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

**PRODUCT ASSESSMENT REPORT OF MINOR CHANGE OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



ALPHACHLORALOSE GRAIN

Product type 14

ALPHACHLORALOSE

Case Number in R4BP: BC-EH56192-51

Evaluating Competent Authority: FR CA

Date: [day/month/year]

Contents

[1 General information about the product application 2](#_Toc340131627)

[1.1 Applicant 2](#_Toc340131628)

[1.1.1 Person authorised for communication on behalf of the applicant 2](#_Toc340131629)

[1.2 Proposed authorisation holder 2](#_Toc340131630)

[1.3 Information about the product application 3](#_Toc340131631)

[1.4 Information about the biocidal product 3](#_Toc340131632)

[1.4.1 General information 3](#_Toc340131633)

[1.4.2 Information on the intended use(s) 4](#_Toc340131634)

[1.4.3 Information on active substance 6](#_Toc340131635)

[1.4.4 Information on the substance(s) of concern 6](#_Toc340131636)

[1.5 Documentation 6](#_Toc340131637)

[1.5.1 Data submitted in relation to product application 6](#_Toc340131638)

[1.5.2 Access to documentation 7](#_Toc340131639)

[2 Summary of the product assessment 8](#_Toc340131640)

[2.1 Identity related issues 8](#_Toc340131641)

[2.2 Classification, labelling and packaging 8](#_Toc340131642)

[2.2.1 Harmonised classification of the active substance 8](#_Toc340131643)

[2.2.2 Classification of the biocidal product 8](#_Toc340131644)

[2.2.3 Labelling of the biocidal product 9](#_Toc340131645)

[2.2.4 Packaging of the biocidal product 10](#_Toc340131646)

[2.3 Physico/chemical properties and analytical methods 10](#_Toc340131647)

[2.3.1 Active ingredient 10](#_Toc340131648)

[2.3.2 Biocidal product 11](#_Toc340131649)

[2.3.3 Analytical methods for detection and identification 18](#_Toc340131650)

[2.4 Risk assessment for physico-chemical properties 18](#_Toc340131651)

[2.5 Effectiveness against target organisms 20](#_Toc340131652)

[2.5.1 Function 20](#_Toc340131653)

[2.5.2 Organisms to be controlled and products, organisms or objects to be protected 20](#_Toc340131654)

[2.5.3 Effect on target organisms and efficacy 21](#_Toc340131655)

[2.5.4 Mode of action including time delay 21](#_Toc340131656)

[2.5.5 Occurrence of resistance - resistance management / Unacceptable Effect 22](#_Toc340131657)

[2.5.6 Evaluation of the label claim 22](#_Toc340131658)

[2.5.7 Conclusion of the efficacy assessment 23](#_Toc340131659)

[2.6 Description of the intended use(s) 24](#_Toc340131660)

[2.7 Risk assessment for human health 25](#_Toc340131661)

[2.7.1 Hazard potential 25](#_Toc340131662)

[2.7.2 Human exposure assessment 28](#_Toc340131663)

[2.7.3 Risk assessment for human health 32](#_Toc340131664)

[2.8 Risk assessment for the environment 36](#_Toc340131665)

[2.8.1 Fate and distribution in the environment of the active substance alphachloralose 36](#_Toc340131666)

[2.8.2 Effects on environmental organisms for active substance alphachloralose 38](#_Toc340131667)

[2.8.3 Effects on environmental organisms for biocidal product 41](#_Toc340131668)

[2.8.4 Environmental exposure assessment 42](#_Toc340131669)

[2.8.5 Risk characterisation for the environment 47](#_Toc340131670)

[2.9 Measures to protect man, animals and the environment 51](#_Toc340131671)

[3 Proposal for decision 52](#_Toc340131672)

[Annexes 56](#_Toc340131673)

[Annex 0a: Practical use claimed by the applicant 56](#_Toc340131674)

[Annex 0b : practical uses validated by RMS France 58](#_Toc340131675)

[Annex 1: Summary of product characteristics 59](#_Toc340131676)

[Annex 2: List of studies reviewed 60](#_Toc340131677)

[Annex 3: Analytical methods residues – active substance 64](#_Toc340131678)

[Annex 4: Toxicology and metabolism –active substance 67](#_Toc340131679)

[Annex 5: Toxicology – biocidal product 68](#_Toc340131680)

[Annex 6: Safety for professional operators 69](#_Toc340131681)

[Annex 7: Safety for non-professional operators and the general public 70](#_Toc340131682)

[Annex 8: Residue behaviour 72](#_Toc340131683)

[Annex 9: Efficacy of the active substance from its use in the biocidal product 73](#_Toc340131684)

**Note to the reader**

The biocidal product family ALPHACHLORALOSE GRAIN comes from the merge of products authorisation**.** This consolidated PAR for the minor change application of the product family authorisation ALPHACHLORALOSE GRAIN is based on the PAR of the initial authorisation for the reference product BLACK PEARL GRAIN, in which all necessary addenda have been included.

The SPC (p.3) corresponds to the authorised uses after the assessment of the minor change application 2020 in France.

In the following assessment report (p.10) of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post-authorisation data…).

The assessments related to the minor change 2020 of the product are at the end of the renewal application in each concerned section and are highlighted in grey.

**Disclaimer regarding user category**

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

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

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

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **Ref MS** | **Case number in the ref MS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | FR | - | 19/03/2013 | Initial assessment : BLACK PEARL GRAIN |
| NA-MRG | FR | BC-BF036893-46 | 26/06/2018 | Merge of product authorisation(s) in a family : ALPHACHLORALOSE GRAIN |
| NA-NPF | FR | BC-VA051689-30 | 18/09/2019 | Notification of product in product family for national authorisation : ALPHA C |
| NA-AAT | FR | - | 30/10/2019 | - |
| NA-MIC | FR | BC-PW056076-06 |  | National authorisation minor change on request :   * Modification of composition * Modification of packaging * Administrative changes |

# CONCLUSION

* **MINOR CHANGE (2020)**

**INTRODUCTION OF THE APPLICATION**

France, as e-CA, received an application from LODI for a minor change of authorisation for the biocidal product family ALPHACHLORALOSE GRAIN.

ALPHACHLORALOSE GRAIN is a biocidal product family with type of product 14 for the control of rodents (house mice) based on 4.4% (technical w/w) alphachloralose. The biocidal product is a ready-to-use bait (grain) , and is currently to be applied indoor by professional or non-professional users.

The minor change request concerns :

* Composition modifications
* Packaging modifications
* Administrative changes

**SUMMARY AND OVERALL CONCLUSION OF THE ASSESSMENT**

**Physico-chemical properties**

The stability data indicates a shelf life of 2 years at ambient temperature when stored in cardboard box + paper sachet. As the formulation is a ready-to-use grain bait, the PET+aluminium+PE doypack, the PP bucket, the carton box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 or 2 x 10g sachet, the PP (woven) bag can be considered as acceptable for 24 months.

Since the flowability test, required for loose grain bait, has not been provided, the claimed packagings “cardboard box case with inner PE or polypropylene (PP) lining” and “bucket PP” are considered not acceptable.

The provided method (Leclercq S., 2019) is fully validated for the determination of the active substance alphacloralose in the product ALPHACHLORALOSE GRAIN. The limit of quantification (LOQ) is 24 mg/L for alphachloralose.

Therefore, the 3 methods are considered validated for the determination of the alphachloralose content in the products of the ALPHACHLORALOSE GRAIN family, since these differences are not considered as being able to modify the performance of these methods.

**Efficacy**

French Competent Authorities (FR CA) assessed that the elements presented in the dossier are sufficient to demonstrate the efficacy of the products of the family ALPHACHLORALOSE GRAIN for the control of mice for indoor use by professional and non-professional users with a shelf life of 2 years.The application rates validated are the following:

* Mice (Mus musculus): 10-25 g / bait point separated by 3-5 m.

Post authorization: In France only: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance alphachloralose. Results of the resistance monitoring must be submitted at the renewal of the product.

**Substance of concern**

No substance of concern has been identified in the frame of the new formulation. Please see the confidential annex for further details.

**Human health**

Minor change is covered by the assessment of exposure performed in the first authorization.

The conclusions of risk assessment of the biocidal product family remain unchanged.

**Environment**

The biocidal product does not contain any substance of concern. Minor change is covered by the risk assessment for the environment performed in the first authorization.

The conclusions of risk assessment for the environment of the biocidal product remain unchanged.

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family ALPHACHLORALOSE GRAIN in the frame of the minor change has been demonstrated.

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| ALPHACHLORALOSE GRAIN |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | LODI S.A.S |
| **Address** | Parc d'activités des quatre routes  35 390 Grand Fougeray  France |
| **Authorisation number** | FR-2013-0004 (professional), FR-2013-1003 (non-professionnal), FR-2013-0016 (professional) and FR-2013-1008 (non-professionnal) | |
| **Date of the authorisation** | 2013/03/19 | |
| **Expiry date of the authorisation** | 2021/06/30 | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | LODI S.A.S. |
| **Address of manufacturer** | PARC D'ACTIVITES DES QUATRE ROUTES, 35390 GRAND FOUGERAY France |
| **Location of manufacturing sites** | PARC D'ACTIVITES DES QUATRE ROUTES, 35390 GRAND FOUGERAY France |

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

|  |  |
| --- | --- |
| **Active substance** | alphachloralose |
| **Name of manufacturer** | LODI S.A.S. |
| **Address of manufacturer** | PARC D'ACTIVITES DES QUATRE ROUTES, 35390 GRAND FOUGERAY France |
| **Location of manufacturing sites** | -HIKAL LTD. T-21. MIDC INDUSTRIAL AREA TALOJA RAIGAD DISTRICT,  410 208 MAHARASHTRA India  SUNTTON CO. LTD JINGYI ROAD, XINYI TANGDIAN CHEMICAL ZONE,  221415 JIANGSU China  SAREX, PLOT n°N129, N130, N131, N232  MIDS, TARAPUR, 401 506, MAHARASHTRA, INDIA |

### Product family composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Alphachloralose |
| **IUPAC or EC name** | (R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose |
| **EC number** | 240-016-7 |
| **CAS number** | 15879-93-3 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | ≥ 91% w/w |
| **Structural formula** | C8H11Cl3O6 |

#### Candidate(s) for substitution

*Not applicable*

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Alphachloralose (technical) | (R)-1,2-O-(2.2,2-Trichloroethylidene)-a-D-glucofuranose | Active Substance | 15879-93-3 | 240-016-7 | 4 | 4 |

#### 

#### Information on technical equivalence

The source of the active substance is not identical as the one indicated in the CAR. A technical equivalence has been obtained for the Suntton Co. Ltd manufacturing site (Decision TAP-D-1274306-31-00/F, dated 2017/11/16).

* **Minor Change application - 2020**

A technical equivalence has been obtained for the SAREX manufacturing site ((Decision TAP-D-1432081-27-00/F, dated 2020/02/12).

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

Please see the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal product family

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| RB, Bait (ready for use) |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

| Suffix | -1 |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 14 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Alphachloralose | (R)-1,2-O-(2.2,2-Trichloroethylidene)--D-glucofuranose | Pure active substance | 15879-93-3 | 240-016-7 | 4 | 4 |

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| RB, Bait (ready for use) |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1, Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning GHS 09 |
| Hazard statements | H410 Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment.  P391: Collect spillage.  P501: Dispose of contents/containers in accordance with local regulations. |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 1

#### Use description

Table 1. Use # 1 – Product for trained professionnal users

|  |  |
| --- | --- |
| **Product Type** | PT14 - Rodenticides (Pest control) |
| **Where relevant, an exact description of the authorised use** | This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations. |
| **Target organism (including development stage)** | *Mus musculus*- House mouse - Juveniles *Mus musculus* - House mouse - Adults |
| **Field of use** | Indoor This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations. |
| **Application method(s)** | Bait application  For use in tamper-resistant bait boxes or covered bait stations |
| **Application rate(s) and frequency** | High infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters.  Low infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.    Adapt number of sachet at the efficacy application rate and respect distance between bait station.  The number of bait station depend of the treatment area, geographical context and level of infestation.  The bait stations should be visited only few 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. Time required for the appearance of the biocidal effect: between 1 and 3 days after ingestion of the bait. |
| **Category(ies) of users** | Trained Professional |
| **Pack sizes and packaging material** | Individual sachets in polyethylene or polyethylene/paper  The products are supplied in:  - Individual sachet in paper (10 or 25g)  Sachets in paper are supplied in:  - Bucket (PP): 1Kg, 2.5Kg, 5Kg  - Cardboard box: 1Kg, 2.5Kg, 5kg, 6kg, 7kg, 8kg, 9kg, 10kg, 15kg, 20kg.  Sales to trained professionals will be done in a package that does not allow the purchase of less than 5 kg of product. |

##### Use-specific instructions for use

|  |
| --- |
| • Alternate products with active substances with different modes of action to avoid the appearance of resistance phenomena. • Adopt integrated management methods such as a combination of chemical, physical control and hygiene measures. • Check the effectiveness of the product on site: if necessary, the causes of the decrease in effectiveness must be sought in order to ensure the absence of resistance. • Do not use the product in areas where resistance cases are suspected or established. • Notify the authorisation holder in the event of treatment ineffectiveness or signs that may be interpreted as the development of resistance. |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

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| --- |
|  |

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

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|  |

#### Use description

Table 2. Use # 2 – **product for professionnal (not relevant in France) and non professional users**

|  |  |
| --- | --- |
| **Product Type** | PT14 - Rodenticides (Pest control) |
| **Where relevant, an exact description of the authorised use** | This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations. |
| **Target organism (including development stage)** | *Mus musculus* - House mouse - Juveniles *Mus musculus* - House mouse - Adults |
| **Field of use** | Indoor This product is to be used inside private, public and agricultural buildings against house mouses in tamper-resistant bait boxes or covered bait stations. |
| **Application method(s)** | Bait application  For use in tamper-resistant bait boxes. |
| **Application rate(s) and frequency** | High infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 3 meters.  Low infestation: (10-25) g of bait per baiting point. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters.  Adapt number of sachet at the efficacy application rate and respect distance between bait station.  The number of bait station depend of the treatment area, geographical context and level of infestation.  The bait stations should be visited only few 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.  Time required for the appearance of the biocidal effect: between 1 and 3 days after ingestion of the bait. |
| **Category(ies) of users** | Professionals General public (non-professional) |
| **Pack sizes and packaging material** | The product is supplied in:  - individual sachet in paper : 10 or 25 g  Sachets in paper or PE/paper are supplied in:  - Carton (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g,  560g)  - doypacks (200 or 500g)  - Can /Tin, Metal + PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g,  440g, 480g, 520g, 560g)  - Can /Tin, Metal (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g,  480g, 520g, 560g)  - Bucket PP (500g)  - PE or PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g,  480g, 520g, 560g)  - Carton Box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 x 10g or 2x 10g sachets  -  Sales to the general public and to professionals will be carried out in a package that does not allow the purchase of a quantity greater than 1.5 kg of product. |

##### Use-specific instructions for use

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|  |

##### Use-specific risk mitigation measures

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##### 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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| - |

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

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| --- |
| - |

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

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| - |

### General directions for use of the meta SPC 1

#### Instructions for use

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| --- |
| •   Do not open the sachets containing the bait  •    When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.  •    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.  •    bait boxes or bait stations should not be used to contain anything other than rodenticides.  •    Remove the remaining bait or the bait stations at the end of the treatment period.  •    Do not place bait stations near water drainage systems where they can come into contact with water.  •    Gloves are recommended.  Users shall properly label bait stations with following informations :  •    Do not open bait stations. |

#### Risk mitigation measures

|  |
| --- |
| * Indicate on the packaging, via well visible pictogram, the risk for humans and non target organisms. * Indicate on the packaging the necessity to use bait box to apply rodenticides. |

