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 | **DERAT ZIARNO** |
| Product type: | **14 (Rodenticide)** |
| Active ingredient(s): | **Brodifacoum** |
| Case No. in R4BP | **BC-WH032954-25** |
| Asset No. in R4BP | **PL-0004791-0000** |
| Evaluating Competent Authority | **PL CA** |
| Internal registration/file no | **UR.DRB.RBR.4250.** |
| Date |  |

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**Overview of applications**

|  |  |  |  |
| --- | --- | --- | --- |
| **Application type** | **Ref MS** | **Decision date** | **Assessment carried out** |
| NA-APP | PL | 21-02-2014 | Initial assessment |
| NA-MIC | PL | 21-02-2017 | Amendment (SPC) |
| NA-AAT | PL | 10-02-2019 | Amendment (Expiry date of the authorisation changed) |
| NA-RNL | PL |  | Renewal of authorisation |

# Conclusion

The Polish CA for the authorisation of biocidal products has processed an application for renewal of the biocidal product **DERAT ZIARNO** which contains the active substance Brodifacoum (0.001% w/w).

The conditions for granting an authorisation according to Article 19(1) of the Regulation (EU) No 528/2012[[1]](#footnote-2) (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. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control 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 Poland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Poland. 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 Poland. Therefore usage of Article 19(5) to renew the authorisation is justified in Poland. 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.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008[[2]](#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 **DERAT ZIARNO** has been conducted (for details see Section 3.10).

As the outcome of the comparative assessment was not sufficiently conclusive to state that the criteria of Article 23(3) BPR are met, the product can be **authorised for a period not exceeding 5 years.**

**Composition and formulation**

The ready-to-use product is a grains 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**

New data has been submitted to be taken into account for the renewal evaluation.

The new data supports the conclusion from the former assessment and extends the shelf life of the product to 4 years.

**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**

Anticoagulant rodenticides are considered essential to ensure appropriate rodent control 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 Poland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Poland.

The assessment presented in the Product Assessment Report for the first authorisation showed acceptable efficacy if the product is used as a rodenticide (product-type 14) for use in buildings, by the non-professionals, professionals and trained professionals. Derat Ziarno is effective after 4 years aged bait amended at the renewal stage in 2019.

**Risk assessment for human health**

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

According to the BPC Opinion[[3]](#footnote-4) the EFSA Guidance on dermal absorption[[4]](#footnote-5) had been taken into account when reviewing the dermal absorption of the product.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to general public, professional users, trained professional users, bystanders and residents if the directions for use are followed.

For risk mitigation measures please refer to 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.

Despite the above, the conclusions from the risk assessment performed for Derat Ziarno in 2014 remain valid and again mammals during primary and secondary exposure. For that reason the biocidal product Derat Ziarno should be authorised in accordance with Article 19 (5) BPR. In addition, the renewal of Derat Ziarno`s authorisation should be subjected to the following conditions:

* primary as well as secondary exposure of humans, non-target animals and the environment are minimised by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
* dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

**Overall conclusion**

The assessment of the biocidal product **DERAT ZIARNO** 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.

# Summary of the product assessment

## Administrative information

### Identifier in R4BP

|  |
| --- |
| **DERAT ZIARNO** |
| Additional trade name(s): |

### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | FREGATA S.A. |
| **Address** | ul. Grunwaldzka 497, 80-309 Gdańsk, Poland |
| **Authorisation number** | PL/2014/0121 | |
| **Date of the authorisation** |  | |
| **Date of the renewal** |  | |
| **Expiry date of the authorisation** |  | |

### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | FREGATA S.A. |
| **Address of manufacturer** | ul. Grunwaldzka 497, 80-309 Gdańsk, Poland |
| **Location of manufacturing sites** | ul. Grunwaldzka 497, 80-309 Gdańsk, Poland |

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

|  |  |
| --- | --- |
| **Active substance** | Brodifacoum |
| **Name of manufacturer** | PelGar International Limited |
| **Address of manufacturer** | Unit 13, Newman Lane Alton, Hampshire GU34 2QR, United Kingdom |
| **Location of manufacturing sites** | PelGar International Ltd, Prazska 54, 280 02 Kolin, Czech Republic |

## 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-[(1RS,3RS;1RS,3SR)-  3-(4′-bromobiphenyl-4-yl)-  1,2,3,4-tetrahydro-1-  naphthyl]-4-hydroxycoumarin | Active Substance | 56073-10-0 | 259-980-5 | 0.001 |

* The product contains a bittering agent and a dye.
* Information on the full composition is provided in the Confidential[[5]](#footnote-6) Annex (see Chapter 5).
* According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of the Regulation No. 528/2012.

