional (amateur) | None | Not relevant | 1.2×10-7 mg/kg/day2) |
| 1) scenario 1, 2) scenario 2. | | | | |

Scenario 1: No dermal contact during placing of baits due to sealed bait boxes. Potential exposure is only during clean-up. Default exposure value for cleanup is 5.75mg product per bait site, bromadialone present at a concentration of 0.005% (w/w), 60kg body mass, 0.047% dermal absorption value. The value is calculated from the cleanup exposure per bait station of ((2.25×10-8 mg/kg) × 5).

Scenario 2: Assuming that conventional bait boxes are loaded then the exposure is equal to that of the non-trained professional (e.g. farmer) with no PPE. As a worst case scenario, scenario 2 can be taken forward to risk assessment.

## Exposure to children/workers/general public

Bait points should be covered or protected in such a way to prevent access to the bait. However, the ingestion of wax block bait by infants has been assessed as a potential secondary exposure route associated with the use of Brodifacoum in rodenticide products. Secondary exposure is anticipated to be acute in nature. Two different scenarios of secondary exposure are available, the ‘handling of dead rodents’ scenario and the ‘transient mouthing of poison bait’ scenario. The former is excluded from the risk assessment due to unrealistic assumptions. The estimated exposure for the ‘transient mouthing of poison bait’ scenario is either 2.5×10-2 mg/kg or 5.0×10-5 mg/kg, depending on the default assumptions. This results in Margin of Exposure (MOE) values of 0.01 or 6.6, respectively. It shows that infants are at significant risk for secondary exposure, i.e. there is no safe use for children.

For the ‘transient mouthing of poison bait’ scenario, either 5g (User Guidance) or 10 mg (TNsG, with bittering agent) of the product is assumed to be swallowed by an infant per poisoning event.

**Oral exposure infant.** TNsG Assumptions: Transient mouthing of poison bait (10mg) treated with repellent: (10mg × 0.00005) / 10kg bw

**Transient mouthing infant.** User Guidance Assumptions: Transient mouthing of poison bait (5000mg) without repellent; (5000mg × 0.00005) / 10kg bw

|  |  |  |
| --- | --- | --- |
|  | **Total dose (mg/kg b.w./day)** | **% AELacute (0.0033 µg/kg b.w.)** |
| Oral exposure infant | 0.00005 | 1515% |
| Transient mouthing infant | 0.025 | 757575% |

The RMS considered that in connection with transient mouthing of poison baits, infants are also exposed via the dermal route while handling the bait. This however is assumed to play a minor role relative to the amount that could be ingested. It is therefore not included in the overall exposure scenario.

## Exposure to consumers from residues in food

Not applicable.

## Overall Summary (initaila PAR 2011)

The exposure data based on measurements in simulated use conditions are acceptable and should be used in risk assessment. The models assume that inhalation exposure is of minor importance compared with dermal exposure. The calculations have been made with the assumptions of rat control, and there are no separate calculations to assess exposure in mice control in which smaller bait sizes are used.

* **Major change and renewal application for ULTIMA PASTE 2017**

## Human exposure assessment updated 2017

## Identification

ULTIMA PASTE rodenticide is applied in and around buildings by professional users and non-professional users. It’s applied in open areas, waste dumps and landfills by professionals. The bait is individually wrapped in paper sachet.

* For mice control, the claimed dose is 10g of bait.
* For rat control, the claimed dose is 60g.

The main exposure path is direct skin contact during the use of the biocidal product for Professional and non-professional users and for general public.

Ingestion is a secondary pathway or an accidental primary exposure during the use of the biocidal product.

In the case of wax blocks, inhalation exposure is irrelevant.

**Identification of main paths of human exposure towards active substance 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 | Yes | n.a |
| Oral | n.a | No | No | n.a | n.a | Yes | n.a |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | **Primary dermal exposure during application and cleaning** | **Primary dermal exposure**  The product is a ready to used product individually wrapped in paper sachet; therefore exposure during loading and cleaning is considered. | Professionals |
| 2. | **Primary dermal exposure during application and cleaning** | **Primary dermal exposure**  The product is a ready to used product individually wrapped in paper sachet, therefore exposure only during cleaning is considered. | Non-professionals |
| 3. | **Ingestion of product by an infant** | **Secondary exposure by oral route**  Oral exposure of toddler by ingestion of a piece of bloc. | General public |

## Exposure for the professional

| **Description of Scenario [1]: Primary dermal exposure during application and cleaning** | | | | |
| --- | --- | --- | --- | --- |
| ULTIMA PASTE is a ready to used product individually wrapped in paper sachet for professional users.    According to the HEEG opinion 10 the following exposure phases are considered:  paper sachet:  - 60 manipulations/day,  - 15 cleanings/day.  Sachets:  - 15 cleanings/day.  Dermal exposure is based on the HEEG opinion 12: Harmonised approach for the assessment of rodenticides.  As a worst-case, the application dose of 60g for the use against rat is taken into account; the dose for the use against mice being lower (10g), the exposure assessment is considered covered.  The exposure assessment during the use of unwrapped formulation is a worst-case compared to a formulation suplied in sachet. | | | | |
|  | Parameters1 | Unit | Value | Source |
| Tier 1 | Amount of exposure to product (75th percentile) during loading | mg | 27.79 | HEEG opinion 12 |
| Manipulation per day | - | 60 | HEEG opinion 10 |
| Amount of exposure to product (75th percentile) during clean-up | mg | 5.7 | HEEG opinion 12 |
| Manipulation per day | - | 15 | HEEG opinion 10 |
| Inhalation absorption value | % | 100 | - |
| Dermal absorption value | % | 0.047 | - |
| Concentration of a.s in the product | % | 0.0025 | - |
| Body weight | kg | 60 | HEAD hoc recommendation 14 |
| Tier 22 | Gloves protection factor | % | 95 | HEEG opinion 9 |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

**Total estimated exposure from professional uses**

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

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| Exposure scenario | Tier/PPE | Estimated inhalation uptake | Estimated dermal uptake | Estimated oral uptake | Estimated total uptake |
| **wraped Formulation** | | | | | |
| Scenario [1] | Tier 1/ No PPE | - | 4.09x 10-7 | - | 4.09x 10-7 |
| Scenario [1] | Tier 2/ PPE (Gloves) | - | 2.04 x 10-8 | - | 2.04 x 10-8 |

## Exposure for non professional

| **Description of Scenario [2]: Primary dermal exposure during cleaning phase** | | | | |
| --- | --- | --- | --- | --- |
| ULTIMA PASTE is a ready to used product individually wrapped in paper sachet for non-professional users.  According to the HEEG opinion 10, an exposure phase of 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 60g for the use against rat is taken into account; the dose for the use against mice being lower (10g), the exposure assessment is considered covered. | | | | |
|  | Parameters1 | Unit | Value | Source |
| Tier 1 | Amount of exposure to product (75th percentile) during clean-up | mg | 5.7 | HEEG opinion 12 |
| Manipulation per day | - | 5 cleaning | HEEG opinion 10 |
| Dermal absorption value | % | 0.047 | - |
| Concentration of a.s in the product | % | 0.0025 | - |
| Body weight | kg | 60 | HEAD hoc recommendation 14 |

**Total estimated exposure from non professional uses**

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

| **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 | - | 5.58 x 10-9 | - | 5.58 x 10-9 |

## Exposure to children/workers/general public - 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 brodifacoum is expected on the fur because the product is an oral bait and toxicokinetics data showed that urine is a minor route of excretion for brodifacoum).

For the scenario “*oral exposure by ingesting bait*”, a reverse scenario was calculated. Based on the AEL of **6.7 x 10-6 mg a.s/kg bw/day**, a body weight of 10 kg and an oral absorption of **100%** [as stated in the Assessment report of brodifacoum], ingestion of more than **2.68 mg** of product per day by an infant is needed to exceed the AEL.

## Risk Characterisation for Human Health- (initial PAR 2011)

## Professional users

**Caulking gun or spatula**

Calculation of the exposure of a professional user when applying rodenticide bait via a caulking gun or spatula was assessed via reverse reference scenario. Assuming that dermal exposure will be predominantly to the hands and in this case, based on the worked examples database, gloves are assumed to be worn since professionals are expected to wear gloves, then the rate of actual hand exposure to the hands is required to exceed:

8400 mg / 30 min

= 280 mg/min

If it is considered that the penetration of brodifacoum through protective gloves is 10%, the operator would need to get about 84 g of product on the outside of the gloves and this would have to remain on the surface until the active had migrated through the paste and penetrated the glove.

84g / 100 min

= 0.84 g/min

Using a reverse reference scenarios for caulking and or spatula application it was calculated that a professional operator would require exposure to 84g per day on his gloves. To recieve an exposure of paste product in excess of the AEL the operator would be required to have almost the same quanity of gel on his protective glove as would load a 100g bait station. This level of exposure is considered very unlikely.

**Wrapped sachet or blocks**

The exposure assessment for professional pest control operators (PCOs) under reasonable worst case assumptions (60 loadings and 15 clean-ups/day), as presented above, yielded a potential dermal exposure leading to a systemic dose 0.0026μg/kg/dayday for an unprotected operator during bait handling operations. Comparison to calculated NOAEL for MOE shows that the use of rodenticide baits containing 0.005% brodifacoum results in a margin of exposure of 257.

Since pest control operators wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting margin of exposure (MOE = 2570) indicates that the use of rodenticide baits containing 0.005% brodifacoum does not cause a risk for PCOs if gloves are worn.

Likewise, the exposure assessment for non-trained professionals (e. g., farmers) under reasonable worst case assumptions (five loadings and five clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 1.2×10-7 mg/kg/day for an unprotected person. Even without PPE, the resulting margin of exposure (MOE = 6700) indicates that use of rodenticide baits containing 0.005 % brodifacoum is not a risk at the stated exposure frequency. A refined assessment was, nevertheless, conducted since wearing of protective gloves is recommended in the instructions for use. The resulting margin of exposure (MOE = 67000) indicates a high level of protection for non-trained professional users when gloves are worn.

The result of the risk assessment concerning use of brodifacoum in bait blocks/sachets indicates that the acceptable exposure level is not exceeded for trained professionals (PCOs) without PPE (gloves). In addition, the risk is at an acceptable level without gloves for non-trained professionals. However, use of protective gloves is recommended in all cases for hygiene reasons. In the case of application for caulking gun or spatula it was concluded that exposure to 84g of bait by a PCO on a glove was exceedingly unlikely and this application method was expected to yield safe exposure levels for trained operators.

## Non-professional users

Blocks/sachets are supplied either in pre-sealed units or as loose blocks for use in covered/protected bait points or refillable bait boxes. An exposure assessment has been performed taking into account potential exposure both from application and post-application tasks as a worst-case scenario. In the calculations, amateurs were assumed to load five bait points and clean five bait points per day without PPE. The estimated daily systemic dose, 1.2×10-7 mg/kg/day, results in an MOE value of 6700 showing that there is also little risk to amateurs.

## Children/Workers/general public

As a potential secondary exposure route, associated with the use of difenacoum in rodenticide products, ingestion of wax block bait by infants has been assessed. Secondary exposure is anticipated to be acute in nature. The estimated exposure for the scenario, 2.5×10-2 mg/kg/day or 5.0×10-5 mg/kg/day, depending on the default assumptions, results in MOE values of 0.01 or 6.6, respectively indicating that infants are at risk of poisoning. This should be addressed by ensuring all bromodialone products targeted for amateur use are provided in sealed packs and tamper resistant bait boxes with a bittering agent. The potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic.

## Consumers from residues in food

Not applicable, product is not used to treat food stuffs.

