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

**PRODUCT ASSESSMENT REPORT**

**OF A BIOCIDAL PRODUCT FOR**

**NATIONAL AUTHORISATION APPLICATIONS**



|  |  |
| --- | --- |
| Product identifier in R4BP | **Ratimor Brodifacoum Wax Block** |
| Product type:  | 14 (Rodenticide) |
| Active ingredient(s): | Brodifacoum |
| Case No. in R4BP | BC-HJ018724-41 |
| Asset No. in R4BP | IE-0000457-0000 |
| Evaluating Competent Authority | Ireland – Department of Agriculture, Food & the Marine |
| Internal registration/file no | **IE/BPA 70515** |
| Date | 09.04.2018 (NA-RNL Renewal) |

**Version 2.2**

**Version History**

| **Date** | **Version** | **Reason for revision** |
| --- | --- | --- |
| 2013/08/06 | Version 1.0 | Initial PAR |
| 2018/01/26 | Version 1.1 | MAC PAR |
| 2018/04/09 | Version 2.0 | Updated at 1st Renewal of authorisation RNL |
| 2020/01/13 | Version 2.1 | National authorisation administrative change on request. Change of manufacturer and location of the site of manufacture of the active substance |
| 15/09/2022 | Version 2.2 | Reduction of non-active substance. Also, a change in CLP (EUH208) |

**Overview of applications**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type**  | **refMS**  | **Case number in the refMS**  | **Decision date**  | **Assessment carried out (i.e. first authorisation / amendment /renewal)**  | **Page**  |
| National Authorisation Dir.98/8/EC | IE | n/a | 2013/08/06 | 1st Authorisation | N/A |
| NA-MAC | IE | BC-FA031636-61  | 2018/01/26 | Major Change | N/A |
| NA-RNL | IE | BC-HJ018724-41 | 2018/04/09 | Renewal | 37 |
| NA-ADC | IE | BC-UH053832-30 | 2020/01/13 | Admin change |  43-44 |
| NA-MIC | IE  | BC-VK070125-31 | 15/09/2022 | Change to formulation and also the change in CLP (EUH208) | 70-71 |
|  |  |  |  |  |  |

Changes made in NA-ADC BC-UH053832-30 are highlighted in green.

Changes made in NA-MIC BC-VK070125-31 are highlighted in yellow

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**1st Renewal PAR – March 2018**

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 THE RENEWAL**

**OF A NATIONAL AUTHORISATION (NA-RNL)**



|  |  |
| --- | --- |
| Product identifier in R4BP | **Ratimor Plus Brodifacoum Wax Block** |
| Product type:  | 14 (Rodenticide) |
| Active ingredient(s): | Brodifacoum |
| Case No. in R4BP | BC-HJ018724-41 |
| Asset No. in R4BP | IE-0000457-0000 |
| Evaluating Competent Authority | Ireland – Department of Agriculture, Food & the Marine |
| Internal registration/file no | **IE/BPA 70515** |
| Date | 09.04.2018 (NA-RNL Renewal) |

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1. **Conclusion**

The Irish Competent Authority for the authorisation of biocidal products has processed an application for renewal for the biocidal product Ratimor Plus Brodifacoum Wax Block which contains the active substance Brodifacoum (0.0029 % w/w).

The assessment presented in the Product Assessment Report for the first authorisation (2013) showed acceptable efficacy but unacceptable risks for the environment, if the product is used as a rodenticide (product-type 14) for use in and around buildings, by the general public, professionals and trained professionals, and in sewers by professionals and trained professionals.

A major change evaluation in 2017 (case number BC-FA031636-61) assessed and authorised the reduction in active substance content from 0.005% 0.0029% w/w.

The conditions for granting an authorisation according to Article 19 (1) of Regulation (EU) No 528/2012[[1]](#footnote-1) (BPR) are not fulfilled.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR, as this Article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product.

Detailed information on the uses appropriate at the renewal of authorisation are presented in section 2.4.

General directions for use of the product are summarised in section 2.5.

Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extend. As an outcome of these discussions a set of three standard SPCs (Summary of Product Characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final).

The specific conditions from Commission Implementing Regulation (EU) 2017/1381[[2]](#footnote-2) for the active substance Brodifacoum were considered for the re-assessment.

The Irish CA concludes that the conditions set out in Article 5(2) b) and c) of the BPR are currently met. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control in Ireland by efficient pest management and as a consequence, to prevent or control any serious danger to human and animal health in which rodents are involved.

Rodent control in Ireland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Ireland. This may not only cause significant negative impacts on human or animal health or the environment, but may also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences in Ireland.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008[[3]](#footnote-3). Detailed information on classification and labelling is provided in Section 2.3.

As a consequence of the new harmonised classification, the active substance Brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Ratimor Plus Brodifacoum Wax Block has been conducted (for details see Section 3.10 ).

**Comparative assessment**

In line with Article 23 (1) BPR a comparative assessment for the product has been conducted (for details see Section 3.10).

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

According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

**Approval of the active substance**

The active substance Brodifacoum is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

The authorisations of biocidal products containing Brodifacoum are subject to the conditions listed in the Annex to Commission Implementing Regulation (EU) 2017/1381:

**Composition and formulation**

The ready-to-use product is a wax block bait and contains the active substance Brodifacoum.

No substance of concern has been identified.

Please refer to section 5.1 for detailed information.

**Physical, chemical and technical properties**

No new data was provided nor had new guidance to be taken into account for the renewal evaluation.

Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

**Physical hazards and respective characteristics**

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

**Methods for detection and identification**

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

**Efficacy**

Effectiveness data has confirmed that Ratimor Plus Brodifacoum Wax Block is effective in the proposed areas of use, at the recommended dose rate. The field trial data provided on mice (*Mus musculus)* and rats *(Rattus norvegicus* and *rattus rattus*) endorses the lowering of active substance from 50 ppm to 29 ppm by confirming that the attractiveness and effectiveness of the bait is unaffected. Complete control of mouse and rat infestations was achieved in all trials. Data previously evaluated demonstrated that Ratimor Plus Brodifacoum Wax Block is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product’s palatability and effectiveness even under adverse environmental conditions has been established.

The conclusion of the evaluation is that the product may be authorised.

**Risk assessment for human health**

The human health risk assessment for this product is based on the active substance.

According to the BPC Opinion the EFSA-Guidance on dermal absorption had been taken into account

when reviewing the dermal absorption of the product.

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely.

For risk mitigation measures please refer to section 2.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding the trained professional users health protection, there are no objections against the intended uses if the directions for use are followed (For details see section 2).

**Risk assessment for the environment**

No new data was provided. The only area where new guidance was relevant was with respect to the groundwater assessment. Following discussion at the CG-18 meeting and subsequent agreement, Tier II PEC groundwater was calculated using the FOCUS models PEARL or PELMO in the instances where Tier I indicated an exceedance of the relevant trigger value.