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

There are no substances of concern.

### Candidate(s) for substitution

Brodifacoum does meet the exclusion criteria according to Article 5(1) BPR because the following exclusion criteria are met:

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

and therefore, Brodifacoum does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

### Type of formulation

|  |
| --- |
| Ready-to-use bait: Grains |

## Classification and Labelling according to the Regulation (EC) No 1272/2008[[6]](#footnote-7)

Table 2

| Classification Hazard classes Hazard categories | Hazard statements |
| --- | --- |
| None | None |
| None | None |

Table 3

| Labelling | Code | Pictogram / Wording |
| --- | --- | --- |
|  | None | None |
| Signal word | None | None |
| Hazard statements | None | None |
| None | None |
| Supplemental label elements | None | None |
| Precautionary statements: | P102 | Keep out of reach of children. |
| P280 | Wear protective gloves. |
| Note | None | None |

## Uses appropriate for further authorisation[[7]](#footnote-8)

Table 4: Summary of Uses

|  |  |
| --- | --- |
| **No.** | **Use** |
| 1 | House mice – general public – indoor |
| 2 | House mice – professionals – indoor |
| 3 | House mice – trained professionals – indoor |

### 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 mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | General public |
| Pack sizes and packaging material | **Maximum pack size: 150 g**  Welded, emptiable ziplock bag (PET/PE) for single use. |

#### Use-specific instructions for use

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

#### Use-specific risk mitigation measures

|  |
| --- |
| None |

#### 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 – House mice – professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | **Minimum pack size 1 kg**   1. Welded PET/PE bag made of foil resistant to tearing, up to 20 kg. 2. Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, up to 20 kg. 3. Welded PE bag resistant to tearing placed additionally in a paper bag, up to 20 kg. |

#### Use-specific instructions for use

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

#### Use-specific risk mitigation measures

|  |
| --- |
| None |

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

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

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

|  |
| --- |
| 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 – House mice – trained professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | **Minimum pack size 1 kg**   1. Welded PET/PE bag made of foil resistant to tearing, up to 20 kg. 2. Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, up to 20 kg. 3. Welded PE bag resistant to tearing placed additionally in a paper bag, up to 20 kg. |

#### Use-specific instructions for use

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

#### Use-specific risk mitigation measures

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

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

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

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

|  |
| --- |
| None |

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

|  |
| --- |
| None |

## General directions for use

### Instructions for use

### Instructions for use – General public

|  |
| --- |
| * Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. * Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered. * Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve. * Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). * Where possible, bait stations must be fixed to the ground or other structures. * Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals. * Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. * Do not place bait stations near water drainage systems where they can come into contact with water. * When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product. * Remove the remaining bait or the bait stations at the end of the treatment period. |

#### Instructions for Use - Professionals

|  |
| --- |
| * Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. * Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation. * Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve. * The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control. * Consider preventive control measures (e.g. plug holes, remove potential food and drink as far as possible) to improve product intake and reduce the likelihood of reinvasion. * Bait stations/ points should be placed in the immediate vicinity of places where rodent activity has been previously observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). * Where possible, bait stations must be fixed to the ground or other structures. * Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened (see section 2.5.3 for the information to be shown on the label). * [If national policy or legislation require it] When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits. * Bait should be secured so that it cannot be dragged away from the bait station. * Place the product out of the reach of children, birds, pets, farm animals and other non-target animals. * Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. * Wear protective chemical resistant gloves during product handling phase (*glove material to be specified by the authorisation holder within the product information*). * When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product. * If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations to further places and the possibility to change to another bait formulation. * If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant 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. * Loose pellets-granules, grains: Place the bait in the bait station by using a dosage devise. |

#### Instructions for Use – Trained Professionals

|  |
| --- |
| * Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it. * Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation. * Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve. * The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control. * The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). * Where possible, bait stations must be fixed to the ground or other structures. * Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 2.5.3 for the information to be shown on the label)*. * *[If national policy or legislation requires it]* When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits. * Bait should be secured so that it cannot be dragged away from the bait station. * Place the product out of the reach of children, birds, pets and farm animals and other non-target animals. * Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these. * Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). * When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product. * The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice. * If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation. * If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure. * Loose pellets-granules, grains: Place the bait in the bait station by using a dosage devise. |