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

|  |
| --- |
| •    In case of exposure, immediately contact a poison control center, a samu or a doctor and in all cases describe the situation (provide the information on the label, assess the exposure dose). -          In case of:  -          Inhalation, breathe fresh air and rest.  -          Dermal exposure, remove contaminated clothes, wash skin with water and soap. Do not use solvents or thinners  -          Eye exposure, rinse eyes with water, keep eyes lids open during several minutes under the stream of water.  -          Oral exposure, seek medical advice immediately and show the container or label. Do not induce vomiting. Regardless of the amount of product ingested, do not eat or drink. Place the victim in a lying position in a safe position and protect him from injury in the event of sudden movement and convulsion. Monitor his breathing. Follow the doctor’s advice. In case of acute distress, contact 15 (or 112). -          Indication for the doctor :  This product contains a rodenticide nervous system depressant and convulsant. Bronchial congestion is precocious. Treatment is symptomatic, there is no specific antidote. -          Bait stations must be labelled with the following information**:**  •   In case of exposure, immediately contact a poison control center, a samu or a doctor and in all cases describe the situation (provide the information on the label, assess the exposure dose).  -          In case of:  -          Inhalation, breathe fresh air and rest.  -          Dermal exposure, remove contaminated clothes, wash skin with water and soap. Do not use solvents or thinners  -          Eye exposure, rinse eyes with water, keep eyes lids open during several minutes under the stream of water.  -          Oral exposure, seek medical advice immediately and show the container or label. Do not induce vomiting. Regardless of the amount of product ingested, do not eat or drink. Place the victim in a lying position in a safe position and protect him from injury in the event of sudden movement and convulsion. Monitor his breathing. Follow the doctor’s advice. In case of acute distress, contact 15 (or 112). -          Indication for the doctor : This product contains a rodenticide nervous system depressant and convulsant. Bronchial congestion is precocious. Treatment is symptomatic, there is no specific antidote. |

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

|  |
| --- |
| Do not dispose of this product and its container without taking all precautions for use.  • Do not discharge the product into the environment or the pipes. • Drop used bait stations or boxes at a recycling center or other appropriate collection center. • The packaging must not be reused or recycled. • Bait that is not consumed, unused and trained outside of bait stations or bait boxes and dead rodents must be collected and deposited in a recycling center or any other appropriate collection center. • Do not clean the bait boxes or bait stations between 2 applications. |

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

|  |
| --- |
| Keep out of the reach of children. • Keep away from food and drink, including animal feed. • Keep only in the original container. • The product will keep for 2 years from the date of manufacture.  Information to be reported on bait stations, for people other than the user: • Keep out of the reach of children. • Keep away from food and drink, including animal feed. |

### Other information

|  |
| --- |
| • The sachets and the label must bear the following statement: "Do not open the sachets". • Baiting points are are tamper resistant bait stations and other bait stations  • Are consider as tamper resistant bait stations boxes whose bait is made inaccessible to children and non-target organisms. In addition, a closing device must be provided to prevent it from being opened by children. The holder of the marketing authorization must ensure the availability of secure opaque bait boxes. • Are considered as other bait stations devices ensuring the same level of protection regarding humans and the environment as bait boxes, fixed so as not to be entrained, thus avoiding direct contact of the bait with the environment. These devices must be designed to keep the baits inaccessible to the general public and to non-target animals, and protect them from the weather.  •The label of the product shall indicate that it contains silicone dioxide (nano) |

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | BLACK PEARL GRAIN LE FOUDROYANT SOURIS GRAIN FLASH GRAIN GRAIN AF MAGIK GRAIN RONGI GRAINS FOUDROYANT | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| alphachloralose | (R)-1,2-O-(2.2,2-Trichloroethylidene)--D-glucofuranose | Pure active substance | 15879-93-3 | 240-016-7 | 4 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | SOURICIDE FOUDROYANT BATU SOURICIDE  ALPHA C | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| alphachloralose | (R)-1,2-O-(2.2,2-Trichloroethylidene)--D-glucofuranose | Pure active substance | 15879-93-3 | 240-016-7 | 4 |

### Packaging of the biocidal product

* Initial authorisation

BLACK PEARL GRAIN is supplied in 10g and 25g individual sealed bags (either made of LD polyethylene or of paper outside and LD polyethylene inside).

For non professional users, these bags are packed in 100g or 150g boxes or in 200g PET/Aluminium/PE doypacks.

For professional users, the bags are packed in 1kg or 5kg buckets.

According to the applicant, the types of packaging fulfil UN requirements for the transport of dangerous goods.

Many years of practical experience with the proposed packaging indicate that no adverse interaction between the preparation and the packaging is to be expected.

* **Minor Change Application - 2020**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Secondary packaging** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Sachet | 10 or 25 g | Paper |  | - Cartons (40g, 80g, 100g, 120g, 150 g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g))  - PET/Aluminium/PE Doypacks (200 g or 500g)  - Can /Tin, Metal + PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g)  - Can /Tin, Metal (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g)  - Bucket PP (500g)  - PE or PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g)  - Carton Box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 or 2 x 10g sachet | Non professional | Yes |
| - Bucket PP (1, 2.5 or 5 kg)  - Cardboard box case (1Kg, 2.5Kg, 5kg, 6kg, 7kg, 8kg, 9kg, 10kg, 15kg, 20kg) | Rodent control professional | Yes |
| Loose grain |  |  |  | - Bucket PP (1, 2.5 or 5 kg)  - Cardboard box case with inner PE or polypropylene (PP) lining (1Kg, 2.5Kg, 5kg, 6kg, 7kg, 8kg, 9kg, 10kg, 15kg, 20kg) | Rodent control professional | No |

### Documentation

#### Data submitted in relation to product application

Please refer to the list of studies in Annex 2

**Efficacy**

* **Minor change application (2020)**

The following efficacy studies were submitted:

* A free-choice laboratory test was carried out with house mice (***Mus musculus***), with exposure to a fresh formulation of **ALPHACHLORALOSE GRAIN (**4 % w/w Alphacloralose) for 4 days.
* A field test was carried out with house mice (***Mus musculus***), with exposure to **ALPHACHLORALOSE GRAIN** (4 % w/w Alphacloralose).

#### Access to documentation

The applicant has submitted alternative studies for the active substance dossier, *i.e.,* new studies on the active substance are available in every section

The submitted alternative studies are considered as equivalent to the protected studies used to support the agreed end-points on the active substance.

# Summary of the product assessment

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

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

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

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

## Identity related issues

The source of the active substance used in the biocidal product BLACK PEARL GRAIN is different from the source used for annex I inclusion. The technical equivalence of the source of active substance used by LODI versus the reference source used for annex I inclusion was assessed by France. The conclusion of the technical equivalence report is that the two sources are technically equivalent based on analytical data. The technical equivalence report can be found in a separate file placed on CIRCABC.

## Classification, labelling and packaging

### Harmonised classification of the active substance

|  |  |
| --- | --- |
| **Classification - Directive 67/548/EEC** |  |
| Class of danger | Xn |
| R phrases | R20/22: Harmful by inhalation and if swallowed. |

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | Acute Tox 4; H302: Harmful if swallowed.  Acute Tox 4; H332: Harmful if inhaled. |

### Classification of the biocidal product

|  |  |
| --- | --- |
| **Classification - Directive 67/548/EEC** |  |
| Class of danger | None |
| R phrases | None |
| S phrases | None |

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | None |
| Precautionary statements | None |

It should be noted that a classification proposal of the active substance alphachloralose was submitted at the inclusion in Annex I to Directive 98/8/EC: **N; R50/53** (very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

This classification would lead to apply a classification **N; R50/53** to the product.

However, the active substance classification has not currently been ratified by the RAC[[2]](#footnote-3). The proposed classification of the product BLACK PEARL GRAIN is therefore based on the current harmonised classification for alphachloralose.

### Labelling of the biocidal product

|  |  |
| --- | --- |
| **Labelling - Directive 67/548/EEC** | |
| Symbols: | None |
| Indications of danger: | None |
| Risk phrases: | None |
| Safety phrases: | None |

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

****

N; R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets.

|  |  |
| --- | --- |
| **Labelling - Regulation (EC) 1272/2008** | |
| Pictograms: | None |
| Signal words: | None |
| Hazard statements: | None |

If the proposed classification and specific concentration limits for the active substance is agreed at the ECHA level, the following labelling according to Regulation (EC) 1272/2008should apply:



H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

P273: Avoid release to the environment.

P391: Collect spillage.

P501: Dispose of contents/container in accordance with local requirements.

### Packaging of the biocidal product

* **Initial authorisation**

BLACK PEARL GRAIN is supplied in 10g and 25g individual sealed bags (either made of polyethylene or of paper outside and polyethylene inside).

For non professional users, these bags are packed in 100g or 150g boxes or in 200g doypacks.

For professional users, the bags are packed in 1kg or 5kg buckets.

According to the applicant, the types of packaging fulfil UN requirements for the transport of dangerous goods.

Many years of practical experience with the proposed packaging indicate that no adverse interaction between the preparation and the packaging is to be expected.

* **Minor Change Application – 2020**

**See section 1.1.10.**

## Physico/chemical properties and analytical methods

### Active ingredient

#### Identity, origin of active ingredient

The source of the active substance used in the biocidal product BLACK PEARL GRAIN is different from the source used for annex I inclusion. The technical equivalence of the source of active substance used by LODI versus the reference source used for annex I inclusion was assessed by France. The conclusion of the technical equivalence report is that the two sources are technically equivalent based on analytical data. The technical equivalence report can be found in a separate file placed on CIRCABC.

#### Physico-chemical properties and Analytical methods for determination of active ingredient and impurities in the technical active ingredient

Physical and chemical properties of the active substance have been submitted in the compensation dossier submitted with this product authorisation dossier.

Analytical methods for determination of active ingredient and impurities in the technical active ingredient have been evaluated in the technical equivalence report related with this product authorisation dossier.

The study of self flammability required at product authorisation stage has been submitted, evaluated and found to be acceptable.

No self-ignition temperature of the test item was observed up to its melting point (about 180°C).

### Biocidal product

#### Identity, composition of the biocidal product

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

Trade name: BLACK PEARL GRAIN.

Code number: Chloralose grain bait.

The product is formulated as a ready-for-use grain (oat) bait, containing 4% w/w alphachloralose.

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

#### Physico-chemical properties

All submitted studies have been performed on the BLACK PEARL GRAIN formulation containing 4% of alphachloralose.

Table 2: Physico-chemical properties of the biocidal product:

| Subsection (Annex Point IIB. 3/TNsG) | Method | Purity/ Specification | Results | Reference |
| --- | --- | --- | --- | --- |
| 3.1 Appearance (IIB3.1/Pt. I-B3.1) |  |  |  |  |
| 3.1.1 Physical state and nature | OPPTS 830.6303  Visual inspection | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317achlo | Oats grain | Magnier C., 2011  B3.1 |
|  |  |  | According to the technical sheet of oat used in BLACK PEARL GRAIN, The oat grains used are hulled. | Technical sheet of formulant |
| 3.1.2 Colour | OPPTS 830.6302  Visual description | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317achlo | Black (Munsell code N 2/0.75) | Magnier C., 2011  B3.1 |
| 3.1.3 Odour | OPPTS 830.6304  Comparison to other characteristic odours | Slightly of cereals | Magnier C., 2011  B3.1 |
| 3.2 Explosive properties (IIB3.2/Pt. I-B3.2) | Statement | n.a. | According to the explosive properties of formulants in the biocidal product, BLACK PEARL GRAIN is not expected to be explosive  BLACK PEARL GRAIN is not explosive | Detrimont H., Ambrosi D., 2011 |
| 3.3 Oxidising properties (IIB3.3/Pt. I-B3.3) | Statement | n.a. | According to the oxidising properties of formulants in the biocidal product, BLACK PEARL PASTA is not expected to expected to have oxidising properties  BLACK PEARL GRAIN does not have oxidizing properties | Detrimont H., Ambrosi D., 2011 |
| **3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)** | | | | |
| Flammability | EC A.10 | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317achlo | Based on the result of the preliminary test, Chloralose grain bait is considered to be "not highly flammable".  BLACK PEARL GRAIN is not highly flammable | Magnier C., 2011  B3.4 |
|  | Statement | n.a. | According to flammable properties of formulants in the biocidal product, BLACK PEARL GRAIN is not expected to be flammable | Detrimont H., Ambrosi D., 2011 |
| Self ignition temperature of solids | Statement | n.a. | According to the self ignition temperature of formulants in the biocidal product, BLACK PEARL GRAIN is not expected to be auto-flammable | Detrimont H., Ambrosi D., 2011 |
| 3.5 Acidity/Alkalinity (IIB3.5/Pt. I-B3.5) | CIPAC method MT 75.3 (preliminary test) | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317achlo | pH of a 1% (w/v) aqueous dispersion of Chloralose grain bait is 7.4 (19°C)  Since this pH is within the range 4-10, the acidity or alkalinity test is not required according to the FAO guideline and thus not performed. | Magnier C.,  2011 |
| 3.6 Bulk density (IIB3.6/Pt. I-B3.6) | OECD method 109 (pycnometer) and NF T20-053 method | Chloralose grain bait (4% alphachloralose)  Batch: AB20110510 | Relative density measured by pycnometer : 1.340 at 20°C ± 2°C  Pour and tap density are more suitable to characterise biocidal product. See below. | Magnier C., 2011 |
|  | CIPAC MT 159 | Chloralose grain bait (4% alphachloralose)  Batch: 20111115L | Pour Density : 0.600 ± 0.009 g/mL  Tap Density : 0.681 ± 0.013 g/mL | Denny O. (2012) |
| 3.7 Storage stability - (IIB3.7/Pt. I-B3.7) | Storage at 54°C for 2 weeks  CIPAC MT 46.1 | Chloralose grain bait (4% alphachloralose).  Batch: AB20110317achlo | **After 2 weeks at 54°C in glass beaker:**   |  |  |  | | --- | --- | --- | |  | T0 | 2W 54°C | | Appearance | As initial | | | Content of AS (ppm) | 4.21 % | 4.31 % |   Concentration of a.s increased by 2.4%  BLACK PEARL GRAIN is demonstrated stable after 2 weeks at 54°C.  See comments below the table | Magnier C., 2011 |
|  | Storage at 54°C for 2 weeks  CIPAC MT 46.1  pH : CIPAC MT 75.3  Dust content: CIPAC MT 171  Flowability CIPAC MT 172 | Chloralose grain bait (4% alphachloralose).  Batch: 20110622L | **After 2 weeks at 54°C in glass beaker:**   |  |  |  | | --- | --- | --- | |  | T0 | 2W 54°C | | Content of AS (ppm) | Not performed | | | Dry sieve analysis | <150 µm 0.1%  >850 µm 96.1% | <150 µm 0.1%  >850 µm 97.3% | | Attrition  resistance | 99.6% | 100% | | Dust content | Nearly dust free  (0.9 mg) | Nearly dust free (0.9 mg) |   Concentration of a.s. was not tested during storage.  Physic chemical properties of BLACK PEARL GRAIN are demonstrated stable after 2 weeks at 54°C glass beaker.  See comments below the table | Baltussen E. (2012) report N°497092. |
| Shelf life study | 6 months at ambient temperature | Chloralose paste bait (4% alphachloralose)  Batch: ER20110706 achlo | **After 6 month at ambient temperature in individual bags (material not precised):**   |  |  |  | | --- | --- | --- | |  | T0 | 6M RT | | Content of AS (ppm) | Not measured | | | Appearance of test item | Black oats in individual bag. No fat, no moisture, no hole | Black oats in individual bag. No fat, no moisture, no hole | | Appearance of secondary packaging | Dry internal wall | Dry internal wall |   Concentration of a.s was not measured in this study  See comments below the table | Richerioux S. 2012 |
| Effects of light |  |  | No data submitted.  Alphachloralose is not known to be light sensitive.  This is acceptable, no more data required. |  |
| **3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)** | | | | |
| Wettability |  |  | Data not required as the product is a ready to use grain bait |  |
| Persistent foaming |  |  | Data not required as the product is a ready to use grain bait |  |
| Suspensibility |  |  | Data not required as the product is a ready to use grain bait |  |
| Spontaneity of dispersion |  |  | Data not required as the product is a ready to use grain bait |  |
| Dilution stability |  |  | Data not required as the product is a ready to use grain bait |  |
| Dry sieve test |  |  | see particle size distribution |  |
| Wet sieve test |  |  | Data not required as the product is a ready to use grain bait |  |
| Dustiness | CIPAC MT 171 | Chloralose grain bait (4% alphachloralose).  Batch: 20110622L | Nearly dust free | Baltussen E. (2012) report N°497092. GLP |
| Attrition/friability of granules; integrity of tablets | CIPAC MT 178 | Chloralose grain bait (4% alphachloralose).  Batch: 20110622L | 99.6% | Baltussen E. (2012) report N°497092. GLP |
| Emulsifiability / Emulsion stability / Re-emulsifiability |  |  | Data not required as the product is a ready to use grain bait |  |
| Stability of dilute emulsions |  |  | Data not required as the product is a ready to use grain bait |  |
| Flowability | CIPAC MT 172 | Chloralose grain bait (4% alphachloralose).  Batch AB20110211achlo | Residue :  - after 5 fall: 50.2%  - after 20 falls: 9.7%  Flowability is not demonstrated.  BLACK PEARL GRAIN shall not be stored in loose packagings | Baltussen E. (2012) report N°495279. GLP |
| Pourability (including rinsed residue) |  |  | Data not required as the product is a ready to use grain bait |  |
| 3.9 Compatibility with other products (IIB3.9/Pt. I-B3.9) |  |  | BLACK PEARL GRAIN is not intended to be used or mixed with other products. |  |
| 3.10 Surface tension (Pt. I-B3.10) |  |  | Data not required as the product is a ready to use grain bait |  |
| 3.11 Viscosity (Pt. I-B3.10) |  |  | Data not required as the product is a ready to use grain bait |  |
| **3.12 Particle size distribution (Pt. I-B3.11)** | CIPAC MT 58.2 | Chloralose grain bait (4% alphachloralose).  Batch: 20110622L | Particle size distribution of BLACK PEARL GRAIN is:   |  |  | | --- | --- | |  | % | | Receiver pan | 0.1 | | 150 | 0.2 | | 250 | 0.3 | | 355 | 0.3 | | 425 | 0.5 | | 500 | 1.7 | | 710 | 0.7 | | 850 | 96.2 |   Size distribution of biocidal product was not measured above 850 µm. The test item should have been tested up to 5 mm.  Complete data up to 5mm is required. | Baltussen E. (2012) report N°497092. GLP |