## Overall Summary

The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0023μg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Workplace operation** | **PPE** | **Exposure path** | **Dose**  **(μg/kg/day)** | **MOE** | **%AEL** |
| *Trained Professional:*  Placing of wax block baits and clean-up | None | Dermal, hands | 0.0026 | 257 | 39 |
| *Trained Professional:*  Placing of wax block baits and clean-up | Protective gloves | Dermal, hands | 0.00026 | 2570 | 3.9 |
| *Trained Professional:*  Application via caulking gun/spatula and clean-up  *Trained Professional:*  Placing of wax block baits and clean-up | None  Protective  Glove | Excess of 8.4g on hands to exceed AEL  Excess of 84g on hands to exceed AEL |  |  |  |
| *Non-Trained Professional:*  Placing of wax block baits and clean-up | None | Dermal, hands | 0.0001 | 6700 | 15 |
| *Non-Trained Professional:*  Placing of wax block baits and clean-up | Protective gloves | Dermal, hands | 0.00001 | 6700 | 1.5 |
| *Amateur:*  Placing of wax block baits and clean-up | None | Dermal, hands | 0.0001 | 6700 | 15 |
| *Secondary Exposure*  *Transient Mouthing of bait by infants* | -- | Oral | 5.0×10-5 (TNsG)  2.5×10-2  (User Guidance) | 6.6  0.35 | --  -- |

* **Major change and renewal applications for ULTIMA PASTA 2017**

## Risk Characterisation for Human Health-(updated 2017)

The estimated exposures are compared to the systemic AELlong-term and AELmedium term of brodifacoum set in AR (September 2016): 3.3 x 10-6 mg/kg bw/day and 6.7 x 10-6 mg/kg bw/day for professionals and non-professionals, respectively.

**Summary of risk characterization for professional and non-professional users:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| 1/ Professionals (paper sachet) | Tier 1/No PPE | 3.3 x 10-6 | 4.09x 10-7 | 12 | Yes |
| 1/ Professionals (paper sachet) | Tier 2/PPE (gloves) | 3.3 x 10-6 | 2.04 x 10-8 | 1 | Yes |

***Pleae note that the validated dose for rat is 100g/bait station, whereas risk assessment has been performed with the claimed dose of 60g.   
Given the calculated risk ration, using 100g/bait station would not have modified the outcome of the risk assessment***

## Primary exposure

The risk for professional users resulting from the intended uses is acceptable for the product supplied in paper sachet, without PPE for the control of rats, and by extension the control of mice.

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

The risk for non-professional users resulting from the intended uses is acceptable with wrapped baits (%AEL of 0.1%).

## Secondary exposure

The scenario “oral exposure by ingesting bait” as a reverse scenario results to an ingestion of more than 2.68 mg of product per day by an infant is needed to exceed the AEL. This indicates that infants are at significant risk of poisoning.

Therefore, even ULTIMA PASTE contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable for children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

## Over all conclusion

For the professionals, the risk resulting from the intended uses is acceptable without PPE for the control of rats, and by extension the control of mice.

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

For non professionals, the risk resulting from the intended uses is acceptable.

## Effect and Exposure Assessment for the Environment

An overview of the EU review of environmental fate and behaviour and ecotoxicology for the active substance is presented below in conjunction with the exposure assessment and environmental effects for the biocidal product.

## 

## Environmental fate and behaviour of the active substance

##### Degradation

###### Biodegradation

Brodifacoum is not readily or inherently biodegradable.

The overall conclusion on biodegradation is that Brodifacoum is not readily or inherently biodegradable.

###### Abiotic Degradation

Brodifacoum is stable to hydrolysis (t½ > 1 year). It is however predicted to undergo rapid indirect photolysis with OH radicals and ozone (t½ = approximately 2 hours) and undergoes rapid direct photodegradation (t½ = 0.217 days). There are no predicted effects on the atmosphere.

The overall conclusion on abiotic degradation is that Brodifacoum is hydrolytically stable to hydrolysis (t½ > 1 year).

###### Distribution

Brodifacoum is a large aromatic organic compound of low volatility with two polar groups, which can potentially ionise at environmental pH. The active substance has a Log Pow (4.92), and is of low solubility in water (5.8 x 10-5 g/l at pH 7 and 20°C).

The DT50 value of 157 days (The Pesticide Manual 13th ed) and the Koc of 50000 (The Pesticide Manual 13th ed) indicate that Brodifacoum would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

On the basis of its low volatility (vapour pressure of 2.6 10-22 Pa at 20°C) the exposure to the atmosphere is highly unlikely.

The overall conclusion on distribution is as follows: Brodifacoum is persistent (DT50 157 days) and immobile in soil (Koc > 9155 l/kg). Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Mobility in soil

The Koc value (50000 The Pesticide Manual 13th Edition) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater (PEC < 0.1 μg/l).

The overall conclusion on mobility in soil is as follows *Brodifacoum* is immobile in soil (Koc > 9155 l/kg). *Brodifacoum* is not expected to contaminate groundwater.

##### Accumulation

Based on a measured Log Kow = 4.92 it is considered that Brodifacoum has a potential for bioaccumulation. The BCFfish (3034) was calculated using the equation 74 of TGD (part II); the BCFearthworm (999) was calculated according to the equation 82d of TGD

The overall conclusion on bioaccumulation potential is as follows: No reliable bioaccumulation study is available. The measured log Kow = 4.92 (retrieved from CAR B) indicates that Brodifacoum can be potentially bioaccumulative and provides a calculated BCFfish = 3034. The experimental Kow confirms the adequacy of using, in CAR A, the calculated log Kow of 6.12 (rather than 8.5) and indicates that this value still overestimated the actual lipophilicity and, consequently, the BCF values estimated herein. The measured log Kow = 4.92 and a BCFfish = 3034 and BCFearthworm = 999, are considered therefore more reliable endpoints to be used in risk assessment.

## Environmental effects (hazard) of the active substance (ecotoxicology)

**Table 3.3.5.2-1: Summary of the eco-toxicological data for the active substance Brodifacoum**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **Test material** | | **Species** | | | **Result** | | **Classification** | | **Ref.** |
| Short term toxicity testing on fish | ECO120140 | | Oncorhynchus mykiss | | | 96-hour LC50 = 0.042 mg/L | | Yes - R50/R53 | | W J Craig - March 2003. Chemex Environmental International Ltd report ENV5803/120140 (2003) |
| **Acceptability (Y/N):** Yes | | | | | **Method:** OECD 203 | | | | **GLP (Y/N):** Yes |
| **Comments:** None | | | | | | | | | |
| **Acceptability (Y/N):** Yes | | | | | **Method:** OECD 202 | | | | **GLP (Y/N):** Yes |
| **Comments:** Recorded under semi-static conditions. | | | | | | | | | |
| Toxicity to aquatic invertebrates | ECO120140 | | Daphnia magna | | | 48 hour - EC50 = 0.25mg/l | | Yes - R51 /R53 | | W J Craig - March 2003. Chemex Environmental International Ltd report - ENV5802/120140 |
| **Acceptability (Y/N):** Yes | | | | | **Method:** OECD 202 | | | | **GLP (Y/N):** Yes |
| **Comments:** Recorded under semi-static conditions. | | | | | | | | | |
| Growth inhibition study on algae | ECO120140 | | Selenastrum capricornutum (Pseudokirkneriella subcapitata) | | | 72h ErC50 = 0.04 mg/l | | Yes - R50 /R53 | | W J Craig - March 2003. Chemex Environmental International Ltd. Report -ENV5801/120140 |
| **Acceptability (Y/N):** Yes | | | | | **Method:** OECD 201 | | | | **GLP (Y/N):** Yes |
| **Comments:** None | | | | | | | | | |
| Inhibition of microbial activity | 7909101 | | 3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage | | | EC10 was set > water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C | | No acute toxicity | | Staniland, J. (2004) Chemex Environmental International Ltd. Ref: ENV7009/120140 |
| **Acceptability (Y/N):** Yes | | | | | **Method:** OECD 209 | | | | **GLP (Y/N):** Yes |
| **Comments:** Although the results of the study (EC50 >1003mg/l) are not reliable, the study can be used to derive the NOECmicroorganisms on the basis of the brodifacoum water solubility (EC50 > 0.058 mg/l). | | | | | | | | | |
| Studies on sediment dwelling organisms | | - | | No experimental data available for sediment dwelling organisms. | - | | - | | - | |
| **Acceptability (Y/N): -** | | | **Method: -** | | | | **GLP (Y/N): -** | |
| **Comments:** The risk for the sediment compartment will be covered by the risk for the aquatic compartment. | | | | | | | | |
| Growth inhibition of aquatic plants | | - | | No study submitted | - | | - | | - | |
| **Acceptability (Y/N): -** | | | **Method: -** | | | | **GLP (Y/N): -** | |
| **Comments:** The evaluation concluded that there is no need for a study as there is no evidence that brodifacoum would be toxic to aquatic plants to a greater extent than to other aquatic organisms. | | | | | | | | |
| Toxicity to earthworms | | Chemex reference: ECO120140 | | 14-day LC50 | > 994 mg/kg dw | | No acute or chronic toxicity | | Staniland, J (2005) Environmental International Ltd. Ref:ENV7010/120140 | |
| **Acceptability (Y/N):** Yes | | | **Method:** Static test conditions according to SOP E260 based on OECD 207. | | | | **GLP (Y/N):** Yes | |
| **Comments:** 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt. | | | | | | | | |
| Toxicity to birds | | Difenacoum | | LD50 (Japanese quail) | 19 mg/kg bw | | Acute toxicity | | XXXX (2005) LAB International. Study code: XXXXX | |
| **Acceptability (Y/N):** Yes | | | **Method:** OPPTS 850.2100 | | | | **GLP (Y/N):** Yes | |
| **Comments:** An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d. | | | | | | | | |
| Toxicity to mammals | | 04359 | | Two-generation fertility study (rat, parent females) | NOAEL (0.001mg/kg bw/day) | | Yes | | Toxicological Research Centre Ltd. report XXXX. | |
| **Acceptability (Y/N):** Yes | | | **Method:** OECD 416 | | | | **GLP (Y/N):** Yes | |
| **Comments:** Although a two-generation study is not normally required for anticoagulant rodenticides, the study is relevant for the establishment of an overall NOAEL for anticoagulant effects in rodents. | | | | | | | | |

## Effects on Aquatic Organisms including the determination of PNECs:

Toxicity data are available for aquatic organisms exposed in an acute test. In a test performed under semi-static conditions, the 96-hour LC50 was 0.042mg/L for Oncorhynchus mykiss, based on measured concentrations. Daphnia magna was less sensitive than fish, with a 48-hour EC50 of 250 µg/L recorded under semi-static conditions. The endpoint was based on immobilisation and on measured concentrations of Brodifacoum in the test media. In a 72-hour algal growth inhibition test with Selenastrum capricornutum (Pseudokirkneriella subcapitata) the ErC50was 40 µg/l. The NOEC was 10µg/l with respect to specific growth rate. Results are based on measured concentrations. The outcome is that Brodifacoum is considered very toxic to aquatic organisms. The PNEC is derived from the algae 72h ErC50 = 0.04 mg/l (or fish 72h LC50 = 0.042 mg/l), and the application of an assessment factor of 1000. Therefore the **PNEC = 0.00004 mg/l**.

No experimental data are available for sediment dwelling organisms. A PNECsediment (0.043 mg/kg wwt) was derived through the Equilibrium Partitioning Method described in the TGD. However, due to the absence of measured data for the determination of a PECsed, according to TGD a quantitative risk characterization cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

Based on the result of a 3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage, no effects of Brodifacoum on aerobic biological sewage treatment processes are expected. As the test was carried out at nominal concentration much higher than the water solubility of Brodifacoum, the EC10 was set as greater than the water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C. According to TGD, PNEC is derived applying an AF=10 to the NOEC from the respiration inhibition test. Therefore, the **PNECmicro-organisms > 0.0058 mg/l.**

No degradation or transformation products of Brodifacoum in water were detected. Toxicity of metabolites is not of concern.