### Risk mitigation measures

#### Risk mitigation measures – General Public

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

#### Risk mitigation measures - Professionals

|  |
| --- |
| * Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [*in accordance with the applicable code of good practice, if any*]". * To reduce risk of secondary poisoning, search for and remove dead rodents at frequent intervals during treatment (e.g. at least twice a week). *[Where relevant, specify if more frequent or daily inspection is required*]. * Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment. * Do not use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities. * The product information (i.e. label and/or leaflet) shall clearly show that: * the product shall not be supplied to the general public (e.g. "for professionals only"). * the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only"). * users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. label bait stations according to the product recommendations"). * 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 wash the bait stations with water between applications. * Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label].* |

#### Risk mitigation measures – Trained Professionals

|  |
| --- |
| - Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*".  - The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only").  - Do not use in areas where resistance to the active substance can be suspected.  - Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.  - Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.  - Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.  - Dispose 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]*. |

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

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

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

|  |
| --- |
| At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. Use of gloves is recommended. |

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

|  |
| --- |
| Shelf-life: 4 years  Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.  Store in places prevented from the access of children, birds, pets and farm animals.  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 consumption of the bait.  Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.  This product contains a bittering agent and a dye.  For general public: The package of the product should be fitted with a tactile warning. |

### Documentation

#### Data submitted in relation to product application

Please see General Annexes Section 4.1.

# Assessment of the product

## 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 mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | General public |
| Pack sizes and packaging material | **Maximum pack size: 150 g**   1. Welded, emptiable ziplock bag (PET/PE) for single use. |

### Use 2 – House mice – professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | Professionals |
| Pack sizes and packaging material | **Minimum pack size 1 kg**   1. Welded PET/PE bag made of foil resistant to tearing, up to 20 kg. 2. Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, up to 20 kg. 3. Welded PE bag resistant to tearing placed additionally in a paper bag, up to 20 kg. |

### Use 3 – House mice – trained professionals – indoor

|  |  |
| --- | --- |
| Product Type(s) | 14 |
| Where relevant, an exact description of the use | Rodenticide |
| Target organism(s) (including development stage) | House mice (*Mus musculus/domesticus*) – 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 | 100 g of bait per bait station placed every 3-4 m. |
| Category(ies) of users | Trained Professionals |
| Pack sizes and packaging material | **Minimum pack size 1 kg**   1. Welded PET/PE bag made of foil resistant to tearing, up to 20 kg. 2. Polyethylene bag closed with clamped seal placed additionally in a HDPE or polypropylene bucket, closed with clamped lid on the container, up to 20 kg. 3. Welded PE bag resistant to tearing placed additionally in a paper bag, up to 20 kg. |

## Physical, chemical and technical properties

One new study was provided and evaluated below. All other conclusions from the former assessments (PAR, 2014 with Amendments) regarding physical, chemical and technical properties remains valid. No new guidance had to be taken into account for the renewal evaluation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| Physical state, colour and odour | Polish Pharmacopoeia, VI edition (2002) | Derat Ziarno (0.001% w/w of brodifacoum) | Before storage:  greenish grains, characteristic odour  After 4 years:  no change was observed | FRE 01/DZ/2017 |
| Acidity / alkalinity | CIPAC MT 75.3 | Derat Ziarno (0.001% w/w of brodifacoum) | Before storage:  pH = 5.63, 1% w/v  After 4 years:  pH = 5.70, 1% w/v | FRE 01/DZ/2017 |
| Storage stability test – **long term storage at ambient temperature** | Techn. Monograph GIFAP No. 17,  4 years at 20º ±2ºC | Derat Ziarno (0.001% w/w of brodifacoum) | Before storage:  0.00100%  After 4 years:  0.00099% | FRE 01/DZ/2017 |
| Storage stability test – **reactivity towards container material** | Techn. Monograph GIFAP No. 17,  4 years at 20º ±2ºC | Derat Ziarno (0.001% w/w of brodifacoum) | Container material: PET/PE bag.  No change to shape and colour of container material was observed after 4 year of storage. Observed weight change was negligible. | FRE 01/DZ/2017 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product, grains is stable and shows no reactivity towards container material after 4 years of storage at 20º ± 2ºC. Therefore, shelf-life of 4 years can be accepted. |

## 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 (PAR, 2014).

## 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 (PAR, 2014).

## Efficacy against target organisms

# Derat Ziarno is intended to be used against *Mus musculus* (house mouse).

# Field trial test was conducted on the house mouse (*Mus musculus*) and brown rat (*Rattus norvegicus*). It used four-years aged bait and fresh bait in the same conditions. All of them demonstrate that the product is acceptable against *Mus musculus*.

# Applicant (at the renewal stage in 2019) submitted test report which is not conducted according to TNSG[[8]](#footnote-9). However, test report demonstrate that the product is acceptable against house mouse.