**Conclusion – Initial assessment 2012**

**Storage stability:**

Results of the accelerated storage stability studies demonstrate that the biocidal product is stable 2 weeks at 54°C in glass beaker. The Biocidal product is therefore expected to be stable 2 years at ambient temperature and a 2-year shelf-life is granted.

The on-going shelf life study does not test the content of active substance during storage.

A new shelf life study must be started including the content of active substance in biocidal product.

Results of this storage stability study are required in post registration.

Compatibility with deposited packaging material (10g PE bags) is not demonstrated. A study demonstrating this compatibility is required in post registration.

**Data requirement:**

Compatibility study with deposited packaging material (10g PE bags) and results of the long-term storage stability study at ambient temperature with intermediary results after 1 year (with measurements of the content of the active substance in the biocidal product).

Particle size distribution of grains according to CIPAC MT 170 with sieves adapted to biocidal product.

* **Post-authorisation 2015:**

Post-authorisation data required in the frame of the initial product authorisation (2012) were assessed in 2014.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Storage stability test – **long term storage at ambient temperature** | 24 months at ambient temperature  Packaging material:  - LDPE bag | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317 achlo | After 24 months at ambient temperature (plastic bag):   |  |  |  | | --- | --- | --- | |  | T0 | 24M RT | | Content of AS (ppm) | 4.21 | 4.29 | | Appearance of test item | Black oats  Color N2/0.75 | Black oats  Color N3/0 | | Dry sieve | < 250 μm  Top 0.2%  Middle 0.3%  Bottom 0.2%  < 850 μm  Top 3.9%  Middle 3.8%  Bottom 3.8%  < 2000µm  0  <4000µm  0 | < 250 μm  Top 0.5%  Middle 0.5%  Bottom 0.6%  < 850 μm  Top 4.3%  Middle 4.2%  Bottom 4.1 %  < 2000µm  Top 13.4%  Middle 12.3%  Bottom 12.6%  < 4000 μm  Top 100%  Middle 100% Bottom 100% | | Attrition resistance | 99.6% | 99.6% | | Dustiness of granular products | Nearly dust free | Nearly dust free | | Acceptable | Richerioux S. 2013 |

**Conclusion:**

Results of the long-term storage stability at ambient temperature demonstrate that the biocidal product is stable 2 years at ambient temperature in commercial packaging (LDPE bags).

Particle size distribution and attrition are acceptable, the product is nearly dust free before and after 2 years storage at ambient temperature.

* **Minor change application - 2020:**

The applicant has submitted a minor change application in order to change the composition of the products of the Alphachloralose grain family.

The following statement was submitted:

“The compositions of the products within the frame formulation varies from the composition of the reference product by the change of the 2 colouring agents, the decrease of content of the holder and the use of a new colouring agent. These changes represent 0.5% of the global composition of the reference product (see confidential annex). “Only the content of the colouring agents changes between the products of the Alphachloralose Grain family, therefore studies on physical, chemical and technical properties were only performed on the product BLACK PEARL GRAIN (also named as Chloralose grain bait (4% alphachloralose)).”

Results provided are summarized below:

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  (14 days at 54 ± 2°C)  Packaging material:  - Cardboard box +paper sachet | Chloralose grain bait (4% alphachloralose grain bait)  Batch: AB20191030  2019-10-30 | |  |  |  | | --- | --- | --- | |  | At initial time | After 14 days at  54 ± 2°C | | Appearance of test item | Black oat grain in individual paper sachets, no spots or holes  Test item color (Munsell book of color): N 2.25/  Fish odor | Black oat grain in individual paper sachets, no spots or holes  Test item color (Munsell book of color): N 2.25/  Fish odor | | Content of alpha-chloralose  Preparation A  Preparation B  Mean content | 3.88% w/w  3.72% w/w  3.80% w/w | 3.89% w/w  3.79% w/w  3.84% w/w  (+1.5% *vs.* initial value) | | Appearance of packaging | Cardboard box, clean and dry, without spots or holes | Cardboard box,  clean and dry,  without spots or holes. | | Packaging + test item weight | 104.05 g | 96.90g  (-6.87% *vs.*  initial value) |   The test item Chloralose grain bait (4% alphachloralose) and its commercial packagings (individual paper sachets in carboard box) were considered to be stable after an accelerated storage procedure for 14 days at 54 ± 2°C | Acceptable  The product is stable 14 days at 54°C  Nevertheless, an explanation of the increase of a.s content should be provided | Leclercq S., 2019  LODI.09/2019 |
| Effects on content of  the active substance  and technical  characteristics of the  biocidal product -  **reactivity towards**  **container material** | GIFAP Monograph n°17 method  (36 months at 20 ± 2°C)  Packaging material:  - Cylindrical metal box (tin plate electrolytic)  Item test:  -paper sachet (outside in paper + inside in LDPE) | Chloralose grain bait (4% alphachloralose grain bait)  Batch: AB20150428Q  Achlo  2015-05-12 | An additional long-term storage study (36 months at 20 ± 2°C) on the product Chloralose grain bait (4% alphachloralose) in its commercial packaging (Cylindrical metal box with black lid) was performed.   |  |  |  | | --- | --- | --- | |  | At initial time | After 36 months at 20 ± 2°C | | Appearance of test item | Cereals in white individual paper sachet. outside of sachets is clean and dry. | Cereals in white individual paper sachet. outside of sachets is clean and dry. | | Appearance of secondary packaging | Cylindrical metal box. opaque box. No porosity. Black lid. All is clean and dry. | Cylindrical metal box. opaque box. No porosity. Black lid. All is clean and dry. | | Packaging + test item weight | 329.53 g | 326.68 g  (-0.86% *vs.* initial value) |   The compatibility of the commercial packagings (Cylindrical metal box with black lid) for the product Chloralose grain bait (4% alphachloralose) was demonstrated after 36 months at 20 ± 2°C | Acceptable  The content of a.s after 3 years storage should be provided.  The product is compatible with the cylindrical metal box for 3 years at ambient temperature. | Richerioux S., 2018  LODI.13/2015 |
| GIFAP Monograph n°17 method  (36 months at 20 ± 2°C)  Packaging material:  - woven PP bag  Test item:  -loose grain | Chloralose grain bait (4% alphachloralose grain bait)  Batch: AB20190424  Achlo  2019-04-24 | An additional long-term storage study (36 months at 20 ± 2°C) on the product Chloralose grain bait (4% alphachloralose) in its commercial packaging (woven PP bag) is still on-going.  Packaging stability and integrity is assessed checking visual aspect and weight of test item packed into woven PP bag. The test was done after 6 months of storage and will be done after 12, 18, 24, and 36 months of storage at 20°C ± 2°C.   |  |  |  | | --- | --- | --- | |  | At initial time | After 6 months at 20 ± 2°C | | Appearance of secondary packaging | - Woven white bag. Clean, no hole, no spot. A seam was made to close the woven PP bag.  - Black oat | - Woven white bag. Clean, no hole, no spot. | | Packaging + test item weight | 232.05 g | 228.60 g  (-1.49% *vs.* initial value) |   The compatibility of the commercial packagings (woven PP bag) for the product Chloralose grain bait (4% alphachloralose) was demonstrated after 6 months at 20 ± 2°C | Acceptable  The product is compatible with the women PP bag for 6 months at ambient temperature. | Leclercq S., 2019  LODI.03/2019 |
| GIFAP Monograph n°17 method  (48 months at 20 ± 2°C)  Packaging material:  - cardboard box +LDPE bag  - PET + aluminium + PE doypack  - PP bucket  Item test:  - chloralose grain in individual sachet | Chloralose grain bait (4% alphachloralose grain bait)  Batch: AB20120127Achlo  2012-01-30 | A long-term storage study (48 months at 20 ± 2°C) on the product Chloralose grain bait (4% alphachloralose) in several commercial packagings was performed.   |  |  |  | | --- | --- | --- | |  | At initial time | After 48 months at 20 ± 2°C | | Appearance of test item | - Black oats in individual  bag. No fat, no moisture and no hole  - Slightly dusty black oats | Oats in individual bag. No fat, no moisture and no hole  - Slightly dusty black oats | | Cardboard box | | | | Appearance of secondary packaging | Grey internal wall | Grey and dry internal wall | | Packaging + test item weight | 119.46 g | 117.10 g  (-1.98% *vs.* initial value) | | Doypack | | | | Appearance of secondary packaging | Smooth internal wall in aluminium. No hole. | Dry internal wall. No hole. | | Packaging + test item weight | 120.15g | 118.69  (-1.22% *vs.* initial value) | | PP bucket | | | | Appearance of secondary packaging | Smooth and white internal wall. | Dry internal wall. No deposit. | | Packaging + test item weight | 263.96 g | 261.71 g  (-0.85% *vs.* initial value) |   The compatibility of severals commercial packagings for the product Chloralose grain bait (4% alphachloralose) was demonstrated after 48 months at 20 ± 2°C | Acceptable  The content of a.s after 4 years storage should be provided, since there is no information about shelf-life after 2 years  The product in individual bag is compatible with the cardboard box+LDPE bag, the doypack and the bucket for 48 months at ambient temperature. | Richerioux S., 2016  LODI.01/2012 |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC MT 178 | Chloralose grain bait (4% alphachloralose grain bait)  Batch: PIL20190926  26-09-19 | The attrition resistance of the test item Chloralose grain bait (4% alphachloralose) was 100% and stable before and after accelerated for 14 days at 54 ± 2°C. | Acceptable | Baltussen E. (2012) report N°497092. GLP  Halbwachs P., 2019  Report No. 19-912011-003 |
| Flowability  /Pourability/  Dustability | CIPAC MT 171.1 | Chloralose grain bait (4% alphachloralose grain bait)  Batch: PIL20190926 | The test item Chloralose grain bait (4% alphachloralose) was nearly dust-free before and after accelerated for 14 days at 54 ± 2°C. | Acceptable | Halbwachs P., 2019  Report No. 19-912011-003 |

**Conclusion on the physical, chemical and technical properties of ALPHACHLORALOSE GRAIN:**

The stability data indicates a shelf life of 2 years at ambient temperature when stored in cardboard box + paper sachet. As the formulation is a ready-to-use grain bait, the PET+aluminium+PE doypack, the PP bucket, the carton box of (1 to 10) pre-filled bait stations (PP or PS) containing 1 or 2 x 10g sachet, the PP (woven) bag can be considered as acceptable for 24 months.

Since the flowability test, required for loose grain bait, has not been provided, the claimed packagings “cardboard box case with inner PE or polypropylene (PP) lining” and “bucket PP” are considered not acceptable.

META SPC 1 is covered by the physico-chemical tests performed on the representative product chloralose grain bait.

**Conclusion on the physical hazards and respective characteristics of ALPHACHLORALOSE GRAIN:**

The products of the ALPHACHLORALOSE GRAIN family do not require classification under Regulation (EC) No 1272/2008 for physical hazards, considering the small changes of composition and the non Phys-Chem classification of formulants.

### Analytical methods for detection and identification

#### Analytical method for determining the active substance and relevant component in the biocidal product

Reference: Magnier C., 2011, Analytical validation for determination of alphachloralose in Paste Bait and Grain Bait, Lodi, Study No.LODI.29/2011

Magnier C., 2011, Chemical stability after accelerated storage of Chloralose Grain bait, Lodi, Study No.LODI.33/2011

These studies validate the method to determine the content of alphachloralose in the biocidal product BLACK PEARL GRAIN by GC-FID using internal standard (imiprothrin).

Validation data on the product BLACK PEARL PASTA (4% alphachloralose paste bait product) for linearity and precision and on the product BLACK PEARL GRAIN for recovery and specificity:

|  |  |  |  |
| --- | --- | --- | --- |
| **Linearity** | **Precision** | **Recovery rate (%) range** | **Specificity** |
| 80 and 120% of the nominal value  n=5  r²=0.992 | 3 samples injected 3 times  RSD= 1.22%  Intralaboratory test:  RSD = 1.12% | At 50% : 105.26% (n=1)  At 100%: 96.77% (n=1)  At 150%: 92.10% (n=1) | No peaks present at retention time in chromatograms of placebo. |

The provided method is acceptable for the product BLACK PEARL GRAIN.

* **Minor change application - 2020:**

Test items are now quantified by LC method using UV detection after solid-liquid extraction. Before to be used, the method must have been validated. The different steps of the analytical method validation are: limit of detection, limit of quantification, linearity, extraction yield, specificity, accuracy, fidelity, bias and robustness.

Reference:

- Leclercq S., 2019, Validation of the analytical method for the determination of alphachloralose in alphachloralose grain bait 4.0% and alphachloralose paste bait 4.0%, Lodi, Study No.LODI.08/2019

Principle of the method

A method to determine alphachloralose in the biocidal product alphachloralose pasta bait 4% by HPLC – UV was submitted. The test item is quantified by HPLC method (Column: reversed phase) using UV detection (209 nm) after solid-liquid extraction.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Linearity** | **Precision** | **Recovery rate (%)** | **Specificity** | **LOQ** |
| 50 and 150% of the nominal value (8 g/L)  n= 5  r= 0.9999 | Intralaboratory test:  RSD = 1.89% (n=10)  Intermediary fidelity test:  RSD= 1.70% (n=5 x 2) | At 80%: 100.95% (n=2)  At 100%: 101.93% (n=2)  At 120%: 101.49% (n=2) | No peaks present at retention time in chromatograms of placebo. | 24 mg/L |

**Conclusion on the methods for detection and identification of the products**

The provided method (Leclercq S., 2019) is fully validated for the determination of the active substance alphacloralose in the product ALPHACHLORALOSE GRAIN. The limit of quantification (LOQ) is 24 mg/L for alphachloralose.

Therefore, the 3 methods are considered validated for the determination of the alphachloralose content in the products of the ALPHACHLORALOSE GRAIN family, since these differences are not considered as being able to modify the performance of these methods.