According to the risk assessment, the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 25 ppm in the ecotoxicology risk assessment.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR.

**Overall conclusion**

The assessment of the biocidal product Ratimor Plus Brodifacoum Wax Block remains valid. However, the authorisation has to be adapted where necessary taking into account the points mentioned above.

The biocidal product will be authorised according to Article 19 (5) BPR in conjunction with Article 23 (6) BPR.

According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

1. **Summary of the product assessment**
	1. ***Administrative information***

**Identifier in R4BP**

|  |
| --- |
| Ratimor Plus Brodifacoum Wax Block |

**Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Unichem d.o.o |
| **Address** | Sinja Gorica 2 1360 Vrhnika Slovenia |
| **Authorisation number** | IE/BPA 70515 |
| **Date of the authorisation** | 09.04.2018 |
| **Expiry date of the authorisation** | 09.04.2023 |

**Manufacturer(s) of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | Unichem d.o.o |
| **Address of manufacturer** | Sinja Gorica 2 1360 Vrhnika Slovenia |
| **Location of manufacturing sites** | Sinja Gorica 2 1360 Vrhnika Slovenia |

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

|  |  |
| --- | --- |
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | **Activa s.r.l,** |
| **Address of manufacturer** | **Via Feltre 32** **20132** **Milan** **Italy** |
| **Location of manufacturing sites** | **Tezza S.r.l via Tre Ponti 22** **37050** **S.Maria di Zevio** **Italy.** |

Addition of a manufacturer of the active substance or change in the manufacturer’s identity or in manufacturing location or process, where the technical equivalence between the substances from the two manufacturers, manufacturing locations and processes has been established by the Agency in accordance with Article 54 of Regulation (EU) No 528/2012, and the manufacturer or importer is listed in accordance with Article 95(2) of Regulation (EU) No 528/2012.

The new manufacturer of the active substance brodifacoum (CAS number: 56073-10-0, EC number: 259-980-5), in the biocidal product Ratimor Brodifacoum Fresh Bait, is Activa s.r.l, Via Feltre 32 20132 Milan Italy with the location of the manufacturing site at Tezza S.r.l via Tre Ponti 22 37050 S.Maria di Zevio Italy.

Deletion of a manufacturer or a manufacturer location of the active substance.

* 1. ***Product composition and formulation***

**Qualitative and quantitative information on the composition**

**Table 1**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Brodifacoum | 3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one | Active substance | 56073-10-0 | 259-980-5 | 0.0029 |

* The product contains a bittering agent and dyes.
* Information on the full composition is provided in the confidential[[4]](#footnote-4) annex (see section 5).
* According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

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

There are no substances of concern

**Candidate(s) for substitution**

The following substance was identified as a candidate for substitution:

* Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

* toxic for reproduction category 1A
* persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

**Type of formulation**

|  |
| --- |
| Ready-to-use bait: block (RB) |

* 1. ***Classification and Labelling according to the Regulation (EC) No 1272/2008[[5]](#footnote-5)***

**Table 2**

| **Classification****Hazard classes, Hazard categories** | **Hazard statements** |
| --- | --- |
| STOT RE 2 | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
|  | EUH208 Contains octhilinone (ISO); 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |

**Table 3**

| **Labelling** | **Code** | **Pictogram / Wording** |
| --- | --- | --- |
|  | GHS08 |  |
| Signal word |  | Warning |
| Hazard statements | STOT RE 2 | H373: May cause damage to organs (blood) through prolonged or repeated exposure |
| Supplemental label elements | EUH208 | EUH208 Contains octhilinone (ISO); 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |
|  |  |
| Precautionary statements | P260 | Do not breathe dust. |
| P314 | Get medical advice/attention if you feel unwell. |
| P501 | Dispose of packaging and unused bait as hazardous waste in accordance with national regulations. |
| Note | - |  |

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

* 1. ***Use(s) appropriate after renewal of the authorisation***

**Table 4: Summary Table of Uses**

|  |  |
| --- | --- |
| **No.** | **Use** |
| 1 | House mice – general public – indoor  |
| 2 | Rats – general public – indoor  |
| 3 | Rats – general public – outdoor around buildings |
| 4 | House mice – professionals – indoor |
| 5 | Rats – professionals – indoor  |
| 6 | House mice and/or rats – professionals – outdoor around buildings |
| 7 | House mice and/or rats – trained professionals – indoor  |
| 8 | House mice and/or rats – trained professionals – outdoor around buildings |
| 9 | Rats – trained professionals – sewers |

**Use 1 appropriate after renewal of the authorisation – House mice – general public – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juveniles |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations. If more than one bait station is needed, the minimum distance between bait stations should be of 5 m apart (2m apart in high infestation areas). |
| Category(ies) of users | General Public (non-professional) |
| Pack sizes and packaging material | Maximum quantity of bait per pack 100gLoose 5g - 20g blocks (with or without hook/wire):- in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags  within cardboard or fibreboard boxes (fitted with tactile warning) up  to 100g- in PE or PP packs (fitted with tactile warning) up to 100g- in PE or PP containers (fitted with tactile warning) up to 100g- in PE or PP buckets (fitted with tactile warning) up to 100g- in cardboard or fibreboard boxes (fitted with tactile warning) up to  100g- in cardboard or fibreboard boxes with PE bag or liner (fitted with  tactile warning) up to 100g- Prefilled or refillable tamper-resistant HDPE or PP rat bait station  containing one or more blocks of 5g - 20g (up to 20 g total bait per  mouse bait station). Bait stations packed in cardboard outer or  plastic heat-sealed container or thermo seal foil (fitted with tactile  warning) up to 100g- Prefilled or refillable tamper-resistant HDPE or PP mouse or rat  bait station containing one or more blocks of 5g - 20g (up to 20 g  total bait per mouse bait station). Bait stations packed in cardboard  outer or plastic heat-sealed container or thermo seal foil (fitted with  tactile warning) up to 100g- HDPE or PP rat bait station (refillable or single use) containing one  or more 5g – 200g (up to 20 g total bait per mouse bait station).  Bait stations then packed in cardboard outer or plastic heat-sealed  container or thermo seal foil (fitted with tactile warning) up to 100g |

**Use-specific instructions for use**

|  |
| --- |
| * For mouse infestations use up to 20 g bait in tamper resistant baiting stations. If more than one bait station is needed, the minimum distance between bait stations should be of 5 m apart (2m apart in high infestation areas).
* 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). Make frequent inspections of the bait points during the first 10-14 days.
* 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.
* 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
* Do not use this product for permanent or pulse-baiting.
 |