#### Efficacy data

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Brodifacoum 0.001 % | House mouse  *(Mus*  *musculus)*  Brown rat  *(Rattus norvegicus)* | Field test done according to  KES-01/2009 | House mouse  The size of rodents population was evaluated  by measure of control bait intake at the beginning and the end of the study (after 69 months).  100 g Derat Ziarno has been placed into each bait station spaced every 3 – 4 meters in infested area. Bait stations were refilled 5 times every 3 days.  After 20 days three parameters were tested:  1) percentage loss of intake control bait,  2) percentage loss of intake poison bait  3) percentage of active holes.  Brown rat  The size of rodents population was evaluated by measure of control bait intake at the beginning and the end of the study (after 69 months).  200 g Derat Ziarno has been placed into each bait station located every 15 meters in infested area. Bait stations were refilled 5 times every 3 days.  After 20 days three parameters were tested:  1) percentage loss of intake control bait,  2) percentage loss of intake poison bait  3) percentage of active holes. | House mouse:  The study indicates that  1) intake of control bait was reduced 94.7%  2) intake of tested bait was reduced 92.3%  3) percentage of active holes was reduced to 4.8%  Brown rat  The study indicates that  1) intake of control bait was reduced 92.7%  2) intake of tested bait was reduced 90.6%  3) percentage of active holes was reduced to 4.3% | Derat Ziarno Ignatowicz 2019 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| **The conclusions from the efficacy performed for Derat Ziarno in 2013 are still valid** with the exception of the claim that Derat Ziarno is effective after 4 years aged bait amended at the renewal stage in 2019. |

## Risk assessment for human health

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

The product has been evaluated using new dermal absorption guidance.

The conclusion from the former assessment regarding effects of the product on human health remains valid, with the following exceptions:

* CLP in accordance with the 9th ATP (Commission Regulation (EU) 2016/1179 of 19 July 2016) has been applied to this renewal.
* Dermal absorption has been re-evaluated in accordance with the EFSA Guidance on Dermal Absorption (2017). As a result, the dermal absorption value is 3% for this product renewal. A revised human health exposure assessment has therefore been conducted and can be found in Sections 3.6.3 and 3.6.4 of this renewal PAR.

### Exposure assessment

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: relevant paths of human exposure** | | | | | | | |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via Food** |
| Inhalation | N/A | Yes | N/A | N/A | N/A | N/A | N/A |
| Dermal | N/A | Yes | Yes | N/A | N/A | N/A | N/A |
| Oral | N/A | N/A | N/A | N/A | N/A | Yes | N/A |

**List of scenarios**

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: scenarios** | | | |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** |
| 1 | Decanting of loose granules | Primary exposure: decanting of loose granules bait from > 10 kg containers | Professional |
| 2 | Loading of bait stations | Primary exposure: securing granules into bait stations | Professional, General public |
| 3 | Clean-up and disposal | Primary exposure: clean-up and empty loaded bait stations | Professional, General public |
| 4 | Oral ingestion of bait | Secondary exposure: toddles transient mouthing of bait | Bystanders |

**Industrial use**

The product is not intended for industrial users.

**Professional exposure**

Where the proposed packaging for loose pellets is >10kg, the decanting of 3 kg pellets from packaging >10 kg into a bucket is assumed according to HEEG Opinion 12[[9]](#footnote-10).

Exposure to loose pellets is considered the worst-case scenario.

**Scenario 1 – Primary exposure during decanting of loose pellet bait**

In accordance with HEEG Opinion 10[[10]](#footnote-11)and 12, the agreed number of manipulations for professional user during loading loose pellets is 63 per day/person.

To assess the number of decanting operations necessary, the highest recommended dose for mouse control is 100 g of bait per bait point/station.

Given that each decanting operation assumes 3 kg bait:

• For 63 manipulations at 100 g per bait point the resulting amount of product used per day is 6.3 kg (63 x 100 g),

• 6.3 kg bait requires 2.1 (6.3 / 3 kg) decanting operations per day,

• based on the 2.1 decanting operations and assuming 3 min/decanting operation the total time decanting is estimated to be 56.3 min or 0.105 h.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 1** | | |
| Potential dermal and inhalation exposure is predicted for professional user during decanting loose pellet baits. Each decanting operation assumes 3 kg bait and the approximate decanting time is 0,105 h (56.3 min) based on the assumption of 3 min/decanting. | | |
| Tier 1 | Parameters | Value |
| Adult body weight | 60 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Dermal penetration | 3% |
| Dermal exposure (indicative 75th percentile for > 4 manipulation) during decanting | 93.0 mg b.p. / 3 kg |
| Number of 3 kg decanting operations | 2.1 |
| Amount of dermal exposure to the product | 93.0 mg b.p. x 2.1 = 195.3 mg b.p. |
| Air concentration of b.p. | 9.62 mg b.p./m3 |
| Exposure time | 0.105 h |
| Inhalation rate | 1.25 m3/h |
| Inhalation absorption | 100% |
| Tier 2 | PPE gloves penetration for challenges by solid formulation | 5% |