#### Analytical methods for determining relevant components and/or residues in different matrices

The analytical methods for determination of residues of active substance in different matrices (soil, air, surface and drinking water, blood, liver) were provided in the CAR of the active substance. Acceptable analytical methods were submitted in the compensation dossier.

Methods provided in the CAR of the active substance for food and feeding stuff were not validated. As no exposure to food and feeding stuff is estimated , no more data is required.

## Risk assessment for physico-chemical properties

The product BLACK PEARL GRAIN is a ready-to-use grain rodenticide. It is not highly flammable, not auto-flammable at ambient temperature, does not have explosive and oxidizing properties.

Results of the accelerated storage stability studies demonstrate that the biocidal product is stable 2 weeks at 54°C in glass beaker. The biocidal product is therefore expected to be stable 2 years at ambient temperature and a 2-year shelf-life is granted.

Compatibility with claimed packaging material (PE) is not demonstrated. A study demonstrating this compatibility is required in post registration.

***Risk mitigation measures linked to assessment of physico-chemical properties***

None.

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

* ~~Compatibility study with claimed packaging material (10 g PE bag).~~
* ~~Results of the long-term storage stability study at ambient temperature with intermediary results after 1 year (with measurements of the content of the active substance in the biocidal product).~~
* ~~Particle size distribution of grains according to CIPAC MT 170 with sieves adapted to biocidal product.~~

## Effectiveness against target organisms

### Function

MG 03: Pest Control.

Product Type 14: Rodenticide.

### Organisms to be controlled and products, organisms or objects to be protected

According to the uses claimed by the applicant, **BLACK PEARL GRAIN** is intended to be used to control rodents. The target organisms to be controlled are house mice (***Mus musculus***).

**BLACK PEARL GRAIN** is used indoor. Products are supplied in sachets. The products, organisms or objects to be protected are human food and animal feedstuffs, public health, historical buildings or technical objects.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Area of use | Dosage claimed | Time delay of the action of the product | Distance between 2 bait points, for high and low infestation | Frequency and method of controls | Methods of application of the bait |
| **PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | 3 to 5 meters | Bait points are inspected frequently and replenished when bait take is observed.  The baiting campaign stops with the end of bait consumption. | Manual application in covered bait points or tamper resistant and securely closed bait boxes when used in public areas or in locations accessible to children and non target animals. |
| **NON PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | 3 to 5 meters | Bait points are inspected daily and replenished when bait take is observed.  The baiting campaign stops with the end of bait consumption. | Manual application in covered bait points or tamper resistant and securely closed bait boxes when used in public areas or in locations accessible to children and non target animals. |

### Effect on target organisms and efficacy

A free-choice laboratory test was carried out mice (**Mus musculus**), with exposure to **BLACK PEARL GRAIN** (fresh and aged of 2 weeks at 54°C) for 4 days. The study shows that the product is palatable (average treated bait intake of respectively 20.8 % and 23.3 % of the total food consumption) and effective (100 % mortality between 1 to 3 days).

A field test was carried out with mice (**Mus musculus**) on a farm raising calves and cows. The product, **BLACK PEARL GRAIN** was highly effective, achieving 97.7 % control.

The results of these studies are described in Section IIIB 5.10.2 and are summarised in annex 9.

According to the applicant, the product is applied manually in covered bait points by professional and non-professional users in dry locations within the infested area in appropriate positions indoor, where the rodents are active, near rodent burrows, against walls, along travel routes (runways) and preferably between the rodents’ place of shelter and their food supply. The baits are also placed in tamper-resistant and securely closed bait boxes when used in public areas or in locations accessible to children and non-target animals. Distances between each bait station, as well as the number and timings of application and the amount of product depends of several factors: the target organism, the treatment site, the size and severity of the infestation.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Area of use | Dosage | Time delay of the action of the product | Distance between 2 bait points, for high and low infestation | Frequency and method of controls | Methods of application of the bait |
| **PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | High infestation:  3 meters  Low infestation:  5 meters | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | Manual application in covered bait points or tamper resistant and securely closed bait boxes. |
| **NON PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | High infestation:  3 meters  Low infestation:  5 meters | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | Manual application in covered bait points or tamper resistant and securely closed bait boxes. |

* **Minor change application - 2020:**

The product ALPHACHLORALOSE GRAIN (4 % w/w alphachloralose), same of the product BLACK PEARL GRAIN, was initially authorized for use against Mus musculus, indoor by professional and non-professional users, with a shelf life of 2 year.

The validated application rates were the following:

Mice (house mice): 10-25 g bait/secured bait point separated by 3-5 m.

The main difference between both products is the deletion and the addition of palatable agents and the change of a dye. The applicant submitted laboratory and field tests to demonstrate that these changes have not affected the efficacy of the product.

A free-choice laboratory test was carried out with mice (**Mus musculus**), with exposure to **ALPHACHLORALOSE GRAIN** fresh for 4 days. The study shows that the product is palatable (mean palatability ratio of the product is 1,7) and effective (100 % mortality between 1 to 3 days).

A field test was carried out with mice (**Mus musculus**) in a cellar of a residential house. The product, **ALPHACHLORALOSE GRAIN** was highly effective, achieving 100 % control in 8 days.

The results of these studies are summarised in annex 9.

Submitted efficacy data are compliant with the requirements of the guidance ECHA, volume II parts (B+C) and the results of these tests are respecting the criteria of the guidance ECHA, volume II parts (B+C).

The product ALPHACHLORALOSE GRAIN (4 % w/w alphachloralose) has shown a sufficient efficacy and can be used for the control of house mice (*Mus musculus*) at doses following :

* 10-25 g grains/secured bait point separated by 3-5 m.

### Mode of action including time delay

III.1 acute action

III.1.1.1 ingestion by eating

Alphachloralose is a narcotic with a rapid effect, slowing down a number of essential metabolic processes. This results in a lowering of body temperature, causing the mouse to die of hypothermia.

### Occurrence of resistance - resistance management / Unacceptable Effect

Alphachloralose acts on several metabolic processes; therefore the risk of resistance can be considered as low. Alphachloralose-based products have been widely used and no well-known resistance problems with this substance are reported. The investigation from published literature raises low concerns for the possibility of the development of rodent resistant populations to alphachloralose, whereas resistance to anticoagulants has been widely observed and reported.

However, resistance management strategies are proposed, in addition to safety precautions for the protection of humans, animals or the environment, to prevent or retard the resistance development as far as possible.

**To avoid the development of resistance in susceptible rodent populations:**

* Ensure that all baiting points are inspected weekly and old bait replaced where necessary.
* Undertake treatment according to the label until the infestation is completely cleared.
* On completion of the treatment remove all unused baits.
* Do not use rodenticides as permanent baits routinely. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas.
* Monitoring of rodent activity should be undertaken using visual survey, through the use of non-toxic placebo monitors or by other effective means.
* Record details of treatment.
* Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting programme or apply alternative control techniques to eliminate the residual infestation (anticoagulant or sub-acute rodenticides, gassing or trapping).
* Ensure that complete elimination of the infestation is achieved.
* As appropriate during the rodenticide treatment, apply effective Integrated Pest Management measures (remove alternative food sources, water sources and harbourage and, proof susceptible areas against rodent access).

The authorisation holder should nevertheless report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management every two years.

* **Minor change application - 2020**

**Post authorization:** In France only: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance alphachloralose. Results of the resistance monitoring must be submitted at the renewal of the product.

### Evaluation of the label claim

French Competent Authorities (FR CA) assessed that the product BLACK PEARL GRAIN has shown a sufficient efficacy for the control of mice for indoor use.

The validated application rates are presented in annex 0b.

The product BLACK PEARL GRAIN is supplied in sachets of different amounts. The applicant has to adapt the amount per sachet to the efficient doses. The amount of bait per bait station or bait points must not exceed the recommended application rates.

* **Minor change application - 2020:**

French Competent Authorities (FR CA) assessed that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product ALPHACHLORALOSE GRAIN for the control of mice for indoor use by professional and non-professional users with a shelf life of 2 years.The application rates validated are the following:

* Mice (*Mus musculus*): 10-25 g / bait point separated by 3-5 m.

**Post authorization**: In France only: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance alphachloralose. Results of the resistance monitoring must be submitted at the renewal of the product.

### Conclusion of the efficacy assessment

The product BLACK PEARL GRAIN has shown a sufficient efficacy and can be used for the control of mice *(Mus musculus)* indoor. Nevertheless, a monitoring of the resistance phenomenon of rodent populations toward the active substance alphachloralose and resistant strategies management must be put in place. The collected information must be sent every 2 years to Anses within the framework of a post-authorisation monitoring.

***Conditions of use linked to efficacy assessment***

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

***Recommandations to be taken into account by the applicant***

* Adapt the amount of bait per bait point to the validated effective dose.
* The product label has to contain information on resistance management for rodenticides.

***Required information linked to efficacy assessment***

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

* **Minor change application - 2020:**

French Competent Authorities (FR CA) assessed that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product ALPHACHLORALOSE GRAIN for the control of mice for indoor use by professional and non-professional users with a shelf life of 2 years.The application rates validated are the following:

* Mice (*Mus musculus*): 10-25 g / bait point separated by 3-5 m.

**Post authorization**: In France only: The authorisation holder has to monitor the resistance phenomenon of rodent populations toward the active substance alphachloralose. Results of the resistance monitoring must be submitted at the renewal of the product.

## Description of the intended use(s)

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

The validated application rates and intended uses are the following:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Target organisms | Area of use | Dosage | Time delay of the action of the product | Distance between 2 bait points, for high and low infestation | Frequency and method of controls | Methods of application of the bait |
| **PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | High infestation:  3 meters  Low infestation:  5 meters | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | Manual application in covered bait points or tamper resistant and securely closed bait boxes. |
| **NON PROFESSIONAL USERS** | | | | | | |
| House mice  *Mus musculus* | Indoor | 10 to 25 g | 1 to 3 days | High infestation:  3 meters  Low infestation:  5 meters | Inspect and resupply the bait stations, 3 days after application then once a week as long as the bait is consumed. | Manual application in covered bait points or tamper resistant and securely closed bait boxes. |

The product BLACK PEARL GRAIN is intended to be used for the control of mice *(Mus musculus)* indoor. The control is based on the principle of applying baits in infested areas with obvious tracking of faeces, and smears next to holes and harbourages.

The product is a ready-to-use grain bait with no dilution nor other substances added for application. The mode of application claimed by the applicant is a manual application by professional users and by non-professional users in covered bait points. It is also applied in tamper-resistant and securely closed bait boxes when used in public areas or in locations accessible to children and non-target animals.

## Risk assessment for human health

### Hazard potential

#### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 “Toxicology and metabolism” must be taken into consideration.

The following corresponds to the summary from the final Assessment report of alphachloralose.

After oral administration of chloralose to rats, at least 80% of the substance is rapidly absorbed, widely distributed, metabolised and excreted. The plasma half-life in rats is between 8.8-12.6 hours. Elimination from the body is not significantly influenced by dose, occurring via urine in the low level at approx. 60% and high level at 70% and faeces in low level at approx. 30% and high level at 20%, in the first 24h after dosing. Urine metabolite examinations showed that chloral hydrate is the main metabolite of chloralose accounting for about 40% of the identified components, at 24h. In faeces, α, ß chloralose were quantified as the most relevant components, at comparable proportions, respectively 16% and 11%, at 24h.

Toxikocinetics evaluation indicates that Chloralose and its metabolites are unlikely to bioaccumulate in mammals.

Chloralose was harmful in the acute toxicity studies carried out in rats by oral and inhalative exposure with LD/C50s of 341 mg/kg and more than 1.99 mg/L respectively. No adverse effects were observed following an acute dermal exposure of 2000 mg/kg. It is not corrosive, does not induce skin or eye irritation and is not a skin sensitiser.

Repeated oral administration of Chloralose in rats (28d and 90d studies) demonstrated critical neurological adverse effects (e.g. prostration, spastic locomotion, drowsiness and piloerection) used for NOAEL setting at 15mg/kg bw/day based on the 90d study results.

These effects proved to be reversible under the study conditions and confirmed a.s. pharmacological mode of action (CNS depression). Human and veterinary use of the substance and its metabolite (chloral hydrate) as sedative and hypnotic drugs confirm that the primary effect of alphachloralose is on the CNS causing sedation. Reading across from its main metabolite, chloral hydrate, it is concluded that delayed neurotoxicity is not a critical endpoint.

The results of the two developmental toxicity studies in rats and rabbits suggest a non species difference for maternal toxicity to Chloralose with a NOAELmaternal toxicity of 15 mg /kg bw/day based on sedation effects and alterations in body weight and food consumption. A NOAELfoetal toxicity of 15 mg/kg bw/day was established based on reduced birth weights. These effects are secondary to CNS depression; hence it was considered that a developmental toxicity classification for Chloralose toxicity is not required. Both alphachloralose and chloral hydrate have therapeutic use, without known history of paediatric susceptibility or other reproductive toxicity. WHO 2005 evaluation on chloral hydrate in infants and conclude that developmental toxicity, including developmental neurotoxicity, and immunotoxicity are not critical effects. It was concluded that reproductive toxicity is not a critical effect of alphachloralose.

The active substance tested negative in all in vitro genotoxicity studies. Reading across from chloral hydrate, it was concluded that similar to chloral hydrate, alphachloralose is an aneugenic agent of very low potency. Supporting evidence from two carcinogenicity (non guideline) studies with mice and dogs both concluded an absence of carcinogenicity potency for alphachloralose. There is no evidence of carcinogenicity in humans despite therapeutic use and long follow-up time. Reading across from chloral hydrate, in which the carcinogenicity potential of this metabolite was evaluated by the US-EPA, IPCS, IARC, and more recently WHO found chloral hydrate to be carcinogenic in mice but not in rats. The evaluations of these organizations all stated that the potential carcinogenicity in mice (occurring only after hepatotoxicity is evident), is of highly questionable relevance to man. More recently, there is now evidence that peroxisome proliferation is postulated as a mechanism of hepatic change with chloral hydrate. Since humans and other primates are less responsive than rats and mice in terms of peroxisomal proliferation, the rodent tumourigenicity of chloral hydrate is therefore of doubtful significance to man. Hence, it was concluded that there was no CMR concerns for chloral hydrate nor for alphachloralose.

A medium/long term AOEL of 0.15 mg/kg bw/day and MOEref of 100 were set based on the rat sub-chronic NOAEL of 15 mg/kg bw/day and the assessment factor (AF) of 100 (10 for interspecies variation and 10 for intraspecies variation)

An acute AOEL of 0.2 mg/kg bw/day and an acute MOEref of 100 were set based on the rat sub-acute NOAEL of 20 mg/kg bw/day and an AF of 100 (factor of 10 for interspecies and 10 for intraspecies variation as described in the repeat dose above).

The current harmonised classification of the active substance is the following:

|  |  |
| --- | --- |
| Classification under directive 67/548/EEC | Classification under regulation (EC) 1272/2008 |
| Xn, R20/22.  No specific concentration limit. | Acute Tox. 4 H302.  Acute Tox. 4 H332.  No specific concentration limit. |

#### Toxicology of the substance(s) of concern

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

It could be noted that the product BLACK PEARL GRAIN contains carbon black which is considered as possibly carcinogenic to humans (Group 2B) by IARC.

* **Minor change application - 2020**

No substance of concern has been identified. Please see the confidential annex for further details.

#### Toxicology of the biocidal product

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

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

##### Percutaneous absorption

No data are available for the ability of alphachloralose in the product BLACK PEARL GRAIN to penetrate the skin. A default value of 100 %, as proposed by LODI, was considered in the risk assessment.

##### Acute toxicity

ORAL ROUTE:

| Route | Method Guideline | Test material | Species, Strain Sex, no/group | dose levels | Value LD50 | Reference |
| --- | --- | --- | --- | --- | --- | --- |
| Oral | OECD 423  G | Chloralose grain bait (4.85% alphachloralose) in distilled water | Sprague Dawley  6 Females | 2000mg/kg bw | > 2000mg/kg bw | Colas S. 2011 |
| Remarks: Neither mortality nor clinical signs were observed in this study. | | | | | | |
| Acceptable: Yes | | | | | | |

Based on these results, no classification is required for this endpoint for the product BLACK PEARL GRAIN.