**Use-specific risk mitigation measures**

|  |
| --- |
| Prevent skin contact when disposing remains of baits. |

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

|  |
| --- |
| None  |

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

|  |
| --- |
| None  |

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

|  |
| --- |
| None |

**Use 2 appropriate after renewal of the authorisation – Rats – general public – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | General Public |
| Pack sizes and packaging material | Maximum quantity of bait per pack 300gLoose 5g - 60g blocks (with or without hook/wire):- in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes (fitted with tactile warning) up to 300g- in PE or PP packs (fitted with tactile warning) up to 300g - in PE or PP containers (fitted with tactile warning) up to 300g- in PE or PP buckets (fitted with tactile warning) up to 300g- in cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes with PE bag or liner (fitted with tactile warning) up to 300g- Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g- Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g- HDPE or PP rat bait station (refillable or single use) containing one or more 5g – 60g (up to 60g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g﻿ |

**Use-specific instructions for use**

|  |
| --- |
| * For rat infestations use up to 60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
* 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
* 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.
* 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.
* Do not use this product for permanent or pulse-baiting.
 |

**Use-specific risk mitigation measures**

|  |
| --- |
| Prevent skin contact when disposing remains of baits. |

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

|  |
| --- |
| None  |

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

|  |
| --- |
| None  |

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

|  |
| --- |
| None |

**Use 3 appropriate after renewal of the authorisation – Rats – general public – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| 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 | For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestationsRegularly 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | General Public (non-professional) |
| Pack sizes and packaging material | Maximum quantity of bait per pack 300gLoose 5g - 60g blocks (with or without hook/wire):- in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes (fitted with tactile warning) up to 300g- in PE or PP packs (fitted with tactile warning) up to 300g - in PE or PP containers (fitted with tactile warning) up to 300g- in PE or PP buckets (fitted with tactile warning) up to 300g- in cardboard or fibreboard boxes (fitted with tactile warning) up to 300g - in cardboard or fibreboard boxes with PE bag or liner (fitted with tactile warning) up to 300g- Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g- Prefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g - 60g (up to 60g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g- HDPE or PP rat bait station (refillable or single use) containing one or more 5g – 60g (up to 60g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil (fitted with tactile warning) up to 300g |

**Use-specific instructions for use**

|  |
| --- |
| * For rat infestations use up to 60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
* Place the bait stations in areas not liable to flooding.
* 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
* 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.
* 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.
* Do not use this product for permanent or pulse-baiting.
 |

**Use-specific risk mitigation measures**

|  |
| --- |
| Prevent skin contact when disposing remains of baits. |

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

|  |
| --- |
| None  |

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

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| --- |
| None  |

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

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| --- |
| None |

**Use 4 appropriate after renewal of the authorisation – House mice – professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juveniles |
| Field(s) of use | Indoors  |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.Loose 5 g - 20 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kgLoose 5 g - 20 g blocks (with or without hook/wire) in PE or PP packs up to 25 kgLoose 5 g - 20 g blocks (with or without hook/wire) in PE or PP containers up to 25 kgLoose 5 g - 20 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kgLoose 5 g - 20 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5 g - 20 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5 g - 20 g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 20 g (up to 20 g total bait per mouse bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 20 g (up to 20 g total bait per mouse bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use-specific instructions for use**

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| --- |
| * For mouse infestations use up to 20 g bait per bait station in tamper resistant baiting stations. If more than one bait station is needed, the minimum distance between bait stations should be of 5 m apart (2m apart in high infestation areas).
* 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). Make frequent inspections of the bait points during the first 10-14 days.
* 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.
* 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.
* 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 resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
* [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.
* 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.
* Do not use this product for permanent or pulse-baiting.
 |

**Use-specific risk mitigation measures**

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| --- |
| * Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
 |

**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 water drainage systems, ensure that bait contact with water is avoided. |

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

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| --- |
| None  |

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

|  |
| --- |
| None |

**Use 5 appropriate after renewal of the authorisation – Rats – professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| Field(s) of use | Indoors  |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg Loose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg﻿ |

**Use-specific instructions for use**

|  |
| --- |
| * For rat infestations use up to 60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
* 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity.
* 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.
* Follow any additional instructions provided by the relevant code of best practice.
* 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.
* 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 resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
* [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.
* 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.
* Do not use this product for permanent or pulse-baiting.
 |

**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.
 |

**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 water drainage systems, ensure that bait contact with water is avoided. |

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

|  |
| --- |
| None  |

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

|  |
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| Keep away from food, drink and animal feeding stuffs. |

**Use 6 appropriate after renewal of the authorisation – House mice and/or rats – professionals – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Outdoors around buildings |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outeror plastic heat-sealed container or thermo seal foil up to 20 kg﻿ |

**Use-specific instructions for use**

|  |
| --- |
| * Up to 60g (rats) or up to20g (mice) of bait in covered tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation).
* Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). 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.
* 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). Make frequent inspections of the bait points during the first 10-14 days.
* 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.
* Follow any additional instructions provided by the relevant code of best practice.
* 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.
* 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 resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use..
* [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.
* 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.
* Do not use this product for permanent or pulse-baiting.
 |

**Use-specific risk mitigation measures**

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

**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 water drainage systems, ensure that bait contact with water is avoided. |

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

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| None  |

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

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| --- |
| None |

**Use 7 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stationsReady-to-use bait to be used in covered and protected baiting points. |
| Application rate(s) and frequency | For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations. 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). Make frequent inspections of the bait points during the first 10-14 days.Pulsed baiting –- High infestation: Up to 60g of bait per baiting point every 5-10m- Low infestation: Up to 60g of bait per baiting point every 2-5m |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use-specific instructions for use**

|  |
| --- |
| * Use up to 60g (rats) or up to 20g (mice) of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation).
* 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). Make frequent inspections of the bait points during the first 10-14 days.
* Follow any additional instructions provided by the relevant code of best practice.
* 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.
* 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.
* 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 use in areas where resistance to the active substance can be suspected.
* [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.
* Remove the remaining product at the end of treatment period.
* Do not use this product for permanent baiting.
* If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

[When available] Follow the specific instructions provided by the applicable code of good practice at national level. |

**Use-specific risk mitigation measures**

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| --- |
| * Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
* 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.
* Wear protective chemical resistant gloves during product handling phase (EN374).
 |

**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 water drainage systems, ensure that bait contact with water is avoided. |

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

|  |
| --- |
| None  |

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

|  |
| --- |
| None |

**Use 8 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Outdoors around buildings |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations.Ready-to-use bait to be used in covered and protected baiting points.Direct application of ready-to-use bait into the burrow. |
| Application rate(s) and frequency | For mouse infestations use 10 g up to 20 g of bait per bait point. Place bait points 5 m apart reducing to 2 m in high infestations.For rat infestations use 10 g up to 60 g of bait per bait points. Place bait points 10 m apart reducing to 5 m in high infestations.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). Make frequent inspections of the bait points during the first 10-14 days.- In burrows: up to 60g of bait per burrow.Pulsed baiting –- High infestation: Up to 60g of bait per baiting point every 5-10m- Low infestation: Up to 60g of bait per baiting point every 2-5m |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.Loose 5 g - 60 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP packs up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in PE or PP containers up to 25 kgLoose 5 g - 60 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5 g - 60 g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5 g - 60 g (up to 20 g total bait per mouse bait station or 60 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use-specific instructions for use**

|  |
| --- |
| * Use up to 60g (rats) or up to 20g (mice) of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation) , or directly into the burrow.
* 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). Make frequent inspections of the bait points during the first 10-14 days.
* 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
* Follow any additional instructions provided by the relevant code of best practice.
* 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.
* 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.
* 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 use in areas where resistance to the active substance can be suspected.
* [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.
* Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
* Remove the remaining product at the end of treatment period.
* Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
* When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
* If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.