**PNECaquatic organisms = 0.00004 mg/l**

**PNECsediment organisms = 0.00004 mg/l**

**PNECmicro-organisms = > 0.0058 mg/l**

**Conclusion on hazard to the aquatic organisms:**

|  |  |
| --- | --- |
| **PNEC** | **Task Force** |
| **PNECaquatic organisms** | 0.00004 mg/l |
| **PNECsediment organisms** | 0.00004 mg/l |
| **PNECmicro-organisms** | > 0.0058 mg/l |

The Brodifacoum a.s. results in the classification of toxic to aquatic organisms.

## Effects on the Atmosphere including the determination of PNECs

Brodifacoum has a low vapour pressure (1 x 10-6 Pa) and a Henry’s Law constant of 2.18 x 10-3 Pa.m3mol-1 (pH 7). Release to air via water is expected to be negligible. This is also supported by calculations using the TGD on risk assessment for percent release to air from a sewage treatment plant where a default of 0 is given (i.e., no release to air). The manufacture of the active substance is in a closed system. There are no releases to air of Brodifacoum from manufacturing, formulating, use or disposal phases.

###### Effects on Terrestrial Organisms including the determination of PNECs:

The effect of Brodifacoum on earthworms was assessed in an acute toxicity test in which E. fetida in artificial soil was exposed to concentrations of Brodifacoum up to 994 mg/kg dw. The 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt. The PNEC for terrestrial organisms is derived from the LC50 with an AF of 1000 used. Therefore, **the PNECsoil ≥ 0.88 mg/kg wwt soil**.

**Conclusion on hazard to terrestrial organisms:**

|  |  |
| --- | --- |
| **PNEC** | **Task Force** |
| **PNECsoil** | > 0.88 mg/kg wwt |

Earthworms were not affected after acute exposure to Brodifacoum at concentration closed to 1 g/kg dw. It is concluded that Brodifacoum is of low toxicity to earthworms. **The PNECsoil ≥ 0.88 mg/kg wwt soil.**

###### Effects on Birds including the determination of PNECs:

Brodifacoum is moderately toxic to birds upon acute oral exposure with a LD50 value of 19 mg/kg bw in the Japanese quail.

No studies are available on the avian short term dietary toxicity.

A 6 weeks reproduction test on the Japanese quail exposure to Brodifacoum in drinking water was submitted but it was judged not adequate for risk assessment purposes. Therefore, acknowledging the decision taken at the Biocides TMIII09, the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants. An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d. According to the TGD, an assessment factor of 30 is applied to derive the PNEC. Therefore the **PNECoral-birds = 0.012 mg Brodifacoum/kg diet/30 = 0.0004 mg Brodifacoum/kg diet.** Inrelation to dose the **PNECoral-birds = 0.0012 mg Brodifacoum/kg bw/d/30 = 0.00004 mg Brodifacoum /kg bw/d**.

**Conclusion on hazard to birds:**

|  |  |  |
| --- | --- | --- |
| **PNEC** | **PNECoral bird diet** | **PNECoral bird** |
| **Task Force** | 0.0004 mg/kg | 0.00004 mg/kg bw/d |

###### Effects on Mammals including the determination of PNECs:

The lowest mammalian NOAEL (0.001mg/kg bw/day) comes from a two-generation fertility study with rats and refers to parent females. This endpoint was converted, according to TGD, to NOEC mammal, food = 0.02 mg/kg food. As the exposure lasted 90 days as a minimum, for PNEC derivation an AF oral of 90 is applied (table 23 of TGD). Therefore, the **PNECoral-mammals = 0.02/90 = 2.22E-04 mg/kg food**, corresponding to **PNECoral-mammals = 0.001 mg/kg bw day/90 = 1.1 E-05 mg/kg bw**.

**Conclusion on hazard to mammals:**

|  |  |
| --- | --- |
| **PNEC** | **Task Force** |
| **PNECoral mammals food** | 2.22E-04 mg/kg |
| **PNECoral mammals** | 1.1 E-05 mg/kg bw |

Brodifacoum is very toxic to mammals.

###### Metabolites

No significant amounts of metabolites are expected to be formed in soil. In rats, no toxicologically relevant metabolites have been identified which could be introduced in soil via urine or faeces.

#### Environmental effects (hazard) of the biocidal product

The example products in the EU-review program for approval of the active substance for inclusion in Annex I of Directive 98/8/EC were pellet bait and wax block mixtures (formulations) containing Brodifacoum.

The aquatic, terrestrial, avian and mammalian toxicity data used for the assessment of the Annex I representative biocidal product was based on data determined in the Brodifacoum active substance studies. This included the following studies.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 7.8.7.1 (1) | Kaukeinen DE | 1982 | A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides  Proceedings of the 10th Vertebrate Pest Conference (1982).  Published | N | Public Domain |
| 7.8.7.1 (2) | Newton I and  Wyllie I | - | Effects of New Rodenticides on Owls, Institute of Terrestrial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published | N | Public Domain |
| 7.8.7.1 (3) | Gray A,  Eadsforth CV and Dutton AJ | 1994 | The Toxicity of Three Second-Generation Rodenticides to Barn Owls,  Pesticide Science, 42, 179-184.  Published | N | Public Domain |
| 7.8.7.1 (4) | Wyllie I, Newton, I and Freestone P | - | The Toxicity of Three Second-Generation Rodenticides to Barn Owls,  Institute of Terrestrial Ecology, Monks Wood, Abbots Ripton, Huntingdon, Cambs PE17 2LS  Published | N | Public Domain |

There were no additional ecotoxicology studies provided for authorisation of the biocidal product in this process.

#### Environmental effects (hazard) of the co-formulants (substances of concern)

Please refer to Annex I of the consolidated Annexes I-IV which contains the confidential information on the co-formulants that are used in this product along with the active substance.

None of the co-formulants that carry an environmental classification are present at a sufficient concentration to trigger the classification of the product.

**Product Classification & Labelling:**

There is no requirement for classification and labelling with regard to the co-formulants used in the product.

There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

## Exposure Assessment for the Environment

The environmental exposure was assessed during the EU active substance review process and the current intended uses are similar.

The rodenticide product is used by professional and amateur users. The product is intended for indoors use, in and around buildings and for outdoors uses in non-agricultural open areas and waste dumps. It is not supported for use in sewers; however the applicant has included this scenario in their application as a worst case scenario.

It is always used in the same manner for all these purposes. Bait points are placed throughout the infested areas with 20g per bait point for mice and 20 to 60 g per bait point for rats. Application sites are located 2-5 m apart for mice and 5-10 m apart for rats. A shorter distance is used in severe infestations. The number of baits and the distances should be adapted to the infestation level. Bait points are inspected frequently and replenished when bait has been eaten.

Bait points are placed securely to help prevent access to non-target animals. For amateur use, the label prescribes to use tamper resistant bait stations for rat control. Baits for amateur mouse control have to be placed into/at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the wax blocks must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Based on the environmental fate and behaviour of Brodifacoum, as outlined in the detailed calculations provided in Annex VI of this Product Authorisation Report, the environmental exposure assessment was conducted.

#### Aquatic compartment

As mentioned previously the product is not supported for use in sewers but the scenario has been included as part of the risk assessment for the other scenarios. Therefore exposure to the aquatic compartment has been assessed through the STP route also. Based on worst case ESD assumptions the maximum predicted environmental concentration (PEC) of the active substance for microorganisms in the STP is 1.93 x 10-5 mg/L. The corresponding amount in surface water is 1.77 x 10-6 mg/L. The maximum permissible concentration by directive 80/778/EEC (amended by 98/83/EC) of 0.1 μg/L is not exceeded in surface waters. Full details of the calculations are contained in Annex VI.

#### Atmospheric compartment

Brodifacoum has a vapour pressure of less than 10-6 Pa at 20oC and a Henry’s Law constant of less than 2.18 x 10-3 Pa.m3.mol-1 at pH 7. In the Assessment Report for brodifacoum it has been concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

#### Terrestrial compartment

Exposures of soil to the active substance occurs via direct (spillages) and disperse release (deposition by urine and faeces) after the use of the product in and around buildings, open areas and waste dumps. As mentioned previously the product is not supported for use in sewers however exposure to agricultural soil via spreading of sludge from an STP has been included as part of the worst case risk assessment.

Using ESD worst-case assumptions of the typical usage patterns and release mechanisms, the maximum concentration in agricultural soil (averaged over 30 d) after 10 years of sludge application from STP is 4.86 x 10-4 mg/kg wwt. When the applicant’s dosage rates are used as inputs the figure for agricultural soil is 3.24 x 10-4 mg/kg wwt. No information on the metabolism of brodifacoum was used to lower the exposure levels further.

The highest concentration of Brodifacoum in soil following use in and around buildings is 0.047 mg/kg wwt under ESD realistic worst case conditions (see table below). For a normal use pattern the ESD recommends a total of 2.6 replenishments (as opposed to 5 for the worst case). This usage pattern leads to an estimated soil concentration of 0.006 mg/kg wwt.

For the open areas scenario ESD realistic worst-case conditions assume one application site is treated twice with the product. The fraction released during use and application is 0.25. The exposed soil area is assumed to be the lower half of the burrow wall surrounding an 8 cm diameter tunnel, with a soil mixing depth of 10 cm and up to 30 cm from the entrance hole. The amount of product used at each refilling in the control operation is not specified by the ESD. However, the Reviewer notes the ESD states “A typical initial dose for a rat hole in the Nordic countries is 100-200 g grain.hole-1. However, in e.g. France a typical dose for a rat hole is about 50-100 g product.” The applicant supports a dosage of 60 g bait per refill but bearing in mind the ESD statements the reviewer feels that a dosage value of 100 g is a sufficiently worst case value to use in the exposure assessment.. The local concentration arising in soil after a campaign is predicted to be 0.173 mg/kg wwt.

The default area for a waste dump defined in the ESD is 1 ha. If bait points are placed at distances of 5 m apart in a grid covering the entire dump this would yield a total of 441 points (21 x 21). 100 g in each bait point corresponds to a total loading of 44.1 kg of bait. This is higher than the default value considered in the ESD under realistic worst-case conditions (40 kg). Consequently the applicant’s exposure calculation is not sufficient to support this use. The Reviewer generated new exposure calculations for this use. The local concentration arising in soil after such a campaign is predicted to be 0.00817 mg/kg wwt. A more realistic campaign would use a total of 11 kg of bait resulting in a local concentration of 0.00204 mg/kg wwt.

|  |  |  |
| --- | --- | --- |
| **In and around buildings**  Amount of product used in control operation for each bait point:  0.25 kg (ESD), 0.06 kg (applicant).  Realistic worst-case:  21 day campaign  Bait stations:  10  No. of replenishments:  5 (2.6 realistic)  Bait stations are 5 m apart.  Fraction released due to spillage:  0.01  Fraction ingested:  0.99  Spillage area:  0.09 m2 (0.1 m around station)  Frequented area:  550 m2 (10 m around building) | **Open areas**  Amount of product used at each refilling in the control operation:  100 g  Realistic worst-case:  6 day campaign  Bait stations:  1  No. of replenishments:  2  Fraction of product released to soil during application:  0.05  Fraction of product released to soil during use:  0.2 | **Waste dumps**  Area of waste dump:  1 ha  Amount of product per station:  100 g  Spacing between blocks:  5 m (worst case), 10 m (realistic)  Total mass of product used:  21 x 21 x 100 g = 44.1 kg (worst case)  11 x 10 x 100 g = 11 kg (realistic)  No. of replenishments:  7  Fraction of active ingredient released to soil through urine, faeces and dead animals:  0.9 |