DERMAL ROUTE:

No acute toxicity study by dermal route was submitted. However, based on the composition of the product BLACK PEARL GRAIN, no ingredient is classified for acute dermal toxicity. Therefore no classification is required for this endpoint.

INHALATION ROUTE:

No acute toxicity study by dermal route was submitted. Based on the vapour pressure of alphachloralose is low (< 1x10-2 Pa at 20°C) and considering the composition of the product BLACK PEARL GRAIN, the product is not classified for this endpoint.

##### Irritation and corrosivity

SKIN IRRITATION:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Species | Method | Test material | Average score 24, 48 and 72 h | | Reversibility yes/no | Result | Reference |
| Erythema | Oedema |
| Albinos NZW rabbit  3 females | OECD 404  Semi-occlusive, 4h | Chloralose grain bait (4.85% alphachloralose)  0.5g | 0.2 | 0 | Totally reversible between day 1 and 2 | Not irritant | Colas S. 2011 |
| Acceptable: Yes | | | | | | | |

EYE IRRITATION TEST:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species | Method | Test material | Average Score (24h, 48h, 72h) | | | | Result | Reversibility yes/no | Reference |
| Cornea | Iris | Redness  Conjunctiva | Chemosis |
| Albinos NZW rabbit  3 Males | OECD 405 | Chloralose past bait (4.85% alphachloralose)  0.1g | 0.33 | 0 | 1.2 | 0.77 | Slightly irritant | Reversible between Day 2 and 9 | Colas S. 2011 |
| Acceptable: Yes | | | | | | | | | |

Based on the results, no classification is required for these endpoints.

##### Sensitisation

No skin sensitisation study was submitted. However, based on the composition of the product BLACK PEARL GRAIN, no ingredient is classified regarding its skin sensitising properties. Therefore no classification is required for this endpoint.

##### Other studies

The product does not contain any substance of concern. Therefore, no additional study was conducted.

* **Minor change application - 2020**

In the framework of the minor change, four non-classified coformulants were replaced by five similar non-classified coformulants. Therefore, this minor change does not impact the classification of the product.

The conclusions of the toxicology of the biocidal product family ALPHACHLORALOSE GRAIN remain unchanged:

* ALPHACHLORALOSE GRAIN is not classified for human health
* A default value of 100 % was considered for the dermal absorption.

See minor changes of composition in the confidential annex for further information.

### Human exposure assessment

The biocidal product is a ready-to-use rodenticide containing 4 % of the active substance (pure: 40 g/kg) intended to be applied indoor only by professionals and non-professionals for the control of mice.

No new exposure studies have been submitted.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use** | **Professional use** | **General public** | ***via* the environment** |
| Inhalation | Not relevant | Yes | Yes | Negligible |
| Dermal | Not relevant | Yes | Yes | Negligible |
| Oral | Not relevant | Negligible | Yes | Negligible |

#### Direct exposure as a result of use of the active substance in biocidal product

The product BLACK PEARL GRAIN is packaged into 10 or 25 g plastic bags for use only indoor by professionals and non professionals at the recommended dose of 10-25 g/bait point.

According to LODI, assessment of exposure was based on the TNsG for human exposure to biocidal products (2007)[[3]](#footnote-4). However, since LODI has an access to the CEFIC studies (Chambers *et al*, 2004 and Snowdon *et al*, 2003) on determination of potential exposure to operators during simulated use of anticoagulant rodenticide baits, the Human Exposure Expert Group (HEEG) opinion on an Harmonised approach for the assessment of rodenticides (anticoagulants) agreed at TM II 2011 was used to assess professional exposure to the product BLACK PEARL GRAIN. Indeed, even if alphachloralose is not an anticoagulant, a similar manipulation of grains is expected with the two types of rodenticides and the parameters set in the simulated studies are considered more realistic than the very worst case scenario presented in the TNsG.

For non professional users, the same studies and assumptions were used for the estimation of human exposure since the values available in the TNsG are considered as unrealistic.

##### Exposure of professional users

As a worst case, exposure has been assessed in a first Tier approach considering the product BLACK PEARL GRAIN supplied as loose grains. In a second Tier, the protection of plastic bag has been considered. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as the plastic sachet prevents dermal contacts and exposure by inhalation.

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

The following parameters were considered:

* duration of manipulation: 1.575 minutes per day (3 minutes per 3 kg decanting; 1.575 kg decanted per day)
* Inhalation rate: 1.25 m3/hour
* Inhalation absorption: 100 %
* Active substance in product: 4 %
* Body weight: 60 kg

Based on these assumptions, the systemic concentration of alphachloralose is 2.1 x 10-4 mg/kg bw/day for the control of mice.

***Dermal exposure***

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the indicative amount of product on fingers/hands **during the decanting** was 93 mg per 3 kg of decanted product, when considering 1 to 4 decanting times per day and 52.3 mg per 3 kg of decanted product when considering more than 4 decanting times per day. Since the quantity of decanted product is 1.575 kg (25 g per bait point; 63 loading), 93 mg of product was considered.

The following parameters were taken into account:

* Active substance in product: 4%,
* Quantity of decanted product: 1.575 kg for rat (25 g of grains per bait boxes; 63 loading of bait boxes[[4]](#footnote-5)),
* Frequency: one manipulation per day,
* Dermal absorption: 100 %,
* Body weight: 60 kg.

The quantity of 25 g corresponds to the maximum validated efficient doses.

Therefore, the systemic dose of alphachloralose on fingers/hands during decanting is 3.3 x 10-2 mg/kg bw/day.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day (the agreed number is 63 manipulations for professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 63 manipulations per day, the systemic dose of alphachloralose on fingers/hands during loading is 8.57 x 10-2 mg/kg bw/day for the control of mice.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg/manipulation for the assessment of more than 4 manipulations per day (the agreed number is 16 cleanings for professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). Therefore, considering 16 cleanings per day, the systemic dose of alphachloralose on fingers/hands during cleaning is 4.04 x10-2 mg/kg bw/day.

In conclusion, the total systemic dermal exposure is set at 1.59 x 10-1 mg/kg bw/day.

***Total exposure***

The total systemic exposure resulting from inhalation and dermal contacts with the product is 1.59 x 10-1 mg/kg bw/day.

The estimations above represent a very worst case since BLACK PEARL GRAIN is only supplied in plastic sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as these sachets prevent dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered: 4.04 x 10-2 mg a.s/kg bw/day without gloves for the control of mice.

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

| **Tier** | **Inhalation exposure** | **Dermal exposure** | **Total exposure** |
| --- | --- | --- | --- |
| PPE | Systemic dose | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task – time frame:** | **Scenario** | | |
| Tier 1:  Without PPE; bulk | 2.1 x 10-4 | 1.59 x 10-1 | 1.59 x 10-1 |
| Tier 2:  Without PPE; sachet | na | 4.04 x 10-2 | 4.04 x 10-2 |

##### Exposure of non-professional users

For non-professional users, considering the available secondary packaging sizes (100 g or 150 g boxes or 200 g Doypacks), it can be assumed that there is no decanting phase and no inhalation exposure is expected. As a worst case, exposure considering the product BLACK PEARL GRAIN supplied as loose grains was assessed in a first Tier approach. In a second Tier, the protection of plastic sachet has been considered. In this case, it can be assumed that no exposure is expected during loading in bait points as the sachet prevents dermal contacts and exposure by inhalation.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the loading** was 2.04 mg for the assessment of more than 4 manipulations per day and 3.57 mg for the assessment of up to 4 manipulations per day (the agreed number is 5 manipulations for non-professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). As a worst-case, considering 5 manipulations per day, the amount of product of 3.57 mg is used and therefore, the systemic dose of alphachloralose on fingers/hands during loading is 1.19 x 10-2 mg/kg bw/day for the control of mice.

Based on the CEFIC study and taking into account the *HEEG opinion on an harmonised approach for the assessment of rodenticides (anticoagulants)* agreed at TMII 2011, the amount of product on fingers/hands **during the cleaning** was 3.79 mg for the assessment of more than 4 manipulations per day and 4.52 mg for the assessment of up to 4 manipulations per day (the agreed number is 5 cleanings for non-professional use based on the HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant) agreed at TMIII 2010). As a worst-case, considering 5 manipulations per day, the amount of product of 4.52 mg is used and therefore, the systemic dose of alphachloralose on fingers/hands during cleaning is 1.51 x 10-2 mg/kg bw/day for the control of mice.

In conclusion, the total systemic dermal exposure is set at 2.70 x 10-2 mg/kg bw/day for the control of mice.

The estimations above represent a very worst case since the product BLACK PEARL GRAIN is only supplied in plastic sachets. In this case, it can be assumed that there is no decanting phase and no exposure is expected during loading in bait points as these sachets prevent dermal contacts and exposure by inhalation. Therefore, only exposure during cleaning can be considered: 1.51 x 10-2 mg a.s/kg bw/day without gloves for the control of mice.

*In Annex 7 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.*

| **Tier** | **Inhalation exposure** | **Dermal exposure** | **Total exposure** |
| --- | --- | --- | --- |
| PPE | Systemic dose | Systemic dose | Systemic dose |
|  | mg a.i. / kg bw /day | mg a.i. / kg bw /day | mg a.i. / kg bw /day |
| **Task – time frame:** | **Scenario** | | |
| Tier 1:  Without PPE; bulk | na | 2.70 x 10-2 | 2.70 x 10-2 |
| Tier 2:  Without PPE; sachet | na | 1.51 x 10-2 | 1.51 x 10-2 |

#### Indirect exposure as a result of use of the active substance in biocidal product

Exposure of non users, especially infants, could result from the handling of dead rodents or ingesting poison baits.

***Handling of dead rodents (adult, child, infant) – acute scenario***

Secondary exposure of users and non users could result in the handling of dead rodents. However, this scenario is excluded because it is considered of low relevance due to unrealistic assumptions (TNsG on human exposure (2007)). Exposure due to this senario is considered negligible.

***Oral exposure by ingesting bait (infant) – acute scenario***

A reverse scenario was calculated. Based on the short-term AEL of 0.15 mg a.s/kg bw/day, a body weight of 10 kg and an oral absorption of 100%, ingestion of more than 50 mg of product per day is needed to exceed the AEL.

#### Exposure to residues in food

The intended use descriptions of the product BLACK PEARL GRAIN indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff. No further data are required concerning the residue behaviour.

#### Combined exposure

Not relevant.

* **Minor change application - 2020**

Minor change includes new packagings (see corresponding section). This minor change is covered by the assessment of exposure performed in the first authorization.

The exposure assessment of the biocidal product remain unchanged for professional and non-professional users.

### Risk assessment for human health

#### Risk for direct exposure

##### Professional users

The estimated exposures for the professional users are compared to the systemic AELs of alphachloralose set in the Assessment Report (0.20 mg/kg bw/day for short-term exposure and 0.15 mg/kg bw/day for medium and long-term exposures).

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable without gloves and considering the protection of the sachet (%AEL is set at 27%) when exposure is compared to the chronic AEL of alphachloralose (see Annex 6 for detailed calculations). However, gloves are recommended to help prevent rodent-borne disease.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Bulk formulation (exposure during decanting, loading and cleaning phases) – worst case** | | | | |
| Professional  (without gloves) | 0.15 | 1.59 x 10-1 | 106 | Unacceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Professional  (without gloves) | 0.15 | 4.04 x 10-2 | 27 | Acceptable |

##### Non-professional users

The estimated exposures for the professional users are compared to the systemic AELs of alphachloralose set in the Assessment Report (0.20 mg/kg bw/day for short-term exposure and 0.15 mg/kg bw/day for medium and long-term exposures).

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable without gloves (%AEL is set at 18% without considering the protection of the sachet and %AEL at 10% considering the protection of the sachet) when exposure is compared to the chronic AEL of alphachloralose (see Annex 6 for detailed calculations).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **%AEL** | **Risk** |
| **Bulk formulation (exposure during loading and cleaning phases) – worst case** | | | | |
| Non professional | 0.15 | 2.70 x 10-2 | 18 | Acceptable |
| **Sachet formulation (exposure during cleaning phase)** | | | | |
| Non professional | 0.15 | 1.51 x 10-2 | 10 | Acceptable |

#### Risk for indirect exposure

Based on a reverse scenario, more than 50 mg of product per day (corresponding to 0.2% of a 25 g bag) should be ingested by infant to exceed the AEL. This indicates that infants are at significant risk of poisoning. Therefore, even if the product BLACK PEARL GRAIN contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable which do not allow access to children.

Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

#### Risk for consumers via residues

Considering the intended uses no dietary risk assessment is necessary.

#### Risk for combined exposure

Not relevant.

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

No unacceptable risk has been observed for professionals and non-professionals using the product BLACK PEARL GRAIN in individual plastic bags, without gloves and considering an indoor application at the maximum recommended dose of 25 g/bait point in the control of mice.

For the indirect scenario “Infant ingesting bait”, an unacceptable risk was observed. Therefore, even if the product BLACK PEARL GRAIN contains a bittering agent which reduces the likelihood of ingestion, the baits should be unattainable which do not allow access to children. Product label (“do not open the sachet”) and good practice advise users to prevent access to bait by children and infants.

The intended use descriptions of the product BLACK PEARL GRAIN indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used as rodenticide and does not come in direct or indirect contact with food and feedstuff.

***Risk mitigation measures linked to risk assessment for human health***

* **Professional users:**
* Gloves have to be worn to help prevention against rodent-borne disease.
* Do not open the sachets.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
* Use in tamper-resistant bait boxes or in covered bait stations. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Covered bait stations must be placed only in areas not accessible to the general public and non-target animals.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these..
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.
* **Non-professional users:**
* Do not open the sachets.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
* Use only in tamper-resistant bait boxes. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.

***Disposal considerations***

* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment.
* Remove all bait points after the end of treatment.

***Required information linked to risk assessment for human health***

None.

* **Minor change application - 2020**

Minor change is covered by the assessment of exposure performed in the first authorization.

The conclusions of risk assessment of the biocidal product family remain unchanged.

## Risk assessment for the environment

* **Minor change application - 2020**

The biocidal product does not contain any substance of concern. Minor change is covered by the risk assessment for the environment performed in the first authorization.

The conclusions of risk assessment for the environment of the biocidal product family remain unchanged.

### Fate and distribution in the environment of the active substance alphachloralose

The summary of information about the active substance alphachloralose is carried out with the data from the CAR of alphachloralose owned by Rentokil Initial plc & Physalys[[5]](#footnote-6).

#### Degradation

##### Abiotic degradation

###### Hydrolysis in function of pH

According to the test OECD 111, alphachloralose is considered stable to hydrolysis. It was concluded that the hydrolytic half-life (DT50) was above one year at environmentally relevant pH. The hydrolytic degradation is deemed negligible.

###### Photolysis in water

Abiotic degradation of alphachloralose through phototransformation in water is not expected to occur based on the UV-Vis absorption spectra of the substance.

###### Photolysis in soil

Not relevant for a use inside buildings of products containing alphachloralose.

###### Photodegradation in air

The photo-oxidative degradation of alphachloralose in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.90 (AOPWIN). The estimated half-live for the hydroxyl reactions in air is 3.19 hours. It is predicted to have a negligible effect on stratospheric ozone, even if the ozone reaction in air has not been estimated. It is predicted not to be a potential greenhouse gas. Finally, alphachloralose has a low volatility (Henry’s law constant = 5.65 \* 10-4 Pa.m3.mol-1) and emissions to the air compartment are expected be low.

##### Biotic degradation

###### Aquatic compartment

* Ready biodegradation / inherent biodegradation:

Alphachloralose is not readily biodegradable under the conditions of the Closed Bottle Test (16.67% after 28 days) and not inherently biodegradable under the conditions of the ’Zahn-Wallens / EMPA Test’ (OECD 302B) performed (5% after 28 days).

* Degradation in water/sediment system:

Due to the only indoor intended uses, no study on water/sediment system of the active substance has been submitted in the CAR of alphachloralose.

###### Degradation in STP

Due to the only indoor intended uses, no study on degradation in STP of the active substance has been submitted in the CAR of alphachloralose.