[When available] Follow the specific instructions provided by the applicable code of good practice at national level. |

**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
* 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.
* When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
* Wear protective chemical resistant gloves during product handling phase (EN374).
 |

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

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

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

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| --- |
| None  |

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

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| --- |
| None |

**Use 9 appropriate after renewal of the authorisation – Rats – trained professionals – sewers**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juveniles |
| Field(s) of use | Sewers |
| Application method(s) | Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.Ready-to-use bait to be anchored or applied in covered and protected baiting points preventing the bait from getting into contact with waste water. |
| Application rate(s) and frequency | For rat infestations in sewers use 10 g up to 200g per manhole.For high rat infestations in sewers use 200g per manhole.Place and fix the bait so it cannot be moved by rodents.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). Make frequent inspections of the bait points during the first 10-14 days.. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Maximum outer pack size up to 25 kg.- Loose 10 g - 200 g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg- Loose 10 g - 200 g blocks (with or without hook/wire) in PE or PP packs up to 25 kg- Loose 10 g - 200 g blocks (with or without hook/wire) in PE or PP containers up to 25 kg- Loose 10 g - 200 g blocks (with or without hook/wire) in HDPE or PP buckets up to 20 kg- Loose 10 g - 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kg- Loose 10 g - 200 g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kg- Loose 10 g - 200 g blocks (with or without hook/wire) blocks in natron bags up to 25 kg- Prefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 10 g - 200 g (up to 200 g total bait per rat bait station). Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg- HDPE or PP rat bait station (refillable or single use) containing one or more blocks of 10 g - 200 g (up to 200 g total bait per rat bait station). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use-specific instructions for use**

|  |
| --- |
| * Use up to 60g of bait in tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation).
* 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). Make frequent inspections of the bait points during the first 10-14 days
* Follow any additional instructions provided by the relevant code of best practice.
* 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.
* 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.
* 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 use in areas where resistance to the active substance can be suspected.
* [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.
* Baits must be applied in a way so that they do not come into contact with water and are not washed away.
* If used for pulsed baiting: Replace eaten bait only after 3 days and then at maximum 7 day intervals.
 |

**Use-specific risk mitigation measures**

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

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

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

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

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| None  |

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

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| None |

* 1. ***General directions for use***

**Instructions for use**

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| * Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
* Professionals & Trained Professionals: 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.
* Professionals & Trained Professionals: 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.
* 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.
* 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.
* Where possible, bait stations must be fixed to the ground or other structures.
* Do not place bait stations near water drainage systems where they can come into contact with water.
* Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
* Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
* When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
* Professionals & Trained Professionals: 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 rodents 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.
* Remove the remaining bait or the bait stations at the end of the treatment period..
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**Risk mitigation measures**

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| * Do not use brodifacoum containing products as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
* Dispose of 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].
* Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
* Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
* Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
* [For products to be authorised for professional users:] 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").
* [For products to be authorised for trained professional users:] 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".
 |

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

|  |
| --- |
| This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.Antidote: Vitamin K1 administered by medical/veterinary personnel only. In case of: Dermal exposure, wash skin with water and then with water and soap.Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.Contact a veterinary surgeon in case of ingestion by a pet.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 the National Poisons Information Centre (01) 809 2166". Hazardous to wildlife. |

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

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| --- |
| At the end of the treatment, dispose of 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]*  Use of gloves is recommended. |

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

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| --- |
| Shelf-life: 24 monthsStore 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.Keep only in original container. |

**Other information**

|  |
| --- |
| 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 dyes. |

**Documentation**

**Data submitted in relation to product application**

Please see General Annexes section 4.1

**Access to documentation**

The access includes the initial active substance and product dossiers but excludes any product studies produced after 10th November 2010.

1. **Assessment of the product**
	1. **Proposed Uses**

**Use 1 – House mice – general public – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juveniles |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 20 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 m apart (2m apart in high infestation areas).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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | General Public |
| Pack sizes and packaging material | Maximum quantity of bait per pack 100gLoose 5g - 100g blocks:(with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 100g (with or without hook/wire) in PE or PP packs up to 100g(with or without hook/wire) in PE or PP containers up to 100g(with or without hook/wire) in PE or PP buckets up to 100g(with or without hook/wire) in cardboard or fibreboard boxes up to 100g(with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 100gPrefilled or refillable tamper-resistant HDPE or PP mouse bait station containing one or more blocks of 5g up to 100g (up to 20 g total bait per mouse bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 100gPrefilled or refillable tamper-resistant HDPE or PP mouse bait station containing one or more blocks 5g up to 100g. . Bait stations packed in cardboard outer or plastic heatsealed container or thermo seal foil up to 100g |

**Use 2 – Rats – general public – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation). 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | General Public |
| Pack sizes and packaging material | Maximum quantity of bait per pack 300gLoose 5g - 200g blocks:(with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 300g(with or without hook/wire) in PE or PP packs up to 300g(with or without hook/wire) in PE or PP containers up to 300g(with or without hook/wire) in PE or PP buckets up to 300g(with or without hook/wire) in cardboard or fibreboard boxes up to 300g(with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 300gPrefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g up to 200g (up to 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300gPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g up to 200g. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300gHDPE or PP rat bait station (refillable or single use) containing one or more 5g up to 200g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300g |

**Use 3 – Rats – general public – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| 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 | Up to 60g of bait in tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation). 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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | General Public |
| Pack sizes and packaging material | Maximum quantity of bait per pack 300gLoose 5g - 200g blocks:(with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 300g(with or without hook/wire) in PE or PP packs up to 300g(with or without hook/wire) in PE or PP containers up to 300g(with or without hook/wire) in PE or PP buckets up to 300g(with or without hook/wire) in cardboard or fibreboard boxes up to 300g(with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 300gPrefilled or refillable tamper-resistant HDPE or PP rat bait station containing one or more blocks of 5g up to 200g (up to 60 g total bait per rat bait station). Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300gPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g up to 200g. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300gHDPE or PP rat bait station (refillable or single use) containing one or more 5g up to 200g. Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 300g |