#### Groundwater

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in the scenarios in and around buildings, open areas and waste dumps. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. A summary of the PECs obtained are presented in the table below. The calculated value for the open areas scenario exceeds the EU trigger value of 0.1 μg/L. However this figure is derived from a soil concentration value in a small localised area in the immediate vicinity of the baiting point. When taken in the context of a larger area (field, park, etc.) this figure would be several orders of magnitude lower. In addition it must be noted that these two scenarios give a value for groundwater under industrial soil – not agricultural soil as specified by the ESD.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **In and around buildings** | | **Open area** | **Waste dump** | | **Sewer system** |
|  | **Worst case** | **Realistic** |  | **Worst case** | **Realistic** |  |
| **PEC groundwater (mg/l)** | 5.3 x 10-5 | 6.62 x 10-6 | 1.96 x 10-4 | 9.26 x 10-6 | 2.31 x 10-6 | 1.93 x 10-5 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A new threshold value in groundwater of 0.03µg/L has been proposed from the human health section for the toxicity of the substance brodifacoum in drinking water. This value should be taken into account for the groundwater risk assessment.  Due to the new threshold value in groundwater, the risk is unacceptable according to the Tier 1. The PEC groundwater for an open area use is the worst case but this application rate is not representative for a wide surface. Indeed, the exposure is very localized, in the rat hole. The rate application for a use in waste dump is more representative for a wide surface treatment leading to leaching towards groundwater. Thus, a FOCUS modelling was realised to refine the PEC groundwater: a worst case leading to a dose rate of 44.1kg product .ha-1 is used.   |  |  | | --- | --- | | Model used | FOCUS PEARL 4.4.4. | | Years of simulation | 1 | | Application rate | 1 x 44.1 kg .ha-1 | | Standard crop for arable land | Alfalfa | | Application depth | Incorporation 0 cm | | Date of application | Twelve application per year | | Molar mass | 523.4 g.mol-1 | | Vapour pressure | 1E-06 Pa at 20°C | | Water solubility | 0.240 mg.L-1 at 20°C | | Kom | 5310.3 L.kg-1 at 25°C | | Freundlich exponent | 1 | | DT50soil | 298 d at 12°C | | Coefficient for uptake for plant | 0 | | Molar activation energy | 54 kJ.mol-1 |   RESULTS :   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **RESULT\_TEXT** | **Substance** | **Brodifacoum** | **Location** | **Irrigation scheme** | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | CHATEAUDUN | FOCUS | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | HAMBURG | No | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | JOKIOINEN | No | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | KREMSMUENSTER | No | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | OKEHAMPTON | No | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | PIACENZA | FOCUS | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | PORTO | FOCUS | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | SEVILLA | FOCUS | | Concentration closest to the 80th percentile (ug/L) | Brodifacoum | 0.000000 | THIVA | FOCUS |   According to the FOCUS modelling, the risk is acceptable in groundwater for the use of the biocidal product in waste dump. |

#### Primary & Secondary Poisoning Exposure Assessment

Non-target vertebrates may be exposed to rodenticides primarily through consumption of bait and secondarily from consumption of poisoned rodents and for predators eating earthworms which have ingested the active substance absorbed to soil. Small pellets and whole grain baits are highly attractive to birds.

**In and around buildings:**

**Primary Poisoning:**

Regarding the possible primary hazard to non-target animals this is assessed for birds and mammals.

**Acute:**

In the first tier scenario, PECoral is the concentration of the rodenticide in the food of a non-target organism. The PECoral is **50 mg/kg** (Brodifacoum present at 0.005% w/w in the product) and is used in the quantitative risk assessment for the acute and long-term situation.

In the second tier (refined) risk assessment the daily uptake (ETE) for birds and mammals is considered. This risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a a default excretion factor.

**Table‑1 Brodifacoum concentrations in non-target birds following a single uptake of the product**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Body weight**  **(g)** | **Daily food intake (FIR)**  **(g/d)a** | **Conc. of a.i. after single meal (mg/kg bw/d) (ETE)** | **Expected conc. after eliminationb (mg/kg bw/d) (EC)** |
| Tree sparrow | 22 | 7.6 | 17.27 | 12.43 |
| Chaffinch | 21.4 | 6.42 | 15.00 | 10.80 |
| Wood pigeon | 490 | 53.1 | 5.42 | 3.90 |
| Pheasant | 953 | 102.7 | 5.39 | 3.88 |
| Dog | 10 000 | 456d | 2.28 | 1.64 |
| Pig | 80 000 | 600e | 0.375 | 0.270 |
| Pig, young | 25 000 | 600e | 1.20 | 0.864 |

**Long-term**:

In the first tier scenario, the risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor.

**Expected concentration of Brodifacoum in the animal after one meal followed by a 24-hour elimination period**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Estimated daily uptake of a compound (ETE)**  **(mg/kg b.w./d)** | | **Fraction of daily uptake eliminated (number between 0 and 1) (EI)** | **Expected concentration of active substance in the animal (EC)**  **(mg/kg b.w./d)** | |
| **Step 1** | **Step 2** | **Step 1** | **Step 2** |
| Tree sparrow | 17.27 | 12.43 | 0.3 | 12.09 | 8.71 |
| Chaffinch | 15.00 | 10.80 | 0.3 | 10.50 | 7.56 |
| Wood pigeon | 5.42 | 3.90 | 0.3 | 3.79 | 2.73 |
| Pheasant | 5.39 | 3.88 | 0.3 | 3.77 | 2.72 |
| Dog | 2.28 | 1.64 | 0.3 | 1.596 | 1.149 |
| Pig | 0.375 | 0.270 | 0.3 | 0.2625 | 0.189 |
| Pig, young | 1.20 | 0.864 | 0.3 | 0.864 | 0.6048 |

In the second tier scenario for primary poisoning long-term exposure according to the guidance agreed at the 23rd Biocides CA meeting, EC5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

**ECoral for different relevant species**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Days** | **ECoral (mg/kg b.w./d)** | | | | | | |
| **Species** | **Tree sparrow** | **Chaffinch** | **Wood pigeon** | **Pheasant** | **Dog** | **Pig** | **Young pig** |
| Day 1 after first meal | 17.27 | 15.00 | 5.42 | 5.39 | 2.28 | 0.375 | 1.20 |
| Day 2 before new meal | 12.1 | 10.5 | 3.79 | 3.77 | 1.60 | 0.266 | 0.840 |
| Day 3 before new meal | 20.6 | 17.9 | 6.45 | 6.41 | 2.72 | 0.449 | 1.43 |
| Day 4 before new meal | 26.5 | 23.0 | 8.31 | 8.26 | 3.50 | 0.577 | 1.84 |
| Day 5 before new meal | 30.7 | 26.6 | 9.61 | 9.56 | 4.05 | 0.666 | 2.13 |

**Secondary Poisoning:**

Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Predators among mammals and birds may occur inside buildings or they may hunt in the immediate vicinity of buildings, e.g. parks and gardens. Scavengers may also search for food close to buildings.

**Tier 1 exposure assessment:**

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been set to a default value of 5-days, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation). Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted. The assessment also takes into account the concentration in resistant rodents.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Residues of rodenticide in target animal,**  **mg a.s./kg b.w. with bait consumption expressed as PD** | | | |
|  | | |
|  | **0.2** | **0.5** | **1.0** | |
| **A normal non-resistant target rodent stops eating on day 5** | | | | |
| Day 1 after the first meal\* | 1.00 | 2.50 | 5.00 | |
| Day 2 before new meal\*\* | 0.70 | 1.75 | 3.50 | |
| Day 3 before new meal | 1.19 | 2.97 | 5.95 | |
| Day 4 after the last meal | 1.53 | 3.83 | 7.66 | |
| Day 5\*\* | 1.77 | 4.43 | 8.86 | |
| Day 7 (mean time to death)\*\* | 1.36 | 3.39 | 6.79 | |
| **A target rodent continues eating due to resistance** | | | | |
| Day 14 after the meal | 2.31 | 5.79 | 11.58 | |

**Tier 2 Exposure Assessment:**

The refined tier 2 considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

**Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Normal susceptible rodents caught on day 5, before their last meal.** | | **Normal susceptible rodents caught on day 5 just after their last meal** | | **Resistant rodents caught on day 14 just after their last meal** | |
| **Species** |  | **Body weight \*)** | **Daily mean food intake\*)** | **Amount a.s. consumed by the non-target animal\*\*** | **Concentration in non-target animal** | **Amount a.s. consumed by the non-target animal\*\*\*** | **Concentration in non-target animal** | **Amount a.s. consumed by the non-target animals\*\*\*\*** | **Concentration in non-target animal** |
|  |  | **(g)** | **(g)** | **(mg)** | **(mg a.s./kg b.w.)** | **(mg)** | **(mg a.s./kg b.w.)** | **(mg)** | **(mg a.s./kg b.w.)** |
| Barn Owl | *Tyto alba* | 294 | 72.9 | 0.32 | 1.10 | 0.51 | 1.72 | 0.61 | 2.06 |
| Kestrel | *Falco tinnuncul.* | 209 | 78.7 | 0.35 | 1.68 | 0.55 | 2.62 | 0.65 | 3.13 |
| Little owl | *Athene noctua* | 164 | 46.4 | 0.21 | 1.26 | 0.32 | 1.97 | 0.39 | 2.35 |
| Tawny Owl | *Strix aluco* | 426 | 97.1 | 0.43 | 1.01 | 0.67 | 1.58 | 0.81 | 1.89 |
| Fox | *Vulpes vulpes* | 5 700 | 520.2 | 2.31 | 0.41 | 3.62 | 0.63 | 4.32 | 0.76 |
| Polecat | *Mustela putorius* | 689 | 130.9 | 0.58 | 0.85 | 0.91 | 1.32 | 1.09 | 1.58 |
| Stoat | *Mustela erminea* | 205 | 55.7 | 0.25 | 1.21 | 0.39 | 1.89 | 0.46 | 2.26 |
| Weasel | *Mustela nivalis* | 63 | 24.7 | 0.11 | 1.74 | 0.17 | 2.72 | 0.21 | 3.25 |

**Calculation of concentration in earthworms:**

Calculations for secondary poisoning are undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

**Brodifacoum concentrations in earthworms**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Tier 1a** | **Tier 2b** |
| **Input** | | | |
| Csoil sewer system | Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt) | 8.70 x 10-5 | 3.70 x 10-5 |
| Csoil building | Concentration in soil immediately after intake divided by 2 (mg/kg wwt) | 0.0056 | 0.0050 |
| BCFearthworm | Bioconcentration factor in earthworm (L/kg wet fish) | 15820 | 15820 |
| Cporewater sewer system | Concentration in porewater (mg/L) divided by 2 | 5.35 x 10-7 | 2.29 x 10-7 |
| Cporewater building | Concentration in porewater (mg/L) divided by 2 | 3.48 x 10-5 | 3.10 x 10-5 |
| Fgut | Fraction of gut loading in worm (kg dwt/kg wwt) | 0.1 | 0.1 |
| CONVsoil | Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt) | 1.13 | 1.13 |
| **Output** | | | |
| PECoral, earthworm building | Predicted environmental concentration in earthworm (mg/kg wet earthworm) | 0.495 | 0.441 |

#### Overall Summary of exposure assessment

The biocidal product is a ready-to-use bait containing 0.005% Brodifacoum as the active substance. Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It is used against rat at the maximal rate of 60 g of product equivalent to 3 mg a.s. per baiting post and against mouse at 20 g product equivalent to 1 mg a.s. by baiting post. This formulation is intended for indoor and outdoor uses.