Calculations for Scenario 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum for professional use** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| 1 (no PPE) | 2.10 x 10-7 | 9.77 x 10-7 | N/A | 1.19 x 10-6 |
| 2 (PPE, gloves) | 2.10 x 10-7 | 4.88 x 10-7 | N/A | 6.98 x 10-7 |

**Scenario 2: Primary exposure during loading of loose pellet bait and placing bait boxes**

Professional loading of bait boxes consists of scooping bait, filling bait points and placing bait boxes.

|  |
| --- |
| **Description of Scenario 2** |
| Potential dermal is predicted for professional user during loading of loose pellet baits. Inhalation exposure is not expected. In accordance with HEEG Opinion 10 and 12, the agreed number of manipulation for professional user during loading of loose pellets is 63 per day/person. The indicative exposure during loading of bait boxes is 3.57 mg b.p<4 manipulations. |

|  |  |  |
| --- | --- | --- |
| Tier 1 | Parameters | Value |
| Adult body weight | 60 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Dermal penetration | 3% |
| Dermal exposure to product (indicative 75th percentile for > 4 manipulation) during 63 manipulations of loading | 3.57 mg b.p. x 63 manipulations = 224.91 mg of product |
| Tier 2 | PPE gloves penetration for challenges by solid formulation | 5% |

Calculations for Scenario 2

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum from professional use** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| 1 (no PPE) | N/A | 1.12 x 10-6 | N/A | 1.12 x 10-6 |
| 2 (PPE, gloves) | N/A | 5.62 x 10-8 | N/A | 5.62 x 10-8 |

**Scenario 3: Primary exposure during clean-up and empty bait boxes**

Post-application professional user may be required to clean-up and empty partly loaded bait station into a bucket. Dermal exposure is likely to be limited to the hands only when emptying loaded bait stations into a bucket.

|  |
| --- |
| **Description of Scenario 3** |
| In accordance with HEEG Opinion 10 and 12, the agreed number of manipulation for professional user during clean-up/empty bait boxes is 16 per day/person. The indicative exposure during clean-up/emptying of bait boxes is 4.52 mg b.p<4 manipulations. |

|  |  |  |
| --- | --- | --- |
| Tier 1 | Parameters | Value |
| Adult body weight | 60 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Dermal penetration | 3% |
| Dermal exposure to product (indicative 75th percentile for > 4 manipulation) during 16 manipulations of clean-up | 4.52 mg b.p. x 16 manipulations = 72.32 mg of product |
| Tier 2 | PPE gloves penetration for challenges by solid formulation | 5% |

Calculations for Scenario 3

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum from professional use** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| 1 (no PPE) | N/A | 3.61 x 10-7 | N/A | 3.61 x 10-7 |
| 2 (PPE, gloves) | N/A | 1.81 x 10-8 | N/A | 1.81 x 10-8 |

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure for brodifacoum for professional uses** | | | | |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario 1: decanting of loose pellet bait (tier 1 – no PPE) | 2.10 x 10-7 | 9.77 x 10-7 | N/A | 2.67 x 10-6 |
| Scenario 2: loading of loose granules and placing bait boxes (tier 1 – no PPE) | N/A | 1.12 x 10-6 | N/A |
| Scenario 3: clean-up and emptying of bait boxes (tier 1 – no PPE) | N/A | 3.61 x 10-7 | N/A |

***Exposure of the general public***

***General public (Non-professional) exposure***

Although non-professional users are untrained and cannot be expected to wear protective clothing, the application pattern of Brodifacoum 0.001% w/w pellet bait by the general public is similar to non-trained professional users. The use is occasional, for a short time in a single day and unlikely to be repeated more than once a week. However, in accordance with the CARs on various Rodenticides and proposed by HEEG (2010), fewer manipulations as compared to professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a non-professional user.

After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels).