**Use 4 – House mice – professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juveniles |
| Field(s) of use | Indoors  |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 20 g bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 m apart (2m apart in high infestation areas). 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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse bait station containing one or more blocks of 5g or 200g up to 20g total bait per mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 20 g total bait per mouse bait station. ). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use 5 – Rats – professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles  |
| Field(s) of use | Indoors  |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 60g of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation).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). Do not move or disturb bait points for several days after laying bait. If no signs of rat activity are seen near the bait after 7-10 days, move the bait to an area of higher rat activity. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse bait station containing one or more blocks of 5g or 200g up to 20g total bait per mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 20 g total bait per mouse bait station. ). Bait stations then packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg |

**Use 6 – House mice and/or rats – professionals – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Outdoors around buildings |
| Application method(s) | Ready-to-use bait to be used in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 60g (rats) or up to 20g (mice) of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation).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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g or 200g up to 40g total bait per mouse bait station or 200 g total bait per rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 40g per mouse bait station or 200g per rat bait station. Bait stations then packed in cardboard outer plastic heat-sealed container or thermoseal foil up to 20 kg |

**Use 7 – House mice and/or rats – trained professionals – indoor**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Indoors |
| Application method(s) | Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 60g (rats) or up to 20g (mice) of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation). 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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g or 200g up to 40g total bait per mouse bait station or 200 g total bait per rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 40g per mouse bait station or 200 g per rat bait station. Bait stations then packed in cardboard outer plastic heat-sealed container or thermoseal foil up to 20 kg |

**Use 8 – House mice and/or rats – trained professionals – outdoor around buildings**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mouse (*Mus musculus*) – adults and juvenilesBrown rats (*Rattus norvegicus*) – adults and juvenilesRoof rats (*Rattus rattus*) – adults and juveniles |
| Field(s) of use | Outdoors around buildings |
| Application method(s) | Ready-to-use bait to be used in covered bait points or in tamper-resistant bait stations |
| Application rate(s) and frequency | Up to 60g (rats) or up to 20g (mice) of bait in covered tamper resistant baiting stations or covered bait points spaced 10m apart (5m apart in areas of high infestation).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). Make frequent inspections of the bait points during the first 10-14 days. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g or 200g up to 40g total bait per mouse bait station or 200 g total bait per rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 40g per mouse bait station or 200g per rat bait station. Bait stations then packed in cardboard outer plastic heat-sealed container or thermoseal foil up to 20 kg |

**Use 9 – Rats – trained professionals – sewers**

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | Brown rats (*Rattus norvegicus*) – adults and juveniles |
| Field(s) of use | Sewers |
| Application method(s) | Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water. |
| Application rate(s) and frequency | Bait products:- High infestation: 60g per manhole. - Low infestation: up to 60g per manhole.In case of high infestation use 60g of bait. For low infestation use up to 60g of bait, depending on the rate of infestation. Place and fix the bait so it can not be moved by rodents.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). Make frequent inspections of the bait points during the first 10-14 days.. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | Minimum pack size of 3 kg.Loose 5g up to 200g blocks (with or without hook/wire) in polyethylene (PE), polypropylene (PP), PE/PP or paper/PE bags within cardboard or fibreboard boxes up to 20 kg.Loose 5g up to 200g blocks (with or without hook/wire) in PE or PP packs up to 25 kg.Loose 5g up to 200g blocks in PE or PP containers up to 25 kgLoose 5g up to 200g blocks in in HDPE or PP buckets up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) in cardboard or fibreboard boxes with PE bag or liner up to 20 kgLoose 5g up to 200g blocks (with or without hook/wire) blocks in natron bags up to 25 kgPrefilled or refillable tamper-resistant HDPE or PP mouse or rat bait station containing one or more blocks of 5g or 200g up to 40g total bait per mouse bait station or 200 g total bait per rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 20 kgHDPE or PP mouse or rat bait station (refillable or single use) containing one or more blocks of 5g up to 200g (up to 40g per mouse bait station or 200 g per rat bait station. Bait stations then packed in cardboard outer plastic heat-sealed container or thermoseal foil up to 20 kg |

* 1. ***Physical, chemical and technical properties***

No new data was provided nor had new guidance to be taken into account for the renewal evaluation.

However, two post authorisation requirements have been identified.

Storage stability:

Based on the original storage stability data, the new formulation (with 29 ppm bromadiolone) is expected to similarly remain stable, therefore, no new data are required for authoirsation.

However, due to the decision reached during the March 2016 Working Group of the Biocidal Products Committee, a new storage stability test is needed to check that the active substance remains stable after storage for the proposed shelf life.

The applicant will have to provide the data as a post authorisation data requirement.

Analytical method for the active in the product formulation:

The analytical method has been validated for formulations containing 0.004 and 0.005 % w/w bromadiolone. However, the method has not been validated for the same formulation with a reduced content of 0.0029 % w/w (linearity, accuracy and precision should be addressed at the nominal content). The applicant will have to provide the data as a post authorisation data requirement.

Therefore, apart from these two post-authorisation requirements outlined above, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

* 1. ***Physical hazards and respective characteristics***

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

* 1. ***Methods for detection and identification***

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation .

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

* 1. ***Efficacy against target organisms***

Ratimor Plus Brodifacoum wax block is a ready-to-use, wax block bait formulation for the control of mice, brown rats and roof rats in a number of proposed use scenarios (section 3.1.1).

 The product is intended for use by general public, professionals and trained professionals for the control of rodent infestations.

**Palatability**

No new palatability studies were provided as the formulation is virtually identical to the 50ppm product evaluated previously. The only difference is the lowering of the active concentration to 29ppm. Accordingly, the conclusion from the previous assessment regarding palatability remains valid.

**Effectiveness**

For the Major Change evaluation (2017), data was provided from three field trials carried out in (COUNTRY) and conducted in-line with EPPO guideline PP 1/114(2) Field tests against synanthropic rodents (*Mus musculus, Rattus norvegicus, Rattus rattus*). In all three field trials complete control (100%) of the target populations was achieved, demonstrating the attractiveness and effectiveness of the bait product.

Data from the field trials has been summarised in table 4.5 which demonstrated that the product, when used in accordance with label instructions can provide effective control of the target organisms.

The applicant should comment on the potential for the development for resistance owing to the reduction in active content in their product.

The label reference to permanent baiting must be removed from each of the general user, professional user and the trained professional user proposed labels in accordance with the BPC opinion.

Data previously evaluated demonstrated that Ratimor Plus Brodifacoum Wax block is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product’s palatability and effectiveness even under adverse environmental conditions has been demonstrated. Therefore, the conclusion from the previous assessment regarding effectiveness under the “sewer-use scenario” remains valid.