PECs were calculated in accordance with the ESD for PT14. These calculations are outlined in the previous sections. Based on environmental fate and behaviour of Brodifacoum the following PEC values were determined:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **In and around buildings** | | **Sewer system** | | **Open Areas** | | **Waste Dumps** | |
|  | **Worst case** | **Realistic** | **Worst case** | **Realistic** | **Worst case** | **Realistic** | **Worst case** | **Realistic** |
| **PEC soil (mg/kg wwt)** | 0.047 | 0.006 |  |  | 0.173 | N/a | 0.00817 | 0.00204 |
| **PEC groundwater (mg/l)** | 5.3 x 10-5 | 6.62 x 10-6 |  |  | 1.96 x 10-4 | n/a | 9.26 x 10-6 | 2.31 x 10-6 |
| **PEC microorganisms (mg/l)** |  |  | 1.93 x 10-5 | 1.27 x 10-5 |  |  |  |  |
| **PEC surface water (mg/l)** |  |  | 1.77 x 10-6 | 1.18 x 10-6 |  |  |  |  |
| **PEC agricultural soil (mg/kg wwt)** |  |  | 4.86 x 10-4 | 3.24 x 10-4 |  |  |  |  |
| **PEC groundwater (ag) (mg/l)** |  |  | 4.66 x 10-7 | 3.11 x 10-7 |  |  |  |  |
| **PECsediment (mg/kg)** |  |  | 1.92 x 10-3 | 1.28 x 10-3 |  |  |  |  |

No new data related to the environment fate and behaviour or the ecotoxicology of the active substance or the biocidal product has been submitted by the applicant. There were three studies submitted related to secondary poisoning to dogs and foxes and the hazard/risk to barn owls which are considered only supplementary data and not considered further in the risk assessment.

PNECs were calculated based on the studies submitted for the EU approval of the active substance. PECS for assessment of primary and secondary poisoning were determined based on the ESD for PT14 and the TGD (2003).

### Risk Characterisation for the Environment

Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals.

Product containing brodifacoum are placed at secured bait points. To maximise exposure of the target rodents and minimise unintended exposure of other non-target vertebrates, the products are placed where they are most likely to be encountered by the target organisms (e.g. on habitual rat-runs).

The type of secured bait point suitable for a given situation is determined on a case-by-case basis, taking into account such factors as shielding from sunlight and moisture necessary to maintain bait integrity and the level of security required to prevent access to and/or interference by non-target animals etc.

The risks posed by products containing 50 mg Brodifacoum/kg are characterised for the following scenarios:

**In and around buildings (houses, animal houses, commercial and industrial sites)**

**Open areas**

**3Dumps**

#### Aquatic compartment

A contamination of surface water with Brodifacoum from the placing of product in and around buildings is highly unlikely. A lack of exposure to surface water is also stated in the EUBEES 2 emission scenario document. Contamination of surface waters is however expected to arise following use of bait in sewers.

The most sensitive organism in the aquatic tests was alga with a nominal 72 hr ErC50 of 0.04 mg/L. This **PNECwater** of 0.04/1000 AF**= 0.00004 mg/L**.

The test with micro-organisms in inhibition of microbial activity showed that concentrations that it is not likely that Brodifacoum will have a negative impact on the microbial processes in a sewage treatment plant at solubility limits. This gives a **PNECSTP** of **= 0.0058 mg/L.**

As no specific data are available, the toxicity of Brodifacoum to sediment-dwelling organisms is covered by the risk to aquatic compartment. The application of an additional factor of 10, as done in CAR A, is considered not necessary as an experimental log Kow = 4.92 (i.e. lower than 5) is available. **Therefore, the PNECsediment organisms = 0.00004 mg/l**.

The risk characterisation for the aquatic compartment is presented in the following table applying the relevant PEC values as indicated in the table in the overall summary of the exposure assessment in the previous section.

**Aquatic PEC/PNEC ratios using the realistic and worst case scenario**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Exposed compartment** | **Endpoint** | **PNEC mg/L** | **PEC**  **Worst case** | **PEC**  **Realistic** | **Risk quotient**  **PEC/PNEC** |
| Surface water | Algae | 0.00004 | 1.77E-06 | 1.18E-06 | 0.044 |
| Sediment | Based on aquatic data and equilibrium partitioning method | 4.348E-02 | 1.92E-03 | 1.28E-03 | 0.044 |
| STP | Inhibition of microbial activity | 0.0058 | 1.93E-05 | 1.27E-05 | 0.003 |

The PEC/PNEC risk quotient in all compartments are below the trigger value of 1 indicating Brodifacoum following the recommended use of the product does not cause an unacceptable risk to aquatic organisms.

Brodifacoum is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes. Accordingly, the degradation of Brodifacoum in sediment is also anticipated to be low. However, it has limited exposure to the aquatic compartment and this is confirmed by the PEC calculations. The PEC/PNEC ratio is below the level that leads to an unacceptable risk, thus the risk for unacceptable accumulation in sediment can be regarded as low.

For an indication of the risk in relation to surface water and groundwater/porewater used for drinking refer to the section on the aquatic compartment and groundwater in the exposure assessment.

Since the potential for metabolites formation is negligible, risk characterisation is not required.

**Summary: No risk is identified**

#### Atmospheric compartment

There are no releases of brodifacoum to air from manufacturing, formulating, use or disposal phases. Based on this and the physical and chemical properties of brodifacoum, the compound is not expected to contribute to global warming, ozone depletions in the stratosphere, or acidification.

**Summary: No risk is identified**

#### Terrestrial compartment

Exposure of the terrestrial compartment (soil) will also occur when product is deployed outdoors. Exposure is assumed to arise through a combination of transfer (direct release) and deposition via urine and faeces (disperse release) onto soil.

As there is only one test result available with soil dwelling organisms the risk assessment is performed on the basis of this result using an AF and on the basis of the equilibrium partition method. For the EPM the PNEC is calculated from the aquatic toxicity data **PNECaquatic**= **0.00004 mg/kg**.

**PEC/PNEC ratios using the realistic worst case scenario**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposed compartment** | **Endpoint** | **PNEC** | **PEC**  **Worst case** | **Risk quotient**  **PEC/PNEC**  **Worst case** |
| In and around buildings | Based on aquatic data and equilibrium partitioning method  Based on the availability of test result with soil dwelling organisms and AF | 1. 4.348 x E-02  2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg | 0.047 | 1. 1.08  2. 0.053 |
| Open areas | Based on aquatic data and equilibrium partitioning method  Based on the availability of test result with soil dwelling organisms and AF | 1. 4.348 x E-02  2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg | 0.173 | 1. 3.97  2. 0.196 |
| Waste dump | Based on aquatic data and equilibrium partitioning method  Based on the availability of test result with soil dwelling organisms and AF | 1. 4.348 x E-02  2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg | 0.00817 | 1. 1.87  2. 9.29 x 10-3 |

The PEC/PNEC ratio was greater than 1 when used **in and around buildings and in open areas** when applying the EPM indicating for this calculation method that Brodifacoum, following recommended use of the product, causes an unacceptable risk to organisms in this terrestrial compartment. However, this PNEC value based in and around buildings and in open areas **represents only a screening value** of contamination and is superseded by the PNEC value determined from the 14-day earthworm toxicity study.

**Summary: No risk is identified**

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

#### Primary poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (*cf.* ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, several non-target species are assessed for primary poisoning risk assessments.

**Acute exposure:**

Non-target mammals and birds are unlikely to enter sewers and feed on product in sewage systems. Therefore, there will be no significant exposure following the use of product in sewers. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. In conclusion, the risks to non-target mammals and birds following the use of bait containing Brodifacoum in sewers are considered to be very low.

Following applications in and around buildings, the empirical risk assumes direct or indirect consumption of the deployed baits. For primary poisoning the initial PECoral values assume that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the product.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The PECoral is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

**Tier I risk assessment: PECoral/PNECoral ratio for birds and mammals exposed to Brodifacoum**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECoral**  **(concentration in food, mg/kg)** | **PNECoral**  **(concentration in food, mg/kg)** | **PEC / PNEC** |
| **Acute** | | | |
| Bird | 50 | 19 | 2.63 |
| Mammal | 50 | - | - |
| **Long-term** | | | |
| Bird | 50 | 0.0004 | 125000 |
| Mammal | 50 | 0.000011 | 4545454 |

The ratios PEC/PNEC are above 1 indicating a potential risk.

Therefore, a refined tier 2 assessment is set out below, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

**Tier 2 acute risk assessment: PECoral/PNECoral for non-target animals accidentally exposed to bait containing Brodifacoum after one meal**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target animals** | **ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)** | | **PNECoral (dose, mg/kg b.w./d)** | **PEC/PNEC** | |
| **Step 1** | **Step 2** | **Step 1** | **Step 2** |
| Tree sparrow | 17.27 | 12.09 | 0.0004 | 43175 | 30225 |
| Chaffinch | 15.00 | 10.50 | 0.0004 | 37500 | 26250 |
| Wood pigeon | 5.42 | 3.79 | 0.0004 | 13550 | 9475 |
| Pheasant | 5.39 | 3.77 | 0.0004 | 13475 | 9425 |
| Dog | 2.28 | 1.596 | 0.000011 | 207272 | 159600 |
| Pig | 0.375 | 0.2625 | 0.000011 | 34090 | 26250 |
| Pig, young | 1.20 | 0.864 | 0.000011 | 109090 | 78545 |

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

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

**Long -term exposure:**

In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides.

**Tier 2 long-term risk assessment: ECoral/PNECoral ratio after 1-day elimination of Brodifacoum**

******

The ratios PEC/PNEC are above 1 indicating a potential risk.

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

**Tier 2 long-term risk assessment: ECoral/PNECoral ratio after 5-day elimination**



The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

**Summary: Risk is identified**

Overall, for primary poisoning all acute and long-term PECoral/PNECoral ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

#### Secondary poisoning

It is unlikely that target rodents that have ingested bait containing Brodifacoum will leave the sewer system and be exposed, in significant numbers, to predators or scavengers. Therefore, the secondary poisoning risks from the use of bait in sewers are considered to be very low.

For the first tier assessment of secondary poisoning in and around buildings the maximum residue levels in target rodents that arise on day-5 after the last meal (ETEoral predator) are compared to the PNEC values for concentration in food. The first tier assessment also assumes the following three levels of Brodifacoum bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide and that the non-target animals consume 50% of their daily intake on poisoned rodents.

**Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Organism group** | **PNECoral**  **(mg a.s./kg b.w.)** | **ETEoral, predator**  **(mg a.s./kg b.w.)** | | | **PECoral/PNECoral – day 5** | | |
| PD values |  | 0.2 | 0.5 | 1.0 | 0.2 | 0.5 | 1.0 |
| **Acute** | | | | | | | |
| Birds | 19 | 2.77 | 6.93 | 13.87 | 3.84 | 9.62 | 19.26 |
| Mammals | - | - | - | - |
| **Long-term** | | | | | | | |
| Birds | 0.0004 | 1.39 | 3.47 | 6.93 | 10692 | 26692 | 53307 |
| Mammals | 0.000011 | 6261 | 15630 | 31216 |

**Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Organism group** | **PNECoral**  **(mg a.s./kg b.w.)** | **ETEoral, predator**  **(mg a.s./kg b.w.)** | | | **PECoral/PNECoral – day 14** | | |
| PD values | - | 0.2 | 0.5 | 1.0 | 0.2 | 0.5 | 1.0 |
| **Acute** | | | | | | | |
| Birds | 19 | 2.31 | 5.79 | 11.58 | 0.121 | 0.30 | 0.60 |
| Mammals | - | - | - | - |
| **Long-term** | | | | | | | |
| Birds | 0.0004 | 1.15 | 2.31 | 5.79 | 287 | 5775 | 14475 |
| Mammals | 0.000011 | 104545 | 231000 | 526363 |

According to the tier 1 assessment the risk for secondary poisoning of non-target predator birds and mammals during long-term exposure via rodents poisoned with Brodifacoum is very high as indicated by the trigger value of 1 being exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

**Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)**

| **Species** | **Exposure** | **ETE oral predators**  **(mg a.s./kg/d)** | **PNECoral**  **(mg a.s./kg/d)** | **Ratio ETE oral predators / PNECoral** |
| --- | --- | --- | --- | --- |
| Barn owl | Day 5 before the last meal | 1.10 | 0.0004 | 2750 |
| Day 5 after the last meal | 1.72 | 4300 |
| Day 14 after the last meal | 2.06 | 5150 |
| Kestrel | Day 5 before the last meal | 1.68 | 0.0004 | 4200 |
| Day 5 after the last meal | 2.62 | 6550 |
| Day 14 after the last meal | 3.13 | 7825 |
| Little owl | Day 5 before the last meal | 1.26 | 0.0004 | 3150 |
| Day 5 after the last meal | 1.97 | 4925 |
| Day 14 after the last meal | 2.35 | 5875 |
| Tawny owl | Day 5 before the last meal | 1.01 | 0.0004 | 2525 |
| Day 5 after the last meal | 1.58 | 3950 |
| Day 14 after the last meal | 1.89 | 4725 |
| Fox | Day 5 before the last meal | 0.41 | 0.000011 | 41000 |
| Day 5 after the last meal | 0.63 | 63000 |
| Day 14 after the last meal | 0.76 | 76000 |
| Polecat | Day 5 before the last meal | 0.85 | 0.000011 | 77272 |
| Day 5 after the last meal | 1.32 | 132000 |
| Day 14 after the last meal | 1.58 | 143636 |
| Stoat | Day 5 before the last meal | 1.21 | 0.000011 | 121000 |
| Day 5 after the last meal | 1.89 | 189000 |
| Day 14 after the last meal | 2.26 | 226000 |
| Weasel | Day 5 before the last meal | 1.74 | 0.000011 | 174000 |
| Day 5 after the last meal | 2.72 | 272000 |
| Day 14 after the last meal | 3.25 | 325000 |

**Summary: Risk is identified**

The ratios PEC/PNEC are all above 1 indicating a potential risk even after refinement.