###### Terrestrial compartment

Due to the only indoor intended uses, no study on fate and behaviour of the active substance has been submitted in the CAR of alphachloralose.

#### Distribution

Based on Koc values from a laboratory study, which ranged from 5.49 to 120 mL/g and according to SSLRC classification index, alphachloralose can be considered:

* very mobile in sandy/loamy sand soil;
* mobile in sandy clay loam, clay and loamy sand soils;
* moderately mobile in clay loam/clay soil.

Due to its low adsorption onto soils and being readily soluble in water, alphachloralose is expected to move from soil into water.

#### Accumulation

Alphachloralose has a log Kow < 3 (0.85) and is not highly adsorptive; consequently these properties indicate that alphachloralose is not likely to bioaccumulate in aquatic or terrestrial species.

The aquatic BCF has been estimated with calculation method in spite of the fact that log Kow is below the stated range of application (2-6):

**BCFfish = 1.05 L/kg**(according to Equation 74; TGD).

The terrestrial BCF has been estimated with calculation method:

**BCFearthworm = 0.92 L/kg**(according to Equation 82d; TGD).

These BCF values confirm the low bioaccumulation of alphachloralose in aquatic and terrestrial species.

#### Behaviour in air

The vapour pressure of alphachloralose has been determined to be 8.83 x 10-3 Pa (EC methods A.4). Furthermore, Henry’s law constant for alphachloralose has been calculated to 5.65 x 10-4 Pa.m3.mol-1) (based on a water solubility of 4.94 g/L). Based on these data alphachloralose is not expected to partition into atmosphere to a relevant extent.

In addition, alphachloralose is expected to be quickly degraded by photo-oxidation. The photochemical oxidative degradation half-life of alphachloralose in air was estimated using the Atmospheric Oxidation Program v1.90 (AOPWIN) to be around 3 h.

### Effects on environmental organisms for active substance alphachloralose

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

##### Aquatic organisms

Based on the results of acute toxicity studies, alphachloralose is very acute toxic to aquatic organisms. No long-term tests have been performed. Two studies, both with a reliability factor of 2 were performed on each of the three trophic levels (fish, Daphnia and algae). *Daphnia magna* is the most sensitive species with a 48h EC50 of 0.027 mg a.s./L.

**Table 2.8.2.1.1 Toxicity to freshwater aquatic organisms**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline / Test method** | **Species** | **Endpoint** | **Results1 (mg a.s./L)** | **Reference** |
| EC Method C.1 | *Oncorhynchus mykiss*  - fish | LC50 – 96h | 2.4 | CAR a.s.  Doc III‑A 7.4.1.1-1 |
| EC Method C.1 | *Oncorhynchus mykiss -* fish | LC50 – 96h | 5.01 | CAR a.s.  Doc III‑A 7.4.1.1-2 |
| EC Method C.2 | *Daphnia magna -* invertebrate | EC50 – 48h | 0.027 | CAR a.s.  Doc III‑A 7.4.1.2-1 |
| EC Method C.2 | *Daphnia magna* - invertebrate | EC50 – 48h | 0.36 | CAR a.s.  Doc III‑A 7.4.1.2-2 |
| EC Method C.3 | *Selenastrum capricornutum* - algae | EbC50 – 72h  ErC50 – 72h | 0.13  0.52 | CAR a.s.  Doc III‑A 7.4.1.3-1 |
| EC Method C.3 | *Pseudokirchneriella subcapitata*- algae | EbC50 – 72h  ErC50 – 72h | 1.00  4.90 | CAR a.s.  Doc III‑A 7.4.1.3-2 |

All concentrations are expressed on nominal concentrations.

Justification of PNECwater:

According to the TGD, if more than one L(E)C50 value is available for the same species and end-point, the geometric mean must be used to calculated the PNECwater. The PNECwater is derived from the geometric mean of the EC50 values (0.099 mg a.s./L) for *Daphnia magna* divided by an assessment factor of 1000. Therefore, **PNECwater = 0.099 µg a.s./L.**

##### Sediment dwelling organisms

According to the TGD, as the log Kow value of alphachloralose is < 3 and the Koc values are < 500 L/kg, sediment effects assessment is not considered as relevant for this active substance.

##### STP micro-organisms

Alphachloralose showed a very low toxicity to micro-organisms in the respiration inhibition test, with EC10 of 702.89 mg a.s./L.

**Table 2.8.2.1.3 toxicity to STP microorganisms**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Guideline/Test method** | **Species / Inoculums** | **Endpoint / Type of test** | **Duration** | **Results [mg a.s/L]** | | | | | **Reference** |
| **EC10** | | **EC20** | **EC50** | **EC80** |
| EC Method C.11 | Activated sludge | Respiration Inhibition | 3h | 702.89 | 1699.63 | | nc | nc | CAR a.s.  Doc III‑A 7.1.4 |

nc: not calculated

Justification of PNECmicroorganisms:

In according to TGD (2003) when an EC10 from a respiration inhibition test is used an assessment factor of 10 should be applied. Hence, **PNECmicro-organisms = 70.29 mg a.s./L.**

#### Atmosphere

Alphachloralose has a low volatility and is not intended to be sprayed or fumigated. It is formulated into a non volatile solid consequently its occurrence in air is highly unlikely. Moreover, significant phototransformation in air due to hydroxyl radicals would be expected. Alphachloralose is not expected to contribute to global warming, ozone depletion in the stratosphere, or acidification on the basis of its physical or chemical properties.

#### Terrestrial compartment

No studies have been submitted since the indicated use of alphachloralose does not evidence a concern for the terrestrial flora and fauna nor a long term exposure. Alphachloralose-based products are intended for indoor use only, no exposure to soil and groundwater is expected.

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

Even if no assessment to consider primary and secondary poisoning has been provided in the CAR, an exposure of alphachloralose directly to non-target mammals (primary poisoning) and indirectly via target rodent carcasses (secondary poisoning) is considered in this risk assessment. The toxicity key studies come from the human health part.

**Table 2.8.2.4 Toxicity to mammals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline/Test method** | **Species/Strain** | **Route / Dose levels / Duration** | **Values** | **reference** |
| EC Method B.1. | Rat  Sprague-Dawley | Oral  Dose level: 125, 200, 320, 2000 mg/kg bw applied as a single dose.  Post exposure period: 14 days. | LD50 = 611 mg/kg (males),  212 mg/kg (females), 341 mg/kg (combined) | CAR Rentokil Initial plc & Physalys dossier |
| OECD 407 | Rat  Sprague-Dawley: | Oral gavage  Dose level: 0, 5, 20, 80 mg/kg bw/day  Repeated dose toxicity 28 days | NOAEL= 20 mg/kg bw/day |
| EC Method B.26 | Rat Wistar | Oral gavage  Dose level: 0, 5, 15, 60 mg/kg bw/day  Repeated dose toxicity 90 days | NOAEL= 15 mg/kg bw/day |

##### Primary poisoning

Acute/short-term qualitative assessment

Acute primary toxicity for mammals is assessed only qualitatively in accordance with the decision from TMIII-06. This assessment has not been carried out in the CAR of alphachloralose. **For mammals** the acute toxicity to rat corresponds to a **LD50 of 341 mg a.s. /kg bw**.

Long-term quantitative assessment

For mammals two studies are available. In the repeated dose 28-day oral toxicity study, a NOAEL of 20 mg/kg bw/day was estimated. In the sub-chronic oral toxicity test (90 days), a NOAEL of 15 mg/kg bw/day was estimated. Only the lower of the resulting PNECs is used in the risk assessment corresponding to the PNEC value from the 28-day study.

In the repeated dose 28-day study, a NOAEL of 20 mg/kg bw/day was estimated. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the AForal of 300 is applied to this NOEC, which results in a

**PNECoral (mammal) = 20/300 = 0.067 mg/kg bw/day**

**equivalent to**

**PNECoral (mammal) = 20\*20/300 = 1.334 mg/kg food**

##### Secondary poisoning

Acute/short-term qualitative assessment

Acute primary toxicity for mammals is assessed only qualitatively in accordance with the decision from TMIII-06. This assessment has not been carried out in the CAR of alphachloralose. **For mammals** the acute toxicity to rat corresponds to a **LD50 of 341 mg a.s. /kg bw** recalculated into **LC50 = 6820 mg/kg food**, using the conversion factor bw/dfi of 20 from table 22 in the TGD II is the lowest value for the acute toxicity.

Long-term quantitative assessment

For mammals two studies are available. In the repeated dose 28-day oral toxicity study, a NOAEL of 20 mg/kg bw/day was estimated. In the sub-chronic oral toxicity test (90 days), a NOAEL of 15 mg/kg bw/day was estimated. Only the lower of the resulting PNECs is used in the risk assessment corresponding to the PNEC value from the 28-day study.

In the repeated dose 28-day study, a NOAEL of 20 mg/kg bw/day was estimated. According to the TGD section 3.8.3.5, the NOAEL is transformed into a NOEC using a conversion factor of 20, and the AForal of 300 is applied to this NOEC, which results in a

**PNECoral (mammal) = 20/300 = 0.067 mg/kg bw/day**

**equivalent to**

**PNECoral (mammal) = 20\*20/300 = 1.334 mg/kg food**

#### Summary of PNECs of the active substance alphachloralose

**Table 2.8.2.5: Summary of the alphachloralose (a.s.) PNECs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Compartment** | | **Test value** | **AF** | **PNEC** |
| **Aquatic** | PNECwater | EC50 = 0.099 mg a.s. /L | 1000 | 0.099 µg a.s./L |
| PNECsediment | NR | | |
| PNECSTP | EC10 = 702.89 mg a.s. /L | 10 | 70.29 mg a.s. /L |
| **Terrestrial** | PNECsoil | NR | | |
| **Primary and secondary poisoning** | PNECoral for birds | NR | | |
| PNECoral for mammals | NOAEL = 20 mg a.s./kg bw/day  NOEC = 400 mg a.s./kg food  Rat repeated dose toxicity 28 days | 300 | 0.067 mg/kg bw/day  1.334 mg/kg food |
|

NR: not relevant.

#### PBT and ED Assessment

Persistence

Alphachloralose is intended to be indoor use that’s why the only available data refers to biodegradation, ready and inherent. According to results given in the CAR Rentokil Initial plc & Physalys dossier, alphachloralose is neither readily nor inherent biodegradable under test conditions. These results indicate according to screening criteria, that alphachloralose can be regarded as potentially persistent (P) or very persistent (vP).

Bioaccumulation

Given its low log Kow (0.85), alphachloralose is not considered to fulfill the B criterion.

Toxicity

For alphachloralose, no long-term data for aquatic organisms is available. Regarding short-term results (invertebrates, 48h EC50 = 0.027 mg a.s. /L < 0.1 mg/L), alphachloralose is considered to potentially fulfill the T criterion.

Alphachloralose is not considered to be a PBT or a vPvB substance, according to the TGD on Risk Assessment (2003).

### Effects on environmental organisms for biocidal product

It is important to notice that the applicant did not provide ecotoxicological data about the biocidal product BLACK PEARL GRAIN. Consequently, all the effects assessment is based on the data obtained from the active substance alphachloralose (Rentokil Initial plc & Physalys, Competent Authority Report According to Directive 98/8EC, Active substance in Biocidal Products, Alphachloralose CAS 15879-93-3, Product Type 14 (Rodenticides), RMS Portugal, October 2007).

Denatonium benzoate is used in the biocidal product as bittering agent. This substance is classified as “Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment” in the frame of the Directive 91/414/EEC. Nevertheless at the concentration used in BLACK PEARL GRAIN, the substance does not contribute to the classification of the biocidal product.

No other substance used in the biocidal product is classified for the environment.

Therefore, FR CA considered that the effects of alphachloralose outweigh those of the non-active components of the product and that the effects assessment for the product BLACK PEARL GRAIN can be extrapolated from the effects assessment of the active substance alphachloralose.

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

##### Aquatic organisms

Refers to section **Erreur ! Source du renvoi introuvable.**

##### Sediment dwelling organisms

Refers to section **Erreur ! Source du renvoi introuvable.**

##### STP micro-organisms

Refers to section **Erreur ! Source du renvoi introuvable.**

#### Atmosphere

Refers to section 2.8.2.2.

#### Terrestrial compartment

Refers to section **Erreur ! Source du renvoi introuvable.**

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

Refers to section 2.8.2.4

#### Summary of PNECs

Refers to section **Erreur ! Source du renvoi introuvable.**

### Environmental exposure assessment

#### Assessment of exposure to the environment

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

The product BLACK PEARL GRAIN is ready-to-use rodenticidal bait containing 4% alphachloralose (40 g/kg), enclosed in individual sealed bags or in cartridges, to be placed in covered bait points. Bait points are placed manually in dry locations inside buildings and in appropriate positions where the rodents are active, preferably between the rodents’ place of shelter and their food supply. When used in public areas or in locations accessible to children and non-target animals, the applicant proposed to use tamper resistant and securely closed bait boxes.

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

#### Aquatic compartment (surface water, sediment, STP)

Exposure of the aquatic compartment *via* the STP after the treatment with rodenticides is only relevant for indoor application of liquid poisons, residues from mixing and cleaning (ESD TP14). The product BLACK PEARL GRAIN is a solid form and is intended to be enclosed in individual sealed bags or in cartridges then to be used in dry locations inside buildings only. Therefore, exposure of surface water and sediment may be considered negligible.

#### Atmospheric compartment

Due to its physico-chemical properties (low vapour pressure of 8.83 x 10-3 Pa at 25°C and low Henry’s law constant of 5.65 x 10-4 Pa.m3.mol-1), alphachloralose is not expected to be present in the atmosphere in significant quantities, and if present in air it is expected to be quickly degraded by photo-oxidation. The exposure of air is therefore considered negligible for the application of BLACK PEARL GRAIN biocidal product.

#### Terrestrial compartment (soil and groundwater)

As the product BLACK PEARL GRAIN is intended to be used indoor only, no exposure to soil and groundwater is expected.

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

##### Primary poisoning

As stated in the ESD (Larsen, 2003), primary poisoning hazard to mammals and birds (both wild and domestic) can be considered small when rodenticides are applied according to the label instructions. No assessment has been carried out in the CAR Rentokil Initial plc & Physalys dossier and in the biocidal product dossier.

Nevertheless and in worst case, the scenario “in and around buildings” has been used considering that the risk for primary poisoning is mainly for birds and mammals of equal size or smaller as the target rodents (when the product is placed in protected bait point), which may be able to enter into the bait stations. Another exposure of non-target animals may arise when target rodents carry bait away from bait stations.

No assessment for birds has been realized by lack of bird’s toxicity data.

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

###### Primary poisoning – Tier 1 assessment

The Tier 1 assessment assumes that the whole day’s food requirement is satisfied by consumption of bait blocks and therefore the concentration in food will be the same as the concentration of the active substance in the bait: 40 g.kg-1 (4% w/w of alphachloralose in the product BLACK PEARL GRAIN). Hence, **the worst case Tier 1 PECoral is 40 000 mg.kg-1**.

###### Primary poisoning – Tier 2 assessment, acute exposure

According to ESD (Larsen, 2003), a Tier 2 assessment can be done estimating a daily uptake of a compound (ETE, mg.kg-1bw.d-1) by non-target animals according to the equation 19 of ESD:

With:

FIR: food intake rate of the indicator species (g.d-1),

BW: indicator species body weight (g),

C: concentration of the active substance in fresh diet (mg.kg-1),

AV: avoidance factor (-),

PT: fraction of diet obtained in treated area (-),

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

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

**Table 2.8.4.5.1-1: Expected concentrations of alphachloralose in non-target animals in the worst case (Step 1) and realistic worst case (Step 2) for acute situations.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Non-target animal** | **BW (g)a** | **FIR**  **(g dry weight.day-1)** | **C (mg.kg-1)** | **ETE = concentration of alphachloralose after one meal**  **(mg.kg-1 bw.d-1)** | |
|  | | | | **Step 1** | **Step 2** |
| **Dog** | **10 000** | **456b** | **40 000** | **1824** | **1313** |
| **Pig** | **80 000** | **600a** | **40 000** | **300** | **216** |
| **Pig young** | **25 000** | **600a** | **40 000** | **960** | **691** |

a From EUBEES 2, Table 3.1, section 3.2.1

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

###### Primary poisoning – Tier 2 assessment, long-term exposure

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

According to the ESD, a default value of 0.3 for daily uptake eliminated (El) can be used if no studies are submitted. The EC values are the expected concentration of active substance alphachloralose in non-target animals in primary poisoning scenarios after one meal followed by 24 hour elimination period.