* 1. ***Risk assessment for human health***

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to 0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%.

**Assessment of effects of the active substance on human health**

As above.

**Assessment of effects of the product on human health**

As above.

**The following new guidance had to be taken into account for the re-assessment:**

A read across from difenacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance (EFSA Journal 2012; 10(4):2665).

**Re-assessment of the relevant data:**

The product has been evaluated using the reduced active ingredient concentration and new dermal absorption.

**Exposure assessment**

|  |
| --- |
| The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to 0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%. Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE. The AELs considered in the risk characterization for *Brodifacoum* were: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/dayAELchr 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/dayFor conducting the risk assessment the chronic AEL was selected as the endpoint.For the ‘transient mouthing of poison bait’ scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 10 Kg. An oral absorption of 100% was assumed for the mouthing scenarios in the toddler risk assessments. The acute AEL was used as the endpoint for the toddler risk assessment. |
| Biocidal Exposure Risk assessment for Ratimor Plus Brodifacoum rodenticide (29 ppm). |
| Professional user  |
|  | Block  |
| Without PPE | 393.2% of AEL(0.000013 mg/kg bw/day) |
| With PPE | 19.7% of AEL(0.000000649 mg/kg bw/day) |
| **Non-trained professional user (farmer)** |
|  | Block  |
| Without PPE | 33.4% of AEL(0.0000011 mg/kg bw/day) |
| With PPE | 1.7% of AEL(0.0000000551 mg/kg bw/day) |
| **Exposure to children (Infant)**  |
|  | Block  |
| Oral exposure -treated with repellent | 878% of AEL(0.000029 mg/kg bw/day) |
| Oral exposure - without repellent | 439393% of AEL(0.0145 mg/kg bw/day) |
| Derived values indicated an unsafe usage scenario for professional users handling the wax block product without PPE and a safe usage scenario when PPE was worn. Derived values for professional users handling the wax block product without PPE were 0.000013 mg/kg bw/day (393.2% AEL). Derived values for professional users handling the wax block product with PPE were 0.000000649 mg/kg bw/day (19.7% AEL).Derived values indicated safe usage for non-trained professional users (farmers) handling the wax block product both with and without PPE. Derived values for non-trained professional users handling the wax block product without PPE were 0.0000011 mg/kg bw/day (33.4% AEL). Derived values for non-trained professional users handling the wax block product with PPE were 0.0000000551 mg/kg bw/day (1.7% AEL).The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.0000011 mg/kg bw/day (33.4% AEL).The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the toddler found transient mounting of a block not containing a repellent to result in a dose of 0.0145 mg (439393% AEL). Derived values for oral exposures in the toddler found transient mounting of a block containing a repellent to result in a dose of 0.000029 mg (878% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system toddlers are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely. |

**Risk characterisation for human health**

**Risk for professional users**

As shown in section 3.6.2.

**Risk for the general public**

As shown in section 3.6.2.

**Risk for consumers via residues in food**

No new data was provided nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

**Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product**

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

**Summary of risk characterisation**

Derived values indicated an unsafe usage scenario for professional users handling the wax block product without PPE and a safe usage scenario when PPE was worn. Derived values for professional users handling the wax block product without PPE were 0.000013 mg/kg bw/day (393.2% AEL). Derived values for professional users handling the wax block product with PPE were 0.000000649 mg/kg bw/day (19.7% AEL).

Derived values indicated safe usage for non-trained professional users (farmers) handling the wax block product both with and without PPE. Derived values for non-trained professional users handling the wax block product without PPE were 0.0000011 mg/kg bw/day (33.4% AEL). Derived values for non-trained professional users handling the wax block product with PPE were 0.0000000551 mg/kg bw/day (1.7% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating wax blocks without PPE indicated daily exposure scenarios of 0.0000011 mg/kg bw/day (33.4% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the block product. Derived values for oral exposures in the toddler found transient mounting of a block not containing a repellent to result in a dose of 0.0145 mg (439393% AEL). Derived values for oral exposures in the toddler found transient mounting of a block containing a repellent to result in a dose of 0.000029 mg (878% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system toddlers are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

* 1. ***Risk assessment for animal health***

No new data was provided, nor had new guidance to be taken into account for the renewal.

Accordingly, the conclusion from the former assessment regarding animal health remains valid.

* 1. ***Risk assessment for the environment***

The previous change in active substance concentration from 0.005% to 0.0029% resulted in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

*Groundwater assessment for rodenticides*

*As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:*

*- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.*

*- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.*

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

*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 and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.*

|  |  |  |
| --- | --- | --- |
| ***Scenario*** | ***In and around buildings*** | ***Sewer system*** |
|  | ***Worst case*** | ***Realistic*** | ***Worst case*** | ***Realistic*** |
| ***PEC groundwater (mg/l)*** | *5.3 x 10-5* | *6.62 x 10-6* | *4.66 x 10-7* | *3.11 x 10-7* |

As the previous major change led to a lower PECgw a new assessment is not necessary here.

**Primary and Secondary Poisoning**

The concentration in the final product is 0.0029% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

**Primary Poisoning**

In the first tier scenario, the risk is characterised by the ratio between PECoral and PNECoral. The ratios PEC/PNEC are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

**Acute risk assessment for primary poisoning of a non-target organism:**

**Tier 2:**

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

**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 | 10 | 7.21 | 0.00013 | 76923 | 55461 |
| Chaffinch | 8.7 | 8.26 | 0.00013 | 66923 | 63538 |
| Wood pigeon | 3.14 | 2.26 | 0.00013 | 24153 | 17384 |
| Pheasant | 3.13 | 2.25 | 0.00013 | 24076 | 17307 |
| Dog | 1.74 | 1.25 | 0.000222 | 7837 | 5630 |
| Pig | 0.218 | 0.157 | 0.000222 | 981 | 707 |
| Pig, young | 0.696 | 0.501 | 0.000222 | 3135 | 2256 |

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

 **Long-risk assessment for primary poisoning of a non-target organism:**

**Tier 2:**

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the ECoral/PNECratioafter 1-day and 5-day elimination of Brodifacoum. The ECoral/PNECratio are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The ECoral/PNECratio for the 5-day elimination of Brodifacoum are shown below.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **ECoral after 5 days****(mg/kg b.w./d) with excretion factor = .3,****AV = 1, PT = 1****(mg/kg bw)a** | **ECoral after 5 days****(mg/kg b.w./d)****with excretion factor = 0.3, AV = 0.9, PT = 0.8****(mg/kg bw)a** | **PNECoral****(mg/kg b.w./d)** | **Ratio****ECoral/PNECoral** |
| Tree sparrow | 17.06 | 12.28 | 0.00013 | 94486 |
| Chaffinch | 15.3 | 11.02 | 0.00013 | 84738 |
| Wood pigeon | 5.35 | 3.85 | 0.00013 | 29631 |
| Pheasant | 5.33 | 3.84 | 0.00013 | 29520 |
| Dog | 2.96 | 2.13 | 0.000222 | 9600 |
| Pig | 0.371 | 0.267 | 0.000222 | 1203 |
| Pig, young | 1.18 | 0.850 | 0.000222 | 3827 |

a calculation according to equation 21 in the ESD

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

**Conclusion:**

Overall, 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**

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The PECoral/PNECoral values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated (ETE oral predators) and compared to the PNECoral