#### Secondary poisoning via the terrestrial food chain

Emissions of brodifacoum to soil take place in two scenarios. In the scenario **in and around buildings** the uptake to soil proceeds directly (when considering outdoor applications as proposed in the ESD PT 14), whereas in the scenario for the **sewer** is not applicable in this PAR.

However, the TGD gives advice to take the 180 days averaged PEClocal for soil with respect to sewage sludge when calculating the PEC in earthworms. Hence, the mode of application given in the TGD is in fact not applicable for direct intake of substances.

In the product dossier PECoral,earthworm for the direct soil intake has been calculated. The applicant advises that these figures be interpreted with care as concentrations in earthworm due to direct soil intake are not dealt with in the TGD. Soil concentrations used for the calculation represent a brodifacoum intake within a soil mixing depth of just 10 cm. Degradation has not been considered. Soil concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm to origin from the contaminated area.

**Table‑2: Secondary poisoning risk to earthworm-eating birds and mammals**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **PECoral,earthworm (mg/kg wet earthworm)** | | **PNEC (mg/kg food)** | **PEC/PNEC** | |
| **Tier 1a** | **Tier 2b** | **Tier 1a** | **Tier 2b** |
| **Birds** | | | | | |
| Sewer system | N/a | N/a | 4.0 x 10-4 | N/a | N/a |
| In and around buildings | 0.495 | 0.441 | 1237 | 1102 |
| **Mammals** | | | | | |
| Sewer system | N/a | N/a | 2.22 x 10-4 | N/a | N/a |
| In and around buildings | 0.495 | 0.441 | 2229 | 2004 |

a Product specific application data and default value for release (90% direct +indirect release)

b Product specific application data and refined metabolism

**Summary: Risk is identified but is likely to have been overestimated**

The results for the **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

#### Overall Summary

Based on toxicity data Brodifacoum presents a hazard to birds and non-target mammals. Non-target vertebrate animals may be exposed to the product containing Brodifacoum, either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain Brodifacoum residues (secondary poisoning). Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals. There are many uncertainties associated with quantification of the risk associated with the use of Brodifacoum products. Overall, because of the toxic nature of rodenticides and the over-riding public health requirement it is more appropriate to develop and validate risk management measures than to refine the risk assessment procedures further. It is noted that the product contains a bittering agent and this may deter some non-target animals. It is also noted that the attractiveness of the product may be impacted by the use of dye.

##### Primary poisoning:

Overall, all acute and long-term PECoral/PNECoral ratios are above the trigger value of 1 indicating acute and long-term unacceptable risks. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals.

###### Secondary poisoning:

**Via ingestion of target rodents by non-target vertebrates**

All ratios of PECoral/PNECoral are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals. Studies are submitted in the product dossier that indicate that the realistic risk for secondary poisoning is significantly lower than that using the PEC/PNEC approach. These studies are only considered as supplementary information.

**Via the aquatic food chain**

Only one of the proposed four use scenarios, namely use in sewers, will lead to exposure of surface water. It is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded it potentially is overestimated.

**Via the terrestrial food chain**

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

##### Conclusion for primary and secondary poisoning:

Due to the risk assessment results for primary and secondary poisoning and the uncertainty associated with quantification of this risk, risk mitigation measures must be taken into account to lead to an acceptable use of the rodenticide product.

##### The following risk mitigation measures are proposed to mitigate the primary and secondary poisoning risk to non-target mammals and lead to an acceptable use of this rodenticide:

* Use of an integrated management strategy and precautionary systems
* Unless under the supervision of a pest control operator use or other competent person do not use anticoagulants as permanent baits
* There should be proper and secure placing of baits so as to minimise the risk of consumption by other animals or children. Where possible secure baits so they cannot be dragged away.
* Users should select tamper-resistant bait boxes, secured bait boxes, covered applications or burrow baiting (placing of bait in appropriate containers or under a curved tile or in a piece of tube) to minimize exposure of non-target animals
* Monitor and replenish bait stations as appropriate
* Frequent visits to bait stations to ensure that any bait that is split or dragged out of bait stations is removed
* Unconsumed baits must be collected after termination of the control campaign and dispose of them in accordance with local requirements
* Remove dead and moribund rodents at frequent intervals, at least as often as baits are checked or replenished during a baiting campaign
* Baits should be deployed in accordance with the product labelling
* Baits should be deployed in accordance with other approved guidance on good practice.
* Restrict the use of the product to treatment campaigns of limited duration
* To minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides, long-term deployment of baits as a preventative control measure is not recommended
* The resistance status of the population should be taken into account when considering the choice of rodenticide to be used.
* When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary and secondary poisoning by the anticoagulant as well as indicating the first measure to be taken in case of poisoning must be made available alongside the baits
* **Major change and renewal applications for ULTIMA PASTE - 2017**

No new ecotoxicological information has been submitted at the renewal of the approval of the active substance brodifacoum and in the product dossier. In the first authorization of the product, based on the assessment of the product SAPHIR PASTE performed by IE, the active substance content assessed was 0.005% w/w of brodifacoum. For the renewal, the applicant claimed an active substance content of 0.0025% w/w of brodifacoum. Regarding this new information, the renewal assessment is covered by the assessment performed by IE and presented here below. Therefore, the conclusion of the environmental risk assessment remains unchanged.

No studies were conducted with the product ULTIMA PASTE for the environment part; therefore the environmental risk assessment has been carried out with data from the combined CAR of brodifacoum. The environmental risk is considered as acceptable for the intended uses except for the primary and secondary poisoning. The specific use restriction must be applied to reduce the risk for primary and secondary poisoning. They are detailed in the SPC

## Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 is provided below.

## Methods and precautions concerning handling, use, storage, transport or fire

**Methods and precautions concerning handling and use:**

* Always read the label before use and follow the instructions provided.
* Do not decant product into unlabelled containers.
* Product must be handled in a safe manner.
* Avoid all unnecessary exposure, in particular avoid ingestion.
* A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
* Baits must be securely deposited in baiting stations or other coverings so as to minimise the risk of consumption by companion animals, other non-target animals and children. Where possible, secure baits so that they cannot be dragged away.
* PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. When the product is being used in public areas, the areas treated must 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. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
* Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
* It is illegal to use this product for the intentional poisoning of non-target, beneficial and protected animals.
* Wash hands and face after application and use of the product, and before eating, drinking or smoking.
* For professional users the use of appropriate personal protective equipment (PPE) is advised.

***Methods and precautions concerning storage:***

* Store in a cool, dry, well-ventilated secure (lockable) place
* Store locked up in the original container
* Store original container tightly closed
* Keep/store out of reach of children and companion animals
* Keep/store away from food, drink and animal feedstuffs and products which may have an odour.

**Methods and precautions concerning transport:**

Hazard classification for transport: TOXIC, MARINE POLLUTANT

UN-No Coumarin derivative pesticide, solid, toxic, n.o.s (BRODIFACOUM)

Class 6.1 Hazard ID 66

Proper Shipping name Coumarin derivative pesticide, solid, toxic (contains brodifacoum)

UN-No 3027 Packing Group 1

Class 6.1

***Methods and precautions concerning fire:***

**Suitable Extinguishing Media:**

Keep fire exposed containers cool by spraying with water if exposed to fire. Fight surrounding fire with foam, water fog, or dry powder.

**Extinguishing media which must not be used for safety reasons:**

DO NOT USE WATER JETS

**Specific hazards:**

This product is not flammable but is combustible. Avoid run-off into water courses. Self-contained breathing apparatus should be won by fire-fighting personnel.

**Special protective equipment for fire-fighters:**

In the event of fire, wear self contained breathing apparatus, a chemical protection suit, suitable gloves and boots.

**Residues:**

Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.

## Specific precautions and treatment in case of an accident

**Personal precautions**

Wear suitable protective clothing, gloves and eye/face protection, if applicable and where appropriate.

* Respiratory Protection: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.
* Hand protection: Wear gloves for professional products.
* Skin protection: No special clothing/skin protection equipment is recommended under normal conditions of use.
* Eye protection: Not required.
* Ingestion: When using this product, do not eat, drink or smoke

**Personal treatment**

* General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible and report the authorisation number).
* Skin contact: Obtain medical advice immediately. Remove contaminated clothing. After contact with skin, wash immediately with plenty of water, followed by soap and water in order to minimise skin contact.
* Contaminated clothing should be washed and dried before re-use.
* Eye contact: Obtain medical advice immediately. Rinse eyes immediately with copious amounts of water.
* Inhalation: Unlikely to present an inhalation hazard unless excessive dust is present. Remove person to fresh air. Obtain medical advice immediately.
* Ingestion: Do no induce vomiting. If swallowed, obtain medical advice immediately. Wash out mouth with water.

**ADVICE FOR DOCTORS:**

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume reatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre; include information on the product authorisation number, product trade name and active substance. In Ireland, this is the National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166)

**Environmental precautions**

* Prevent accidental exposure of the product to the environment.
* Keep un-used bait locked-up and in secure storage containers
* Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms.

**Environmental treatment**

* Clean up accidental spillages promptly by sweeping or vacuum.
* If the product gets into water or soil, it should be removed mechanically. In the event of a significant accidental release, inform the appropriate authority.
* Transfer to a suitably labelled container and dispose of to a certified waste disposal operator for incineration and licensed waste disposal site.
* Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.
* For further instructions, see section 3.4.6 below.

## Procedures for cleaning application equipment

No application equipment is required, therefore, no specific cleaning for equipment is required

If necessary, following use, bait boxes should be washed with detergent and water. The bait box should be washed out 3 times (triple rinsed).

## Identity of relevant combustion products in cases of fire

This product contains paraffin wax.

## Procedures for waste management of the biocidal product and its packaging

The best means of disposal of any product is through proper use according to the label. For the product incinerate under controlled conditions. For the pack, do not dispose of the pack in domestic refuse. Empty completely, puncture or crush and dispose of safely to Local Authority and National requirements. Dispose of packaging, remains of unused product and dead rodents to a certified waste disposal operator for incineration and licensed waste disposal site.

## Possibility of destruction or decontamination following accidental release

**Air:**

Brodifacoum has a low vapour pressure, therefore the potential for evaporation is low The vapour pressure is 5 x 10-5 Pa. As a rodenticide, this material is not intentionally aerosolised. Therefore, destruction in air is not a concern.

**Water (including drinking water):**

Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.

**Soil:**

Direct and/or intentional release to soil is not anticipated for the use of the product as a rodenticide. In the event of a significant accidental release, inform the appropriate authority.