**Table 2.8.4.5.1-2: Expected concentrations of alphachloralose in non-target animals in realistic worst case (Step 2) for long-term situation.**

|  |  |
| --- | --- |
| **Non-target animal** | **EC, conc. of alphachloralose after one day of elimination (mg.kg-1 bw)** |
|  | **Step 2** |
| **Dog** | 919 |
| **Pig** | 151 |
| **Pig young** | 484 |

##### Secondary poisoning

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

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

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

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

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

According to the ESD (Larsen, 2003) document, for uses ‘in and around buildings’ it is assumed that predators among mammals and birds may occur inside buildings or they may hunt rats in the immediate vicinity of buildings (parks and gardens or further away). Scavengers may also search for food close to buildings. Therefore secondary poisoning through poisoned rats exists, even in case of an indoor use. Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access.

No assessment for birds has been realized by lack of bird’s toxicity data.

###### Secondary poisoning - Tier 1 assessment, acute

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of alphachloralose in their food, i.e. the poisoned rodents. This PECoral is then compared to the LC50 values for a qualitative risk assessment in accordance with the decision from TM III-06. According to the ESD section 3.3.1, the consumption of rodenticides makes up at least 20 % of total consumptions in a choice test and could in a worst case be up to 100 %, whilst 50 % would be considered as the normal situation. Therefore, in the calculations the fractions of the food type in the diet (PD) are set to 0.2, 0.5 and 1.0. The FIR/BW quotient (food intake rate of the indicator species/indicator species body weight) is a default value set to 0.1, i.e. it is assumed that the rats eat 10 % of their bodyweight each day. The avoidance factor (AV) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PT) obtained in the area is set to 1.

The calculation is done according to equation 19 in the ESD:

(mg.kg-1bw.d-1)

This equation gives the concentration of alphachloralose in the rat (PECoral) after a meal the first day. Considering the elimination rate and that the mean time to death is seven days the concentration in the rodents each day can be calculated by the equation 21 in the ESD:

For the active substance alphachloralose, the default value of 0.3 is used for elimination (El).

Table 2.8.4.5.2-1: Residues of alphachloralose in target animals at specific point in times and varying bait consumption

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Residues in target animal (mg.kg-1bw)** | | |
| **20%** | **50%** | **100%** |
| **Day 1 after the first meal** | 800 | 2 000 | 4 000 |
| **Day 2 before new meal** | 560 | 1 400 | 2 800 |
| **Day 5 after the last meal** | 2 218 | 5 546 | 11 092 |
| **Day 7 mean time to death** | 1 087 | 2 717 | 5 435 |

According to the ESD, the concentrations of alphachloralose in rats are at peak after consuming bait for 5 days; thereafter the concentrations in rodents are decreasing until day 7 due to excretion and metabolism of the rodenticide. The values from day 5 are used as PECoral.

Moreover and due to the mode of action of alphachloralose with a mean time to death of 1.8 day ± 0.8 for the fresh test item group and 1.3 day ± 0.5 days for the aged test item group, observed in laboratory choice feeding test (see section 2.5.4), the values from day 1 after the first meal are used as PECoral too.

###### Secondary poisoning - Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning to mammals, the PEC in rodents after 1 day and after 5 days are used considering that the consumption of rodenticides makes up 100% of total consumptions (refer to Table 2.8.4.5.2-1)

**Table 2.8.4.5.2-1: Residues of alphachloralose in target animals at specific point in times and varying bait consumption used in the long term assessment**

|  |  |
| --- | --- |
| **Mammals** | **PECoral**  **Alphachloralose conc. in target rodent (mg.kg-1 bw),**  **ESD default values** |
| **Day 1 after the first meal** | 4 000 |
| **Day 5 after the last meal** | 11 092 |

###### Secondary poisoning - Tier 2 assessment, long-term

For the Tier 2 assessment the average food intake for each species and the average weight of the species have been considered, according to the Table 3.5 in the ESD. The calculations are based on the expected values for uptake of active substance by a mammal predator after a single day of exposure presented as an illustrative example in the ESD.

The amount of a.i. consumed by the non-target animal is 4 000 mg.kg-1 bw for rodents caught on day 1, also assuming that the non-target animals feed to 50 % on the rodents, all in accordance with the ESD. By knowing the amount of a.i. consumed by the non-target animal and the weight of the animal, the PEC (concentration in non-target animal) after one day consumption of rodents can be calculated. The results are presented in Table 2.8.4.5.2-1.

**Table 2.8.4.5.2-1: Expected concentrations of alphachloralose in non-target animals (predators/carnivores) due to secondary poisoning after a single day of exposure (concentration of alphachloralose in rodenticide bait 0.005%). Rodents fed 100% on rodenticide and predators/carnivores fed 50% on poisoned rodents.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | **Normal susceptible rodents caught**  **on day 1** | |
| **Species** | **Body weight**  **(g)** | **Daily mean food intake**  **(g.d-1)** | **Amount a.i. (mg)1** | **Conc. (mg.kg-1)2** |
| **Fox**  ***(Vulpes vulpes)*** | 5700 | 520.2 | 1 040 | 183 |
| **Polecat**  ***(Mustela putorius)*** | 689 | 130.9 | 262 | 380 |
| **Stoat**  ***(Mustela erminea)*** | 205 | 55.7 | 111 | 543 |
| **Weasel**  ***(Mustela nivlis)*** | 63 | 24.7 | 49 | 784 |

1Amount a.i. consumed by non-target animal

2 Conc. in non-target animal

### Risk characterisation for the environment

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC and/or LD50) according to the guidance in Technical guidance document (TGD, 2003) and “Emission Scenario document for biocides used as rodenticides” (Larsen, 2003, ESD PT14).

The environmental risk characterization has been carried out for alphachloralose.

#### Primary poisoning

No risk assessment for primary poisoning has been carried out in the final CAR of Rentokil Initial plc & Physalys. Consequently concentrations below which effects on mammals will not occur (PNEC and/or LD50) have been estimated in this dossier from toxicological study provided in the final CAR of Rentokil Initial plc & Physalys. Due to a lack of bird’s toxicity data no assessment for birds could have been performed.

##### Tier 1 assessment

The PEC value for Tier 1 assessment is compared to the long-term PNEC for mammals.

**Table 2.8.4.5.1-1: Tier 1 risk characterization of primary poisoning – Long-Term**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PEC1**  **mg.kg food-1** | **PNEC1**  **mg.kg food-1** | **PEC/PNEC** |
| **Mammals** | 40 000 | 1.334 | 29 985 |

1 Concentration of alphachloralose in food.

The resulting PEC/PNEC ratio reveals a high risk for mammals of long-term primary poisoning.

##### Tier 2 assessment – acute

For the acute situation of primary poisoning only a qualitative risk assessment is carried out in accordance with the decision from TM III-06. In this Tier 2 acute qualitative assessment, the PEC values are compared to the LD50 value.

**Table 2.8.4.5.1-2: Tier 2 acute qualitative risk assessment of primary poisoning**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **PECoral1**  **mg.kg-1 bw** | | **LD50 dose**  **mg.kg-1 bw d-1** | **PECoral > LD50**  **(y/n)** | |
| **Step 1** | **Step 2** | **Step 1** | **Step 2** |
| **Dog** | 1 824 | 1 313 | 341 | y | y |
| **Pig** | 300 | 216 | n | n |
| **Pig young** | 960 | 691 | y | y |

1 PECoral = ETE, concentration of alphachloralose after one meal

This comparison indicates that the situation for mammals is uncertain. Dogs and young pigs are at risk while pigs are not at risk but very close to being at risk.

##### Tier 2 assessment – long-term

The PEC values are compared to the PNEC value.

**Table 2.8.4.5.1-3: Tier 2 long-term risk assessment of primary poisoning**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECoral1**  **mg.kg-1 bw** | **PNEC**  **mg.kg-1 bw d-1** | **PEC /PNEC** |
| **Step 2** | | |
| **Dog** | 919  151  484 | 0.067 | 13 716 |
| **Pig** | 2 253 |
| **Pig young** | 7 223 |

1 PECoral = EC, concentration of alphachloralose after one day of elimination

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

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

#### Secondary poisoning

The only relevant scenario of secondary poisoning in the case of an indoor application only is for the rodent-eating mammal or bird. Due to a lack of bird’s toxicity data no assessment for birds could have been performed.

##### Tier 1 assessment, acute

The PECoral are compared to the LC50 value presented in the section above for qualitative risk assessment in accordance with the decisions taken at the TMII-06.

**Table 2.8.4.5.2-1: Tier 1 long-term risk assessment of secondary poisoning**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Mammals** | **PECoral**  **mg.kg-1 bw** | | | **LC50 dose**  **mg.kg-1 food** | **PECoral > LC50**  **(y/n)** | | |
| **PD=0.2** | **PD=0.5** | **PD=1** | **PD=0.2** | **PD=0.5** | **PD=1** |
| **Day 1** | 800 | 2 000 | 4 000 | 6 820 | n | n | n |
| **Day 5** | 2 218 | 5 546 | 11 092 | n | n | y |

PECoral = Expected concentration in rodent caught on day 1 after meal and on day 5 after meal

PD = fraction of the food type in the diet

This qualitative risk assessment indicates risk for mammals with a fraction of the food type in the diet of 1 and with a PEC in rodent caught on day 5 after meal.

##### Tier 1 assessment, long-term

To assess the risk of long-term secondary poisoning, the PEC in rodents after 1 day and 5 days are used and compared to the long-term PNECoral for mammals.

**Table 2.8.4.5.2-2: Tier 1 long-term risk assessment of secondary poisoning**

|  |  |  |  |
| --- | --- | --- | --- |
| **Mammals** | **PECoral**  **mg.kg-1 bw** | **PNEC**  **mg.kg-1 food** | **PEC /PNEC** |
| **Day 1** | 4 000 | 1.334 | 2 999 |
| **Day 5** | 11 092 | 8 314 |

1 PECoral = Expected concentration in rodent caught on day 1 after meal and on day 5 after meal

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

##### Tier 2 assessment, long-term

**Table 2.8.4.5.2-3: Tier 2 long-term risk assessment of secondary poisoning**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECoral**  mg.kg-1 bw | **PNEC**  mg.kg-1 bw | **PEC/PNEC** |
| Day 1 | Day 1 |
| **Fox (*Vulpes vulpes)*** | 183 | 0.067 | 2 731 |
| **Polecat (*Mustela putorious*)** | 380 | 5 672 |
| **Stoat (*Mustela erminea*)** | 543 | 8 104 |
| **Weasel (*Mustela nivlis*)** | 784 | 11 701 |

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

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

Nevertheless, in order to reduce the risk of secondary poisoning, it is very important to follow the use instructions of the rodenticide baits (see section 3).

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

No studies were conducted with the product BLACK PEARL GRAIN for the environment part; therefore the environmental risk assessment has been carried out with data from the CAR of alphachloralose. The environmental risk is considered as limited for the use indoor by professional and non professional, in strict compliance with the specific use instructions of rodenticidal baits and the use restrictions to reduce the risk for primary and secondary poisoning.

***Risk mitigation measures linked to risk assessment for environment***

* **Professional users:**
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment[[6]](#footnote-7).
* Dispose of the tamper-resistant bait boxes or in covered bait stations, uneaten baits and dead rodents in accordance with local requirements.
* Never wash the tamper-resistant bait boxes or in covered bait stations with water.
* Place the tamper-resistant bait boxes and covered bait stations in areas non-liable to floodings.
* Remove all bait points after the end of treatment.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Use in tamper-resistant bait boxes or in covered bait stations. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Covered bait stations must be placed only in areas not accessible to the general public and non-target animals
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.
* **Non-professional users:**
* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes and dead rodents, during and after treatment5.
* Dispose of the tamper-resistant bait boxes, non-consumed baits and dead rodents in accordance with local requirements.
* Never wash the tamper-resistant bait boxes with water.
* Place the tamper-resistant bait boxes in areas non-liable to floodings.
* Remove all bait points after the end of treatment.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Use only in tamper-resistant bait boxes. Tamper-resistant bait boxes should be clearly marked to show that they contain rodenticides and that they should not contain other products than rodenticides.
* Baits must be unattainable to children, pets or other non-target animals in order to minimize the risk of poisoning.

***Disposal considerations***

* Collect uneaten bait, bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations and dead rodents, during and after treatment5.
* Dispose of the tamper-resistant bait boxes and covered bait stations, uneaten baits and dead rodents in accordance with local requirements.
* Never wash the tamper-resistant bait boxes and covered bait stations with water.
* Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.
* Remove all bait points after the end of treatment.

***Required information linked to risk assessment for environment***

None.

## Measures to protect man, animals and the environment

*See Summary of Product Characteristics (SPC).*

# Annex

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Annexes

Annex 0a: Practical use claimed by the applicant

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the product and type of formulation (grains, powder, paste, block…)** | **Target organism (rat, mice…)\*** | **User category (professional/non professional)\*** | **Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps,…)\*** | **Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)** | **Time delay of the action of the product** | **Frequency and method of controls** | **Size(s) of the bait (g/block, g/grain, g/sachet, g/paste  …)** | **Distance between 2 bait points, for high and low infestation (if appropriate)** | **Methods of application of the bait (ex: pre-filled secured bait box)** | **Package details : Individual packaging (yes/no)\*\*** | **Primary packaging : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes** | **Secondary packaging** |
| **BLACK PEARL GRAIN**  Formulation: Granular bait (cereal bait) | *Mus mus­culus* | Non profes­sionals/ general public | Indoor | 10-25 g/bait point, in function of the infestation rate | First effects within a few minutes to a few hours. Death within 24-72 hours. | Bait points are inspected daily and replenished when bait take is observed. The baiting campaign stops with the end of bait consumption. Residual baits are removed at the end of the campaign. | individual sealed bags (10 g or 25 g) | 3-5 m. The shortest distance is to be used in severe infes­tations. | Bait points are covered. When used in public areas or in locations accessible to children and non-target animals, tamper resistant and securely closed bait boxes are used. | Yes | In individual bags made either of polyethylene or of paper outside and polyethylene inside | In 100 g or 150 g boxes or in 200 g Doypacks. |
| **BLACK PEARL GRAIN**  Formulation: Granular bait (cereal bait) | *Mus mus­culus* | Profes­sionals | Indoor | 10-25 g/bait point, in function of the infestation rate | First effects within a few minutes to a few hours. Death within 24-72 hours. | Bait points are inspected frequently and replenished when bait take is observed. The baiting campaign stops with the end of bait consumption. Residual baits are removed at the end of the campaign. | individual sealed bags (10 g or 25 g) | 3-5 m. The shortest distance is to be used in severe infes­tations. | Bait points are covered. When used in public areas or in locations accessible to children and non-target animals, tamper resistant and securely closed bait boxes are used. | Yes | In individual bags made either of polyethylene or of paper outside and polyethylene inside | In 1 kg or 5 kg buckets |

Annex 0b : practical uses validated by RMS France

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the product and type of formulation (grains, powder, paste, block…)** | **Target organism (rat, mice…)** | **User category (professional/non professional)** | **Area of use (sewers, in and around buildings, indoor only, open areas, waste dumps…)** | **Dosage claimed expressed in g/bait point, for high and low infestation (if appropriate)** | **Methods of application of the bait (ex: pre-filled secured bait box)** | **Primary packaging : type : bulk, individual wrapping…** | **Autho-risation** |
| **Black pearl GRAIN**  Formulation: paste bait | *Mus mus­culus* | Non profes­sionals | Indoor | 10-25 g/bait point, in function of the infestation rate | Use in tamper-resistant bait boxes. | Individual paper bags (10 and 25g) made either of polyethylene or of paper outside and polyethylene inside |  |
| Professionals | Indoor | 10-25 g/bait point, in function of the infestation rate | Use in tamper-resistant bait boxes or covered bait stations. | Individual paper bags (10 and 25g) made either of polyethylene or of paper outside and polyethylene inside |  |

Annex 1: Summary of product characteristics

*See separated file.*

Annex 2: List of studies reviewed

##### List of new data[[7]](#footnote-8) submitted in support of the evaluation of the active substance

The applicant has submitted alternative studies for the active substance dossier, i.e., new studies on the active substance are available in every section

The submitted alternative studies are considered as equivalent to the protected studies used to support the agreed end-points on the active substance (please refer to the matching table list placed on CIRCABC).