**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 | 0.637 | 0.00013 | 4901 |
| Day 5 after the last meal | 0.996 | 7667 |
| Day 14 after the last meal | 1.19 | 9155 |
| Kestrel | Day 5 before the last meal | 0.967 | 0.00013 | 7444 |
| Day 5 after the last meal | 1.51 | 11644 |
| Day 14 after the last meal | 1.80 | 13903 |
| Little owl | Day 5 before the last meal | 0.727 | 0.00013 | 5593 |
| Day 5 after the last meal | 1.13 | 7848 |
| Day 14 after the last meal | 1.35 | 10446 |
| Tawny owl | Day 5 before the last meal | 0.585 | 0.00013 | 4506 |
| Day 5 after the last meal | 0.916 | 7048 |
| Day 14 after the last meal | 1.09 | 8416 |
| Fox | Day 5 before the last meal | 0.234 | 0.000222 | 1056 |
| Day 5 after the last meal | 0.366 | 1652 |
| Day 14 after the last meal | 0.438 | 1973 |
| Polecat | Day 5 before the last meal | 0.488 | 0.000222 | 2199 |
| Day 5 after the last meal | 0.763 | 3440 |
| Day 14 after the last meal | 0.911 | 4107 |
| Stoat | Day 5 before the last meal | 0.698 | 0.000222 | 3145 |
| Day 5 after the last meal | 1.09 | 4920 |
| Day 14 after the last meal | 1.30 | 5874 |
| Weasel | Day 5 before the last meal | 1.00 | 0.000222 | 4538 |
| Day 5 after the last meal | 1.57 | 7099 |
| Day 14 after the last meal | 1.88 | 8477 |

All ratios ETEoral predators / PNECoral are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

**Overall conclusion**

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 29 ppm in the ecotoxicology risk assessment.

* 1. ***Assessment of a combination of biocidal products***

A use with other biocidal products is not intended.

* 1. ***Comparative assessment***

The Irish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Brodificaoum. The active substance Brodificaoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).

Therefore, in line with Article 23 (1) BPR, a comparative assessment for this product has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of the BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

1. Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
2. For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
3. Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
4. Are these alternatives sufficiently effective?;
5. Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532[[6]](#footnote-6). In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Irish CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

**Conclusion**

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the Irish CA came to the conclusion that 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. These products also showed some significant practical or economical disadvantages for the relevant uses.

The Irish CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view do not provide sufficient alternatives to anticoagulant rodenticides.

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.

1. **General Annexes**
	1. ***List of studies for the biocidal product***

| **Author** | **Year** | **Title** | **Publication** | **Report no.** | **Legal entity owner**  | **Report date** | **GLP/****GEP** | **Data Protection Claimed** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | 2017 | Efficacy evaluation of Ratimor Brodifacoum Wax block (brodifacoum 0.029 g/kg a.i., wax block) against Roof rat (*Rattus rattus* L.) | unpublished | Trial Code: 2017.BCD.SAG17 | Unichem | 05/02/2017 | GEP | Y |
|  | 2017 | Efficacy evaluation of Ratimor Brodifacoum Wax block (brodifacoum 0.029 g/kg a.i., wax block) against House mouse (*Mus musculus* L.) | unpublished | Trial code: 2018.BCD.SAG17 | Unichem | 05/02/2017 | GEP | Y |
|  | 2017 | Efficacy evaluation of Ratimor Brodifacoum Wax block (brodifacoum 0.029 g/kg a.i., wax block) against Roof rat (*Rattus norvegicus* Berk.) | unpublished | Trial code: 2013.BCD.SAG17 | Unichem | 05/02/2017 | GEP | Y |

* 1. ***Output tables from exposure assessment tools***

None

* 1. ***New information on the active substance***

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

* 1. ***Residue behaviour***

No assessment necessary.

* 1. ***Summaries of the efficacy studies (B.5.10.1-xx)[[7]](#footnote-7)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Function and field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method, test system/concentrations applied/ exposure time** | **Test results; effects** | **Reference** |
| Ratimor Plus Brodifacoum Wax block (PT14) | A wax block Bait containing 29 ppm Brodifacoum | Roof rat (*Rattus rattus* L.)Wild population located in stables and storage buildings in (COUNTRY)(resistance status unknown) |  Droppings, sightings and activity established these rodents to be roof rats.Unpoisoned bait and tracking patcheswere employed to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.A 3-day lag period was used.The trial was then undertaken using the product as per the proposed label instructions.29ppm Ratimor Plus Brodifacoum Wax block was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily. Bait points which dropped below 60g or that had been spoilt were either topped up or swapped with wax block.After a further 4-day lag phase a post-treatment census was undertaken. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Bait consumption** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total bait consumption (g) | 2221 | 0 | 100 |
| Maximum daily bait consumption (g) | 569 | 0 | 100 |
|  |  |  |  |
| **Activity over sand patches** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total activity score | 108 | 0 | 100 |
| Maximum daily activity score | 24 | 0 | 100 |

Conservative estimate of population calculated as 30-35 rats based on pre-census bait take of 2,221g over a five day period.3,094g of treated bait was consumed during the 15 day baiting phase.Tracking patch activity dropped to zero on day 13 of the baiting period as did bait consumption.Complete (100%) effectiveness against *Rattus rattus* population across the trial site.No evidence was found during the trial that the use of 29ppm Ratimor Plus Brodifacoum Wax block when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. | AUTHOR, 2017 |
| Ratimor Plus Brodifacoum Wax block (PT14) | A wax block Bait containing 29 ppm Brodifacoum | House mouse (*Mus musculus* L.)Wild population located on an agricultural farm(Private dwelling house with equipment warehouse) in (COUNTRY)(resistance status unknown) | Droppings, sightings and activity established these rodents to be mice.Unpoisoned bait and tracking patches were used to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.A 3-day lag period was observed.The trial was then undertaken using the product as per the proposed label instructions.29ppm Ratimor Plus Brodifacoum Wax block was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily. Bait points which dropped below 20g or that had been spoilt were replenished with a fresh wax block.After a further 3-day lag phase a post-treatment census was undertaken. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Bait consumption** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total bait consumption (g) | 774 | 0 | 100 |
| Maximum daily bait consumption (g) | 175 | 0 | 100 |
|  |  |  |  |
| **Activity over tracking patches** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total activity score | 77 | 0 | 100 |
| Maximum daily activity score | 17 | 0 | 100 |