## Undesirable or unintended side-effects

Toxic to mammalian and avian species, including domesticated animals, wildlife and humans. Therefore the risk to these non-target species should be considered when using bait.

## Poison control measures

The paste baits are dyed (e.g. red or blue) to make them unattractive to wildlife, and birds in particular. In addition, in case of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

The product contains a human taste deterrent (adversive agent – Bitrex).

To report human poisoning incidents call the relevant national poison information centre. Include information on the product authorisation number, product trade name and active substance. Where possible provide a copy of the label or safety data sheet (SDS).

In Ireland to report a poisoning incident, call: 01 (8092566 / 8379964) The Poisons Information Centre of Ireland, Beaumont Hospital, Beaumont Road, Dublin 9.

**ADVICE FOR DOCTORS:**

Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume reatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre (include information on the product authorisation number, product trade name and active substance)

* **Major change and renewal applications for ULTIMA PASTE - 2018**

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

# Proposal for Decision – major change and renewal - 2017

**1 Administrative information**

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

| **Trade name(s)** | ULTIMA PASTE |
| --- | --- |
|  | BRODIFACOUM PASTA  BRODIGRAIN PASTA  PASTE BR 25  PATE BRODIF 25 |

**1.2. Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | Name | LODI S.A.S |
| Address | Parc d’activités des Quatre Routes  Grand-Fougeray  35390  France |
| **Authorisation number** | BC-NA000642-67 | |
|  | Major change and renewal oft he national autorisation | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | LODI SAS |
| **Address of manufacturer** | - Parc d’activités des Quatre Routes  - Parc d’activités du Pays du Grand Fougeray Espace Nord 24 et 26 rue des Pionniers  Grand-Fougeray  35390  France |
| **Location of manufacturing sites** | Parc d’activités des Quatre Routes  Grand-Fougeray  35390  France |

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

|  |  |
| --- | --- |
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | PELGAR Ltd |
| **Address of manufacturer** | Unit 13, Newmann Lane Industrial Estate Alton  GU34 2 QR  Ampshire  United Kingdom |
| **Location of manufacturing sites** | Prazska 280 02 Kolin  Czech Republic |

**2. Product composition and formulation**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Brodifacoum  (pure) | 3-[3-(4'-bromobiphenyl- 4-yl)-1,2,3,4-tetrahydro -1-napthyl]-4-hydroxycoumarin | Active substance | 56073-10-0 | 259-980-5 | 0.0025 |

**2.2. Type of formulation**

|  |
| --- |
| RB-(bait ready for use)-PASTA |

**3. Hazard and precautionary statements according to Regulation (EC) 1272/2008**

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | |
| Hazard category | STOT RE 2 |
| Hazard statements | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
| Labelling |  |
| Signal words | Warning |
| Hazard statements | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
| Precautionnary statements | P260: Do not breathe dust/fumes/gas/mist/vapours/spray  P314: Get medical advice/attention if you feel unwell  P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation (to be specified)]. |
| Note | - |

**4. Authorised use(s)**

**4.1. Use description**

**Table 3. 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[[11]](#footnote-11)  - *[Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Rats  - High infestation: 100 g of bait per baiting point every 5 meters  - Low infestation: 100 g of bait per baiting point every 10 meters  Mice:  - High infestation: 10 g of bait per baiting point every 3 meters  - Low infestation: 10 g of bait per baiting point every 5 meters |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper:10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC) in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg   Cartridge in PE: 50, 100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg) |

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

|  |
| --- |
| - Remove the remaining product at the end of treatment period.  - *[*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***

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

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

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

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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:  Rats  - High infestation: 100 g of bait per baiting point every 5 meters  - Low infestation:100 g of bait per baiting point every 10 meters  Mice:  - High infestation: 10 g of bait per baiting point every 3 meters  - Low infestation: 10 g of bait per baiting point every 5 meters |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper 10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC) in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg   Cartridge in PE: 50,100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg) |

***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.  - 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 use this product in the burrow. |

***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***

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

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

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

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**4.3. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) – in open areas only  *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat) |
| **Field(s) of use** | Outdoor open areas  Outdoor waste dumps |
| **Application method(s)** | - Ready-to-use bait to be used in tamper-resistant bait stations.  *- [Covered and protected baiting points]* |
| **Application rate(s) and frequency** | Bait products:  Rats  - High infestation: 100 g of bait per baiting point every 5 meters  - Low infestation: 100 g of bait per baiting point every 10 meters  Mice:  - High infestation: 10 g of bait per baiting point every 3 meters  - Low infestation: 10 g of bait per baiting point every 5 meters |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC) in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg   Cartridge in PE: 50,100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg.  (In France only : minimum pack size of 5 kg) |

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

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

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

|  |
| --- |
| - Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.  - To reduce risk of secondary poisoning, search for and remove dead rodents during treatmentat frequent intervals*,* in line with the recommendations provided by the relevant code of best practice.  - Do not use this product in the burrow. |

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

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

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

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

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**4.4. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait to be used in tamper-resistant bait stations[[12]](#footnote-12) |
| **Application rate(s) and frequency** | 10 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 to 5 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper:10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC)   in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg  Cartridge in PE: 50,100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg. |

***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.  - Follow any additional instructions provided by the relevant code of best practice. |

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

|  |
| --- |
|  |

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

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

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

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

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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** | 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper 10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC) in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg   Cartridge in PE: 50,100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg*.* |

***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: 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters.  Mice: 10 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 to 5 meters. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | ULTIMA PASTE is packed in individual tea sachet paper: 10 g and cartridge in PE (50-500 g).  Individual sachets are packed in   * Bucket: (PP,PE): 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Cardboard box with inner PE liner: 3 kg, 3.5 kg, 4 kg, 4.5 kg, 5 kg, 5.5 kg, 6 kg, 6.5 kg, 7 kg, 7.5 kg, 8 kg, 8.5 kg, 9 kg, 9.5 kg, 10 kg * Pre-baited station (PP,PS,PVC) in cardboard box with inner PE liner of 3 kg, 3.5 kg, 4 kg, 4.5 kg and 5 kg   Cartridge in PE: 50,100 g, 150 g, 200 g, 250 g, 260g , 270 g, 280 g, 310 g, 500 g  Minimum pack size of 3 kg. |

***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***

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| --- |
| - 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. |

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

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

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**4.7. Use description-General public**

**Table74. Use # 7 – House mice – general public – indoor**

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Mus musculus* (house mice) |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations. |
| **Application rate(s) and frequency** | Bait products:  - 10 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 3 to 5 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | ULTIMA PASTE is supplied in 10 g sachets (tea paper sachet).   * in prefilled bait station (PVC, PP, or PS) - secondary packaging: carton sleeve of 20, 30, 40, 50, 60, 70, 80, 90, 100, 110 120, 130, 140 and 150 g * in cardboard box: 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g. * in plastic can (PE or PP) : 20, 30,40, 50, 60, 70, 80, 90, 100, 110 g, 120, 130, 140 and 150 g. * in metal box : 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g.   Maximum pack size: 150 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. |

***4.71.2 Use-specific risk mitigation measures***

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

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

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

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**4.8. Use description**

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

|  |  |
| --- | --- |
| **Product Type** | 14 |
| **Where relevant, an exact description of the authorised use** | Not relevant for rodenticides |
| **Target organism(s) (including development stage)** | *Rattus norvegicus* (brown rat)  *Rattus rattus* (black or roof rat)) |
| **Field(s) of use** | Indoor. |
| **Application method(s)** | Ready-to-use bait *[in sachets for loose bait]* to be used in tamper-resistant bait stations |
| **Application rate(s) and frequency** | Bait products:  100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | ULTIMA PASTE is supplied in 10 g sachets (tea paper sachet).   * in prefilled bait station (PVC, PP, or PS) - secondary packaging: carton sleeve of 20, 30, 40, 50, 60, 70, 80, 90, 100, 110 120, 130, 140 and 150 g * in cardboard box: 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g. * in plastic can (PE or PP) : 20, 30,40, 50, 60, 70, 80, 90, 100, 110 g, 120, 130, 140 and 150 g. * in metal box : 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g.   Maximum pack size of 150 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***

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

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

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

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**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 stations. |
| **Application rate(s) and frequency** | Bait products:  100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 to 10 meters. |
| **Category(ies) of users** | General public |
| **Pack sizes and packaging material** | ULTIMA PASTE is supplied in 10 g sachets (tea paper sachet).   * in prefilled bait station (PVC, PP, or PS) - secondary packaging: carton sleeve of 20, 30, 40, 50, 60, 70, 80, 90, 100, 110 120, 130, 140 and 150.g * in cardboard box: 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g. * in plastic can (PE or PP) : 20, 30,40, 50, 60, 70, 80, 90, 100, 110 g, 120, 130, 140 and 150 g. * in metal box : 20, 30,40, 50, 60, 70, 80, 90,100, 110 g, 120, 130, 140 and 150 g.   Maximum pack size of 150 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 use6**

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| **TRAINED PROFESSIONAL and PROFESSIONNAL 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.  Do not open the sachets containing the bait.  Do not deteriorate the cartridge containing the bait.  **NON PROFESSIONNAL 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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| **TRAINED PROFESSIONAL and PROFESSIONNAL 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.  **NON PROFESSIONNAL USERS**   * Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion. * Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity). * The product information (i.e. label and/or leaflet) shall clearly show that: * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations"). * Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service. * Search for and remove dead rodents during treatment, at least as often as bait stations are inspected. * Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*. |

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

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

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

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

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

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| * Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight. * Store in places prevented from the access of children, birds, pets and farm animals. * Shelf life: 2 years |

**6. Other information**

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| * 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. * Provide the long term stability study report within 1 year post authorisation * **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. |

# Annex

Annex 1: List of studies for the biocidal product submitted for the major change and renewal

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| **Sections** | **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)** |
| 3.4.1 / Accelerated storage test (14 days at 54°C ±2°C) | Théo Picardat | 2017 | Chemical satbility of brodifacoum paste bait 25ppm after accelerated storage  LODI SAS – LODI.13/2017 | YES | LODI SAS |
| 3.4.1 / Chemical stability after storage at 20°C\_6 months | Théo Picardat | 2017 | Interim report A\_Chemical stability of brodifacoum paste bait 25ppm after one year of storage at 20°C ±2°C.  LODI SAS – LODI.14/2017 | YES | LODI SAS |
| 5/ Brodifacoum in 25ppm brodifacoum paste bait | Théo Picardat | 2017 | Validation of the analytical method fo the determination of brodifacoum in brodifacoum paste bait 25ppm  LODI SAS – LODI.10/2017 | YES | LODI SAS |
| 6.7/01\_Laboratory\_Mice\_Fresh bait | XXX | 2017 | Palatability and efficacy study of a paste bait containing 25mg/kg Brodifacoum in House Mouse (Mus Musculus)  XXX | YES | LODI SAS |
| 6.7/02\_Laboratory\_Rats\_Fresh bait | XXX | 2017 | Palatability and efficacy study of a paste bait containing 25mg/kg Brodifacoum in Brown Rat (rattus norvegicus) xxx | YES | LODI SAS |
| 6.7/03\_Field\_Mice | XXX | 2017 | Evaluation of the efficacy of a paste rodenticide containing 25mg/Kg brodifacoum for the control of house mouse infestations in Buildings.  XXX | YES | LODI SAS |
| 6.7/04\_Field\_Rats | XXX | 2017 | Evaluation of the efficacy of a paste rodenticide containing 25mg/Kg Brodifacoum for the control of brown rat infestations in and around buildings.  XXX | YES | LODI SAS |
| 6.7/05\_Field\_Black Rats | XXX | 2017 | Evaluation of the efficacy of a paste rodenticide containing 25 mg/kg Brodifacoum for the control of Black Rat infestations in and around agricultural buildings.  XXX | YES | LODI SAS |
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Annex 2: Analytical methods residues – active substance