**Scenario 4: Deploying bait station (Application phase)**

|  |
| --- |
| **Description of Scenario 4** |
| In this scenario the user may be in contact with the bait when the bait is loaded and placed. General public (non-professional user) is not bounded to use PPE during the development of the different tasks of product’s application although its use is recommended in the product’s label. Inhalation exposure is considered as negligible during this scenario. |

|  |  |  |
| --- | --- | --- |
| Tier 1 | Parameters | Value |
| Adult body weight | 60 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Dermal penetration | 3% |
| Number of manipulations | 5 |
| Dermal exposure to product (indicative 75th percentile for > 4 manipulation) during 63 manipulations of loading | 2.04 mg b.p. x 5 manipulations = 10.2 mg of product |

Calculations for Scenario 4

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum from professional use** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| 1 (no PPE) | N/A | 5.25 x 10-8 | N/A | 5.25 x 10-8 |

**Scenario 5: Primary exposure during clean-up and empty bait boxes**

|  |
| --- |
| **Description of Scenario 5** |
| During the process of cleaning the bait boxes, non-professional users are expected to collect and dispose of unused or part-used products.  After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels).  Bait stations for use by the non-professional user (general public) may be supplied as lockable, tamper-proof units that may be refilled by the user. |

|  |  |  |
| --- | --- | --- |
| Tier 1 | Parameters | Value |
| Adult body weight | 60 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Dermal penetration | 3% |
| Number of manipulations | 5 |
| Dermal exposure to product (indicative 75th percentile for > 4 manipulation) during 5 manipulations of clean-up | 3.79 mg b.p. x 5 manipulations = 18.95 mg of product |

Calculations for Scenario 5

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum from professional use** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| 1 (no PPE) | N/A | 9.48 x 10-8 | N/A | 9.48 x 10-8 |

**Scenario 6 - Secondary exposure of a toddler transient mouthing of block bait**

|  |
| --- |
| **Description of Scenario 6** |
| The critical scenario for secondary exposure in relation to the use of rodenticide block baits is the consumption of the formulation by toddlers. The likelihood of this is reduced by the positioning of the bait in stations and boxes which have been designed to prevent access to the contents. The formulation also contains a human aversive agent that in some cases may help to prevent toddlers chewing and ingesting bait. However, instances of exposure could occur. The TNsG and the User Guidance indicate that an estimate of exposure can be made by assuming that either 10 mg (TNsG 2002, part 2, p.58) or 5 g (TNsG User Guidance, version 1, p. 73) of bait is swallowed by a 10 kg toddler. It should be noted that the User Guidance states that there is a risk of ingestion “if no bait box is used”. Exposure can be calculated as follows, assuming 100% oral absorption: |

|  |  |  |
| --- | --- | --- |
| Tier 1 | Parameters | Value |
| Toddler body weight | 10 kg |
| Active substance | Brodifacoum |
| Concentration of active substance | 0.001% |
| Oral penetration | 100% |
| Amount of bait ingested by toddler (in absence of bittering agent) | 5 g |
| Tier 2 | Amount of bait ingested by toddler (considering presence of bittering agent) | 10 mg |

Calculations for Scenario 6

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated exposure to brodifacoum to the general public** | | | | |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake**  **(mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| 1 | N/A | N/A | 5 x 10-3 | 5 x 10-3 |
| 2 | N/A | N/A | 1 x 10-5 | 1 x 10-5 |

Combined scenarios

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure for brodifacoum for general public** | | | | |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario 4: loading of loose granules and placing bait boxes (tier 1 – no PPE) | N/A | 5.25 x 10-8 | N/A | 1.47 x 10-7 |
| Scenario 5: clean-up and emptying of bait boxes (tier 1 – no PPE) | N/A | 9.48 x 10-8 | N/A |

**Dietary exposure**

No dietary exposure is foreseen from the use of the product.

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

Given that the modelling of exposures and subsequent risk characterisation during production and formulation of this product is addressed under other EU legislation (e.g. Directive 98/24/EC[[11]](#footnote-12))(as agreed at Biocides Technical Meeting TMI06), the PL CA has not considered exposure from production of the biocidal product further.

**Summary of exposure assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment of brodifacoum** | | | |
| **Scenario number** | **Exposed group (eg. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake (mg a.s./kg bw/day)** |
| 1. | Decanting of loose granules (including inhalation exposure); professionals | 1 (no PPE) | 1.19 x 10-6 |
| 2 (PPE, gloves) | 6.98 x 10-7 |
| 2. | Loading of bait stations; professionals | 1 (no PPE) | 1.12 x 10-6 |
| 2 (PE, gloves) | 5.62 x 10-8 |
| 3. | Clean-up and disposal; professionals | 1 (no PPE) | 3.61 x 10-7 |
| 2 (PE, gloves) | 1.81 x 10-8 |
| 4. | Loading of bait stations; non-professionals | 1 (no PPE) | 5.25 x 10-8 |
| 5. | Clean-up and disposal; non-professionals | 1 (no PPE) | 9.48 x 10-8 |
| 6. | Oral ingestion of bait; bystanders | 1 | 2,5 x 10-2 |
| 2 | 5 x 10-5 |

### Risk characterisation for human health

**Risk for industrial users**

The product is not intended for industrial users.