Pre-baiting census indicated 40-50 mice in the on-site population.1,040g of treated bait was consumed by day 11 of the 14 day baiting phase.Tracking patch activity dropped to zero by day 12 and no more bait was consumed.Complete (100%) effectiveness against *Mus musculus* population across the trial site.No evidence was found during the trial that the use of 29ppm Brodifacoum Wax block when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. | AUTHOR, 2017 |
| Ratimor Plus Brodifacoum Wax block (PT14) | A wax block Bait containing 29 ppm Brodifacoum | Brown Rat (*Rattus norvegicus*)Wild population located in farm buildings (cow housing, fodder, equipment and wood storage buildings) in (COUNTRY)(resistance status unknown) | Droppings, sightings and activity established these rodents to be brown rats.Unpoisoned bait and tracking patches were used to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.A 3-day lag period was observed.The trial was then undertaken using the product as per the proposed label instructions.29ppm Ratimor Plus Brodifacoum Wax block was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily. Bait points which dropped below 60g or that had been spoilt were replenished with a fresh wax block.After a further 6-day lag phase a post-treatment census was undertaken. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Bait consumption** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total bait consumption (g) | 2525 | 0 | 100 |
| Maximum daily bait consumption (g) | 578 | 0 | 100 |
|  |  |  |  |
| **Activity over sand patches** | **Pre-treatment census** | **Post-treatment census** | **% control** |
| Total activity score | 110 | 0 | 100 |
| Maximum daily activity score | 24 | 0 | 100 |

Conservative estimate of population calculated as a minimum of 25-30 rats based on pre-census baiting.4,040g of treated bait was consumed by day 14 of the 17 day baiting phase after which no more bait was consumed.Tracking patch activity dropped to zero on day 12 of the baiting period.Complete (100%) effectiveness against *Rattus norvegicus* population across the trial site.No evidence was found during the trial that the use of 29ppm Brodifacoum Wax block when used in accordance to the label guidelines posed a significant risk to non-target or companion animals. | AUTHOR, 2017 |

* 1. ***Other***

None

* 1. ***MINOR CHANGE BC-VK070125-31 (SUBMITTED MARCH 2022)***

The IE CA has processed an application for minor change of a national authorisation (NA-MIC) for the biocidal product Ratimor Brodiacoum Was Blocks.

To support the statement, an Efficacy and palatability study (AUTHOR, 2005) and a Storage stability study (AUTHOR, 1999) have been provided. The studies were conducted for a different product formulation (50 ppm bromadiolone pellets), which does not contain a preservative.

1. *Physical, chemical and technical properties*

A storage stability study (AUTHOR ,1999) for a bromadiolone pellet formulation containing no preservative is referenced in support of the proposed minor change. The pellet formulation contains many of the same perishable ingredients as the wax block formulation, and it is indicated that mould growth is not observed in the absence of a preservative. It is also noted that the inclusion of paraffin wax in the wax block formulation may have an inhibitory effect on mould growth.

The reduction in preservative content is therefore expected to maintain resistance of the product to mould.

The reduction in preservative content is considered a non-significant change and it is unlikely to impact the physicochemical properties or stability of the product.

1. *Efficacy and palatability*

Ratimor Brodifacoum Wax Blocks are a ready to use bait formulation for the control of house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*) for indoor and outdoor use per label claim. Intended users includes the general public, professional and trained professionals. More specially for trained professional users, uses include in open areas, waste dumps and sewers.

In support of this request, as supplementary data, the applicant wishes to consider an aged palatability study completed for a similar product. Compared to Ratimor Brodifacoum Wax Blocks, the former does not contain preservative; contains bromadiolone instead of brodifacoum; has 50ppm active substance concentration; has similar inert fillers/bait materials; and one of main components of both formulations is wheat. The provided palatability study was conducted on *Rattus norvegicus* which exhibits the efficacy and palatability of the aged (2 year) for a similar product without any preservative (Author, 2005) . The mean bait consumption was 47.2% of the total food consumption with 100% mortality 7-9 days after exposure to bait. As the similar product does not contain preservative and contains bait ingredients wheat flour, sugar, water and milk powder which should enable mould growth, even without the preservative the mould growth was resisted and remained palatable and efficacious. Therefore the IE CA confirms that this study is applicable, and that data demonstrated an acceptable level of palatability and mortality at the end of the 2-year shelf life.

In addition, Ratimor Brodifacoum Wax blocks also contains a preservative ingredient paraffin wax binder. The paraffin wax binder offers protection to mould growth as it’s used as a coating agent to enhance stability and preservation. Therefore, the previously evaluated data for Ratimor Brodifacoum Wax Blocks per efficacy section 3.5, remains applicable.

In order to minimize the number of experiments on animals, the IE CA accepts the additional study provided by (AUTHOR, 2005) and the previously submitted efficacy data package for Ratimor Brodifacoum Wax Blocks (per section 3.5) as sufficient to demonstrate efficacy and palatability of the product.

*List of studies and documents:*

| **Author(s)** | **Year** | **Title.Source (where different from company)Company, Report No.GLP /(Un)published** | **Data Protection Claimed(Yes/No)** | **Owner** |
| --- | --- | --- | --- | --- |
|  | 1999 | Storage stability and Physical-Chemical Characteristics of a 0.05 g/kg pelleted bait formulation also containing 0.01 g/kg denatonium benzoate.School of Pure and Applied Biology, University of Wales Cardiff, Ref. Code: 95021260Yes / Unpublished | Yes |  |
|  | 2005 | Palatability and Efficacy of Aged Rodex Pellet Bait Formulation in Laboratory Rats. BioTest s.r.o., 16/2005No / Unpublished | Yes |  |
|  | 2014 | Product Data. No. 4982-E, Rev. 01-2014N/A / Published | No |  |
|  | 2021 | Statement regarding efficacy, palatability and stability studies related to formulation change of Ratimor Brodifacoum Wax Blocks.Unichem, 17.09. 2021N/A / Unpublished | No | Unichem d.o.o. |

1. **Confidential annex (Access level: “Restricted” to applicant and authority)**
	1. ***Full composition of the product***
1. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014. [↑](#footnote-ref-1)
2. Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of Brodifacoum as an active substance for use in biocidal products of product-type 14 [↑](#footnote-ref-2)
3. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. [↑](#footnote-ref-3)
4. Access level: “Restricted” to applicant and authority [↑](#footnote-ref-4)
5. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. [↑](#footnote-ref-5)
6. Commission Implementing Decision (EU) 2017/532 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. [↑](#footnote-ref-6)
7. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-7)