Na

Annex 3: Toxicology and metabolism –active substance

Na

Annex 4: Toxicology – biocidal product

Na

Annex 5: Safety for professional operators

Na

Annex 6: Safety for non-professional operators and the general public

Na

Annex 7: Residue behaviour

Na

**Annex 8a: Experimental data on the effectiveness of Saphir Paste containing 40 mg/kg brodifacoum (initial PAR 2011)**

| **Test organisms** | **Test system / Concentrations applied / exposure time** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference** |
| --- | --- | --- | --- | --- |
| Norway rats (*Rattus norvegicus* Berkenhout).  10 wild animals.  House mice (*Mus musculus* L.).  10 wild animals.  Albino laboratory Norway rats (*Rattus norvegicus*)  22 animals (11 males and 11 females, 10 to 20 weeks old, including one control pair). | Laboratory test.  Choice feeding test: fresh baits.  5-day pre-test control diet intake assessment and 21-day bait feeding period.  During the test period, rats and mice received the test item from two symmetrically-placed food pots, one filled with the test product, the other with the challenge diet. The positions of the pots were alternated daily. The contents of the food pots were made up daily to provide an excess of the animals’ daily requirement from each pot (about 40 g of ground wheat grains and 45 g of the test item per day for rat and about 10 g of ground wheat grains and 15 g of the test item per day for mice)  Brodipasta, equivalent to Saphir Paste, freshly manufactured | The animals were individually caged.  The wild animals were acclimatised to test conditions for at least 3 weeks in order to discard pregnant females or sick individuals.  The laboratory rats were acclimatised to test conditions for at least 5 days.  Normal laboratory requirements. | The mean acceptance of the test item was 38.7% (s.d. 28.4%) for wild Norway rats, 43.4% (s.d. 9.5%) for wild house mice and 43.8% (s.d. 18.9%) for albino Norway rats.  The efficacy was excellent. Mortality was total (100%) in all test groups after a 21-day choice between this test substance and the challenge diet.  The mean time to death ranged from 3 to 19 days after the first intake of treated baits. | B5.10/01 |
| Albino laboratory Norway rats (*Rattus norvegicus*)  22 animals (11 males and 11 females, 10 to 20 weeks old, including one control pair) for each test group.  Laboratory House mice (*Mus musculus*)  22 animals (11 males and 11 females, including one control pair) for each test group. | Laboratory test.  Choice feeding test: fresh and aged baits.  5-day pre-test control diet intake assessment and 21-day bait feeding period.  During the test period, rats and mice received the test item from two symmetrically-placed food pots, one filled with the test product, the other with the challenge diet. The positions of the pots were alternated daily. The contents of the food pots were made up daily to provide an excess of the animals’ daily requirement from each pot (about 30 g of ground wheat grains, in competition with the test item)  Brodipasta, equivalent to Saphir Paste, stored at 20°C for respectively 6, 12 and 24 months | The animals were individually caged.  The laboratory rodents were acclimatised to test conditions for 8 days.  Normal laboratory requirements. | For rats, the mean acceptance of the test item was 43.8% (s.d. 18.9%) for the fresh bait, 42.0% (s.d. 16.2%) for the 6-month aged bait, 33.7% (s.d. 13.0%) for the 12-month aged bait and 37.5% (s.d. 15.9%) for the 24-month aged bait.  For mice, the mean acceptance of the test item was 46.9% (s.d. 15.1%) for the 12-month aged bait and 36.0% (s.d. 14.2%) for the 24-month aged bait.  The efficacy was excellent. Mortality was total (100%) in all test groups after a 21-day choice between this test substance and the challenge diet.  The mean time to death ranged from 3 to 20 days after the first intake of treated baits. | B5.10/02 |
| Norway rat (*Rattus norvegicus*).  20 animals (10 males, 10 females) | Laboratory test.  Choice feeding test: fresh baits.  4-day pre-test control diet intake assessment, 4-day bait feeding period and 15-day control bait period.  Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet) during the pre-test period. During the 4-day test period, the quantity of food placed in each pot was sufficient to meet each animal’s daily needs (approximately 50 g of aged rodenticide paste bait and approximately 50 g of challenged diet, in each corresponding pot)  Brodifacoum paste bait, similar to Saphir Paste, aged for 3 weeks at 54°C | The animals were individually caged.  Normal laboratory requirements: 20 - 24°C, a relative humidity range of 45% to 65%, with between 15 and 20 air changes per hour, and with a 12-hour light-dark cycle | The mean acceptance of the test item during the whole test period (from day 7 to day 10) was 48.9% (s.d. 9.89%).  The efficacy was excellent. Mortality was total (100%) in all test groups after a 4-day choice between this test substance and the challenge diet.  The mean time to death was 4.7 days (3 to 7 days) after the first intake of treated baits. | B5.10/03 |
| House mouse (*Mus musculus*).  20 animals (10 males, 10 females) | Laboratory test.  Choice feeding test: fresh baits.  4-day pre-test control diet intake assessment, 4-day bait feeding period and 15-day control bait period.  Unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet) during the pre-test period. During the 4-day test period, the quantity of food placed in each pot was sufficient to meet each animal’s daily needs (approximately 10 g of aged rodenticide paste bait and approximately 20 g of challenged diet in each corresponding pot)  Brodifacoum paste bait, similar to Saphir Paste, aged for 3 weeks at 54°C | The animals were individually caged.  Normal laboratory requirements: 20 - 24°C, a relative humidity range of 45% to 65%, with between 15 and 20 air changes per hour, and with a 12-hour light-dark cycle | The mean acceptance of the test item during the whole test period (from day 7 to day 10) was 48.8% (s.d. 10.2%).  The efficacy was excellent. Mortality was total (100%) in all test groups after a 4-day choice between this test substance and the challenge diet.  The mean time to death was 5.8 days (4 to 7 days) after the first intake of treated baits. | B5.10/04 |
| Wild Norway Rats (*Rattus norvegicus*).  At least 41 animals estimated by pre-treatment bait census | Field test carried out in a farm raising cows.  After a pre-bait until the rats were feeding readily on the bait (25 days), baiting were carried out. The non-poisoned baits were replaced by the product to be tested for 10 days. At each day's treatment, the bait stations were emptied then refilled. Post-baiting (8 days) is done to assess the level of the survival rodent population.  The quantity of food placed in each bait station was sufficient to meet each animal’s daily needs (approximately 150 g of bait in each bait station).  Brodifacoum paste 0.004%, equivalent to Saphir Paste | Natural conditions. | The efficacy measured was 95.18%.  Dead rodents found during and after the baiting and the post-baiting phases were only *Rattus norvegicus.*  The field assay showed a very good efficacy with a fast decrease of the population. | B5.10/05 |
| Wild house mouse (*Mus musculus*)  At least 72 animals estimated by pre-treatment bait census | Field test carried out in a farm.  After a pre-bait until the mice were feeding readily on the bait (31 days), baiting were carried out. The non-poisoned baits were replaced by the product to be tested for 8 days. At each day's treatment, the bait stations were emptied then refilled. Post-baiting (7 days) is done to assess the level of the survival rodent population.  The quantity of food placed in each bait station was sufficient to meet each animal’s daily needs (approximately 30 g of bait in each bait station).  Brodifacoum paste 0.004%, equivalent to Saphir Paste | Natural conditions. | The efficacy measured was 89.9%.  Dead rodents found during and after the baiting and the post-baiting phases were only *Mus musculus.*  The field assay showed a very good efficacy with a fast decrease of the population. | B5.10/06 |

**Annex 8b: Efficacy data submitted in the frame of major change of ULTIMA PASTE (0.0025 % brodifacoum)**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Rodenticide | Indoor, outdoor | ULTIMA PASTE (25 ppm brodifacoum) fresh bait | House mice  *Mus musculus*  5 males  5 females | Laboratory test | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given:  - 10 g per animal of challenge diet (non-poisoned source) for the assessment of palatability,  - 10 g per animal of biocidal product during 4 consecutive days with daily consumption measurements.  Mortality was observed during 4 days every 24 hours. | Palatability = 57 %  Mortality = 100 %  in a period from day 5 to day 8  R.I= 1 | xxx |
| Rodenticide | Indoor, outdoor | ULTIMA PASTE (25 ppm brodifacoum) fresh bait | Brown rat  *Rattus norvegicus*  10 males  10 females | Laboratory test | Acclimatization: 4 days in individual cage at room temperature.  Day 0: reference food and bait biocidal product have been given:  - 10 g per animal of challenge diet (non-poisoned source) for the assessment of palatability,  - 10 g per animal of biocidal product during 4 consecutive days with daily consumption measurements.  Mortality was observed during 8 days every 24 hours. | Palatability = 53 %  Mortality = 100 %  in a period from day 4 to day 8  R.I= 1 | xxx |
| Rodenticide | Indoor, outdoor | ULTIMA PASTE (25 ppm brodifacoum) Fresh bait | House mice  *Mus musculus* | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying rats around the sites. | Acclimatization: 8 days (30 g of semolina per station per day)  Treatment : 10 g of bait per day in each lockable bait station –total 8 bait stations) during11 days  Post-baiting: 4 days  (30 g of semolina per station per day)  Mortality was observed from the first day of intoxication and noted about every 1-4 days until the end of the trial. | Estimated efficacy = 100 %  Pre-baiting plateau = 51.3 g/day  Post-baiting = 0 g  R.I= 1 | xxx |
| Rodenticide | Indoor, outdoor | ULTIMA PASTE (25 ppm brodifacoum) Fresh bait | Brown rats  *Rattus norvegicus* | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 10 days (100 g of wheat per station per day)  Treatment : 100 g of paste bait in each lockable bait station (total 10 bait stations) during 14 days  Post-baiting: 4 days  (100 g of wheat per station per day)  Mortality was observed from the first day of intoxication and noted about every 1-4 days until the end of the trial. | Estimated efficacy = 100 % %  Pre-baiting plateau = 513.3 g/day  Post-baiting = 0 g  R.I= 2  The dose tested is higher that the claimed one | xxx |
| Rodenticide | Indoor, outdoor | ULTIMA PASTE (25 ppm brodifacoum) Fresh bait | Black rats  *Rattus Rattus* | Field test  Census baiting technique, which involved the following phases:  Pre-treatment census  Pre-treatment lag phase  Treatment census  Post-treatment lag phase  Post-treatment census  During each assessment the food/bait at each station was weighed and replenished, and the consumption in grams was calculated. During the treatment census, searches were conducted for dead and dying mice around the sites. | Acclimatization: 18 days (60 g of oat per station per day)  Treatment : 60 g of paste bait in each lockable bait station (total 10 bait stations) during 14 days  Post-baiting: 6 days  (60 g of oat per station per day)  Mortality was observed from the first day of intoxication and noted about every 1-4 days until the end of the trial. | Estimated efficacy = 100 % %  Pre-baiting plateau = 330 g/day  Post-baiting = 0 g  R.I= 1 | xxx |

1. A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided. [↑](#footnote-ref-1)
2. Please insert additional columns as necessary [↑](#footnote-ref-2)
3. PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride [↑](#footnote-ref-3)
4. [↑](#footnote-ref-4)
5. xxx.; xxx. .; xxx. (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *xxx*. [↑](#footnote-ref-5)
6. LUND, M. (1984): Resistance to the second generation anticoagulant rodenticides. *xxx*, Ca. March 6-8, 1984: 89-94. [↑](#footnote-ref-6)
7. Pelz H-J, Ha¨nisch D, Lauenstein G (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus. xxx* [↑](#footnote-ref-7)
8. xxx. (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, xxx [↑](#footnote-ref-8)
9. xxx. (1992): Bait avoidance and effectiveness of anticoagulant rodenticides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *xxxx*, February 1992, Pages 14-20 [↑](#footnote-ref-9)
10. Human exposure to Biocidal products-Technical Notes for Guidance, June 2007 [↑](#footnote-ref-10)
11. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-11)
12. See document CA-Nov16-Doc.4.x-Final on the concept of tamper-resistant bait stations. [↑](#footnote-ref-12)