**Risk for professional users**

**Systemic effects for brodifacoum**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/scenario** | **Tier** | **AEL (long-term) mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **Estimated uptake/AEL (%)** | **Acceptable (yes/no)** |
| Scenario 1: decanting of loose pellet bait | 1 (no PPE) | 3,3x10-6 based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day | 1.19 x 10-6 | 36% | Yes |
| 2 (PPE, gloves) | 6.98 x 10-7 | 21% | Yes |
| Scenario 2: Primary exposure during loading of loose pellet bait and placing bait boxes | 1 (no PPE) | 3,3x10-6 based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day | 1.12 x 10-6 | 34% | Yes |
| 2 (PPE, gloves) | 5.62 x 10-8 | 2% | Yes |
| Scenario 3: Primary exposure during clean-up and empty bait boxes | 1 (no PPE) | 3,3x10-6 based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day | 3.61 x 10-7 | 1% | Yes |
| 2 (PPE, gloves) | 1.81 x 10-8 | <1% | Yes |

**Combined scenarios for brodifacoum**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL (long-term) mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **Estimated uptake/AEL (%)** | **Acceptable (yes/no)** |
| Scenario 1: decanting of loose pellet bait (tier 1 – no PPE) | 1 | 3,3x10-6 based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day | 2.67 x 10-6 | 81% | Yes |
| Scenario 2: loading of loose granules and placing bait boxes (tier 1 – no PPE) |
| Scenario 3: clean-up and emptying of bait boxes (tier 1 – no PPE) |

#### Risk for the general public

Systemic effects for brodifacoum

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AEL (short term) mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable (yes/no)** |
| Scenario 4: Loading of bait stations | **1** | 6.67x10-6  Rabbit: Maternal toxicity from a Developmental study (NOAEL = 0.002 mg/kg bw/d) | 5.25 x 10-8 | <1% | Yes |
| Scenario 5: Clean-up and disposal | **1** | 6.67x10-6  Rabbit: Maternal toxicity from a Developmental study (NOAEL = 0.002 mg/kg bw/d) | 9.48 x 10-8 | 1% | Yes |
| Scenario 6:  Secondary exposure of a toddler transient mouthing of block bait (5 g) | 1 | 6.67x10-6  Rabbit: Maternal toxicity from a Developmental study (NOAEL = 0.002 mg/kg bw/d) | 2,5 x 10-2 | 374 813% | No |
| 2 | 5 x 10-5 | 750% | No |

**Combined scenarios for brodifacoum**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL (short term) mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **Estimated uptake/AEL (%)** | **Acceptable (yes/no)** |
| Scenario 2: loading of loose granules and placing bait boxes (tier 1 – no PPE) | 1 | 6.67x10-6  Rabbit: Maternal toxicity from a Developmental study (NOAEL = 0.002 mg/kg bw/d) | 1.47 x 10-7 | 2% | Yes |
| Scenario 3: clean-up and emptying of bait boxes (tier 1 – no PPE) |

**Conclusion**

* Exposure for general public (non-professional) applying ‘Brodifacoum 0.001% w/w pellet bait’ for control of mice is acceptable without the use of PPE under the assumption of 5 manipulations per day.
* The secondary exposure of a toddler transient mouthing of block bait is predicted to result in systemic exposure over 100% of the AEL of brodifacoum and therefore there is a potential risk for the general public. To mitigate the risk of secondary human exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:
* Keep locked up and out of reach of children.
* Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pig sand poultry).
* Baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

#### Risk for consumers via residues in food

Not applicable. The product is not used where food can be contaminated with residues.

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid (PAR, 2014).

#### 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 no safe usage combined scenarios for professional users the brodifacoum pellet product without PPE during decanting phase, loading phase and cleaning/disposal, derived values amounted to 2.67 x 10-6 (**81%** AEL). Derived values indicated a safe usage combined scenarios for professional users the brodifacoum pellet product with PPE during loading phase and without PPE during cleaning/disposal, derived values amounted to 2.23 x 10-6 (**68%** AEL).

Derived values indicated a safe usage combined scenarios for non-professional users the brodifacoum pellet product without PPE during loading phase and cleaning/disposal, derived values amounted to 1.47 x 10-7 (**2%** AEL).

Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the pellet product due its teratogen properties. Derived values for oral exposures in the toddler found transient mounting of a pellet not containing a repellent to result in a dose of 5 mg (**374 813**% AEL). Derived values for oral exposures in the toddler found transient mounting of a grains containing a repellent to result in a dose of 10 mg (**750**% 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 assessment for animal health

To mitigate the risk of secondary animal exposure, all anticoagulant rodenticides are required to be labelled with precautionary phrases. These include:

* prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry),
* baits must be securely deposited in a way so as to minimize the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away.

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 animal health remains valid (PAR, 2014).

## Risk assessment for the environment

**The conclusions from the risk assessment performed for Derat Ziarno in 2014 are still valid**  with the exception of the following parts amended at the renewal stage in 2019:

**3.8.1. Groundwater assessment**

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 have to address the groundwater assessment. Due to absence of specific PT 14 guidance on the assessment for groundwater a standard approach should be used:

- Tier I according to Vol. IV Part B+C (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 (2014) exposure assessment for biocidal product Derat Ziarno contained Tier 1 assessment for the groundwater only and resulted in the following concentrations of brodifacoum:

|  |  |
| --- | --- |
| **Scenario** | **Concentration in groundwater [μg/L]** |
| In building | 0.0039 |

Since above results indicate that the maximum permissible concentration of brodifacoum in groundwater of 0.1 μg/L (as laid down by directive 2006/118/EC) has not been exceeded there is no need to perform the higher tier assessment.

**3.8.2. Primary and Secondary Poisoning**

In light of the high risk indicated for the primary and secondary poisoning for non-target animals resulting from the use of the biocidal product Derat Ziarno (please refer to the former PL assessment from 2014) and according to the BPC Opinion (ECHA/BPC/113/2016) and Regulation renewing the approval of brodifacoum in PT 14[[12]](#footnote-13) it should be stressed that the current authorisation of Derat Ziarno should be subjected to the following conditions:

* primary as well as secondary exposure of humans, non-target animals and the environment are minimised by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
* dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

## Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

## Comparative assessment

The Polish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Brodifacoum. 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 (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:

(a) 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?;

(b) 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?;

(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;

(d) Are these alternatives sufficiently effective?;

(e) 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) 2017/15326. In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Polish 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 Polish 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 Polish 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.

# General Annexes

## List of studies for the biocidal product

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Publication** | **Report no.** | **Legal entity owner** | **Report date** | **GLP/**  **GEP** | **Data Protection Claimed** |
| „FREGATA” S.A. | 2017 | Derat Ziarno  Badania właściwości fizykochemicznych przed i po czterech latach składowania preparatu w temperaturze 20oC | not published | Kod badania: FRE 01/DZ/2017 | „FREGATA” S.A. | 06.07.2017 | No | Yes |
| Prof. Dr hab. Ignatowicz Stanisław | 2019 | Badanie skuteczności preparatu Derat Ziarno przeznaczonego do zwalczania zgodnie z „Metodyką badań skuteczności preparatu przeznaczonego do zwalczania gryzoni”, KES-01/2009 | not published | - | „FREGATA” S.A. | 30.05.2019 | No | Yes |

## Output tables from exposure assessment tools

None

## 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 with a specific concentration limit of 0.003%. The product Derat Ziarno contains 0.001% of active substance, therefore could be authorised for use by general public.

## Residue behaviour

No assessment necessary.

## Other

None.

# Confidential annex (Access level: “Restricted” to applicant and authority)

## Full composition of the product

Full composition of the product is available in Confidential Annex.

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 (O. J. of the EU L 167/1, 27.6.2012 with amendments). [↑](#footnote-ref-2)
2. Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (O. J of the EU L 195/11, 20.7.2016). [↑](#footnote-ref-3)
3. Biocidal Products Committee (BPC) Opinion on the application for renewal of the approval of the active substance: Brodifacoum Product type: 14, ECHA/BPC/113/2016. [↑](#footnote-ref-4)
4. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. [↑](#footnote-ref-5)
5. Access level: “Restricted” to applicant and authority [↑](#footnote-ref-6)
6. 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 (O.J. of EU L 353, 31.12.2008). [↑](#footnote-ref-7)
7. Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR. [↑](#footnote-ref-8)
8. Technical Notes for Guidance on Product Evaluation Product Type 14 - Efficacy Evaluation of Rodenticidal Biocidal Products (February 2009). [↑](#footnote-ref-9)
9. HEEG opinion on an Harmonised approach for the assessment of rodenticides (anticoagulants), 07/02/2012. [↑](#footnote-ref-10)
10. HEEG opinion on Harmonising the number of manipulations in the assessment of rodenticides (anticoagulants), 13/08/2010 [↑](#footnote-ref-11)
11. COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (O. J. of the EU L 131/11, 7.04.1998) [↑](#footnote-ref-12)
12. 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-13)