##### List of new data submitted in support of the evaluation of the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Yes** | **No** | **Yes** | **No** |
| B3 | B3  (submitted with confidential doc. C4) | Detrimont H., Ambrosi D. | 2011 | Literature survey on flammability, auto-flammability, explosive properties and oxidising properties of the ingredients of the product BLACK PEARL GRAIN,  A.S.C., France  Report No.11/23, 27 June 2011  Not GLP, not published | LODI |  |  |  |  |
| B3 | B3.1 | Magnier C. | 2011 | Determination of physical properties of Chloralose Grain Bait,  Study No.LODI.25/2011, 17 May 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.4 | Magnier C. | 2011 | Flammability of Chloralose Grain Bait, Study No.LODI.27/2011, 17 May 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.5 | Magnier C. | 2011 | Acidity-Alkalinity of Chloralose Grain Bait, Study No.LODI.28/2011, 17 May 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.6 | Magnier C. | 2011 | Relative density of Chloralose Grain Bait, Study No.LODI.42/2011, 30 May 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/01 | Magnier C. | 2011 | Chemical stability after accelerated storage of Chloralose Grain bait, Study No.LODI.33/2011, 24 May 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/02 | Leclercq S. | 2019 | Aspect, color, odor and chemical stability of alpha-chloralose in alpha-chloralose grain bait 4.0% and alpha-chloralose paste bait 4.0% after accelerated storage  Study n°LODI.09/2019  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/03 | Magnier C. | 2011 | Chemical stability of Chloralose Grain bait stored 2 years under 20°C ± 2°C conditions,  Study plan No.LODI.34/2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/05 | Magnier C. | 2011 | Chemical stability of Chloralose Grain bait stored 3 years under 20°C ± 2°C conditions,  Study plan No.LODI.35/2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/06 | Richerioux S. | 2018 | Compatibility between Alpha-Chloralose grain bait and packagings after 3 years of storage at 20°C±2°C  Study n°LODI.13/2015  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/07 | Leclercq, S. | 2019 | INTERIM REPORT A: Compatibility between alpha-chloralose grain bait and woven PP bag after three years of storage at 20°C ±2°C (6 months)  Study N°LODI.03/2019  GPL, not published | LODI |  |  |  |  |
| B3 | B3.7/08 | Magnier C. | 2011 | Chemical stability of Chloralose Grain bait stored 4 years under 20°C ± 2°C conditions,  Study plan No.LODI.36/2011  GLP, not published | LODI |  |  |  |  |
| B3 | B3.7/09 | Leclercq | 2016 | Packaging stability used for Alpha-chloralose grain bait  Study n°LODI.01/2012  GLP, not published | LODI |  |  |  |  |
| B3 | B3.8/01 | Baltussen E. | 2011 | Determination of the flowability of Chloralose Grain bait after heat test under pressure,  NOTOX B.V., The Netherlands  Study plan No.495279  GLP, not published | LODI |  |  |  |  |
| B3 | B3.8/02 | Halbwachs P. | 2019 | Physico-chemical tests before and after an accelerated storage procedure for 14 days at 54 °C ± 2°C on ALPHACHLORALOSE GRAIN BAIT 4%  DEFITRACES, France  Report No. 19-912011-003  GPL, not published | LODI |  |  |  |  |
| B3 | B4.1/01 | Magnier C. | 2011 | Analytical validation for determination of α-chloralose in Paste Bait and Grain Bait, Lodi, Study No.LODI.29/2011, 14 March 2011  GLP, not published | LODI |  |  |  |  |
| B3 | B4.1/02 | Leclercq S. | 2019 | Validation of the analytical method for the determination of alpha-chloralose in alpha-chloralose grain bait 4.0% and alpha-chloralose paste bait 4.0%  Study n°LODI.08/2019 | LODI |  |  |  |  |
| B5 | B.5.10/01 | Loiseau M. | 2011 | Choice feeding trial for a chloralose grain bait (fresh and aged product) against albino house mice, Briotrial Pharmacology Study code 0LODI2, Briotrial Pharmacology, 20 June 2011. Not GLP, not published | LODI |  |  |  |  |
| B5 | B5.10/02 | Biannic M.-L. | 2010 | Assessment of the efficacy of a rodenticide, in natural conditions, LODI, Assay number BPE.LODI.03/2010. Not GLP, not published | LODI |  |  |  |  |
| B5 | B5.10/03 | Guicherd A | 2019 | Rodenticide palatability and eficacy study of the bait ’Alphachloralose Grain Bait 4%’ in house mouse (*Mus musculus*), STUDY No 19LODMmLab002, Not GLP, not published | LODI |  |  |  |  |
| B5 | B5.10/04 | Guicherd A | 2019 | Evaluation of the efficacy of Alphachloralose grain bait, containing 4% alpha-chloralose for the control of house mouse infestation in cellar, STUDY No 19LODMmF002, Not GLP, not published | LODI |  |  |  |  |
| B6 | B6.1.1 | Colas S. | 2011 | Chloralose grain bait - Evaluation of acute oral toxicity in rats – acute toxic class method,  Phycher Bio Développement, France  Study No.TAO423-PH-11/0068, 21 April 2011  GLP, not published | LODI |  |  |  |  |
| B6 | B6.2/01 | Colas S. | 2011 | Chloralose grain bait – Assessment of acute dermal irritation,  Phycher Bio Développement, France  Study No.IC-OCDE-PH-11/0068, 21 April 2011  GLP, not published | LODI |  |  |  |  |
| B6 | B6.2/02 | Colas S. | 2011 | Chloralose grain bait – Assessment of acute eye irritation,  Phycher Bio Développement, France  Study No.IO-OCDE-PH-11/0068, 21 April 2011  GLP, not published | LODI |  |  |  |  |

Annex 3: Analytical methods residues – active substance

Alphachloralose

Date: 03.09.2012

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

Extract from document IIA of final CAR of alphachloralose except for food and feeding stuff as the methods were not validated. As no exposure to food and feeding stuf is estimated , no more data required.

**Table 3 – Analytical methods for determination of residues of alphachloralose and betachloralose in different matrices**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sample** | **Test substance** | **Analytical method** | **Fortification range / Number of measurements** | | **Linearity** | | **Specificity** | | **Recovery rate (%)** | | | | | | **Limit of quantify-cation** | | **Refe-rence** |
| Range | | Mean | | RSD | |
| Soil | Alphachloralose  (derivatised with Tri-Sil Z) | GC-MS | 0.05 mg/kg  5 measurements | | Five different concentrations through bracketed calibration.  0.02 – 1.0 µg/ml  r2 = 0.9962 | | The response in the controls was < 30% of the LOQ | | 81.6 – 92.2 | | 85.6 | | 5.1 | | 0.05 mg/kg | | Doc IIIA\_A4.2a-3 |
| 0.5 mg/kg  5 measurements | | 51.9 – 78.8 | | 70.2 | | 15.2 | |
| Beta-  chloralose (derivatised with Tri-Sil Z) | GC-MS | 0.05 mg/kg  5 measurements | | Five different concentrations through bracketed calibration.  0.02 – 1.0 µg/ml  r2 = 0.9956 | | The response in the controls was < 30% of the LOQ | | 69.2 – 86.8 | | 78.9 | | 8.6 | | 0.05 mg/kg | | Doc IIIA\_A4.2a-4 |
| 0.5 mg/kg  5 measurements | | 62.2 – 78.5 | | 70.3 | | 9.5 | |
| Drinking water | Alphachloralose | LC/MS/MS | 0.1 µg/L  5 measurements | Single determinations of 5 concentrations  0.008 – 0.025 µg/ml  r2 = 0.999 | | No interferences detected | | 84 – 91 | | 88 | | 3.4 | | 0.1 µg/L | | Doc IIIA\_A4.2c-2 | | |
| 1.0 µg/L  5 measurements | 95 – 103 | | 99 | | 2.9 | |
| Beta-  chloralose | LC/MS/MS | 0.1 µg/L  5 measurements | Single determinations of  5 concentrations 0.008 – 0.025 µg/ml  r2 = 0.997 | | No interferences detected | | 84 – 90 | | 87 | | 2.8 | | 0.1 µg/L | |
| 1.0 µg/L  5 measurements | 88 – 97 | | 93 | | 3.8 | |
| Surface water | Alphachloralose | LC/MS/MS | 0.1 µg/L  5 measurements | Single determinations of 5 concentrations 0.008 – 0.025 µg/ml  r2 = 0.999 | | No interferences detected | | 87 – 95 | | 90 | | 3.9 | | 0.1 µg/L | | Doc IIIA\_A4.2c-2 | | |
| 1.0 µg/L  5 measurements | 98 – 106 | | 102 | | 3.6 | |
| Beta-  chloralose | LC/MS/MS | 0.1 µg/L  5 measurements | Single determinations of 5 concentrations 0.008 – 0.025 µg/ml  r2 = 0.997 | | No interferences detected | | 86 – 98 | | 92 | | 5.8 | | 0.1 µg/L | |
| 1.0 µg/L  5 measurements | 90 – 97 | | 93 | | 2.9 | |
| Cucumber | Alphachloralose (derivatised with Tri-Sil Z) | GC-ECD | 0.01 mg/kg  5 measurements | Four different concentrations through bracketed calibration.  0.03 – 1.2 µg/ml  r2 = 0.9762 - 0.9981 | | The response in the controls was < 30% of the lowest fortification level | | 62 – 108 | | 94 | | 19 | | 0.01 mg/kg | | Doc IIIA\_A4.3-3 | | |
| 0.1 mg/kg  4 measurements | 86 – 95 | | 89 | | 5 | |
| GC-MS | 0.01 mg/kg  5 measurements | Four different concentrations through bracketed calibration.  0.03 – 1.2 µg/ml  r2 = 0.9664 - 0.9954 | | The response in the controls was < 30% of the lowest fortification level | | 71 – 120 | | 104 | | 19 | | 0.01 mg/kg | |
| 0.1 mg/kg  4 measurements | 90 – 103 | | 98 | | 6 | |

**Methods for air** (Reference: Doc IIIA\_A4.2b)

A method for detection in air needs to be submitted if the active substance is volatile (vapour pressure ≥0.01 Pa) or sprayed or occurrence in air is otherwise likely. The vapour pressure of Chloralose is 0.00883 Pa. It is not sprayed, it is formulated into a non-volatile solid and there is no reason to think occurrence in air is possible.

**Methods for body fluids/tissue** (Reference: Doc IIIA\_A4.2d)

An analytical method for detection of residues in animal and human body fluids and tissues is only required when the active substance is classified as toxic or highly toxic. Chloralose is not classified as such according to the proposed classification, and therefore it is not necessary to submit an analytical method to detect Chloralose residues in animal and human body fluid and tissues.

Annex 4: Toxicology and metabolism –active substance

Alphachloralose

Threshold Limits and other Values for Human Health Risk Assessment

Date: 22.12.2011

| **Summary** | | | | |
| --- | --- | --- | --- | --- |
|  | Value | | Study | SF |
| AEL long-term | 0.15 mg/kg bw/day | | Rat subchronic study | 100 |
| AEL medium-term | 0.15 mg/kg bw/day | | Rat subchronic study | 100 |
| AEL acute | 0.2 mg/kg bw/day | | Rat subacute study | 100 |
| ADI | Not applicable | |  |  |
| ARfD | Not applicable | |  |  |
|  | | | | |
| Inhalative absorption: 100% | |  | | |
| Oral absorption: at least 80% | |  | | |
| Dermal absorption: 3.11% (*in vitro* study) | |  | | |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | Xn, R20/22 |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4, H332/H302 |

Annex 5: Toxicology – biocidal product

BLACK PEARL GRAIN

Date: 22.12.2011

|  |  |
| --- | --- |
| **General information** | |
| **Formulation Type** | Grain |
| **Active substance(s) (incl. content)** | 4% alphachloralose |
| **Category** |  |

| **Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)** | | | | |
| --- | --- | --- | --- | --- |
| Rat LD50 oral (OECD 423) > 2000 mg/kg bw |  |  |  |  |
| Rat LD50 dermal: justification for non submission |  |  |  |  |
| Rat LC50 inhalation: justification for non submission |  |  |  |  |
| Skin irritation (OECD 404): Non irritant |  |  |  |  |
| Eye irritation (OECD 405): Non irritant |  |  |  |  |
| Skin sensitisation: justification for non submission |  |  |  |  |

| **Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)** | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies |  |  |  |  |
| Toxicological data on active substance(s): None (not tested with the preparation)  Refer to the compensation dossier. |  |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s): None (not tested with the preparation) |  |  |  |  |
|  |  |  |  |  |
| Further toxicological information: None |  | | | |

|  |  |
| --- | --- |
| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
| Directive 1999/45/EC | None |
| Regulation 1272/2008/EC | None |

Annex 6: Safety for professional operators

BLACK PEARL GRAIN

Date: 23.07.2012

Exposure assessment

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

Primary exposure of professionals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/kg/d]** | **Model** |
| Tier 1: BLACK PEARL GRAIN in bulk | Alphachloralose | 15879-93-3 | 1.59 x 10-1 | 2.10 x 10-4 | CEFIC study |
| Tier 2: BLACK PEARL GRAIN in sachet | Alphachloralose | 15879-93-3 | 4.04 x 10-2 | na | CEFIC study |

**Risk assessment**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Component** | **AEL [mg/kg/d]** | **Absorption [%]** | | **Total syst exposure**  **[mg/kg bw/d]** | **% AEL** | **Risk** |
|  |  |  | **Inhala-tion** | **dermal** |  |  |  |
| Tier 1: BLACK PEARL GRAIN in bulk | Alphachloralose | **0.15** | **100** | **100** | **1.59 x 10-1** | **106** | **Unacceptable** |
| Tier 2: BLACK PEARL GRAIN in sachet | Alphachloralose | **0.15** | **100** | **100** | **4.04 x 10-2** | **27** | **Acceptable** |

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

BLACK PEARL GRAIN

Date:23.07.2012

| General information | |
| --- | --- |
| Formulation Type | Grains |
| Active substance(s) (incl. content) | alphachloralose 4% |
| Category |  |
| Authorisation number |  |

| **<Alphachloralose >** |
| --- |

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

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 ) | |
| --- | --- |
| Primary exposure | Non-professional use |
| Secondary exposure, acute | Infant ingesting bait |
| Secondary exposure, chronic | None |

Conclusion:

The risk related to exposure of non-professionals to the biocidal product containing alphachloralose as active substance is considered acceptable.

The accidental ingestion of baits poses a risk to infants since the AEL is exceeded when infant ingests more than 50 mg of product per day.

Details for the exposure estimates:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Component** | **CAS** | **Actual Dermal Total**  **[mg/kg/d]** | **Inhalation Exposure**  **[mg/m³]** | **Model** |
| Tier 1: BLACK PEARL GRAIN in bulk | Alphachloralose | 15879-93-3 | 2.70 x 10-2 | na | CEFIC study |
| Tier 2: BLACK PEARL GRAIN in sachet | Alphachloralose | 15879-93-3 | 1.51 x 10-2 | na | CEFIC study |

**Risk assessment**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Component** | **AEL [mg/kg/d]** | **Absorption [%]** | | **Total syst exposure**  **[mg/kg bw/d]** | **% AEL** | **Risk** |
|  |  |  | **inhalation** | **dermal** |  |  |  |
| Tier 1: BLACK PEARL GRAIN in bulk | Alphachloralose | 0.15 | 100 | 100 | 2.70 x 10-2 | 18 | Acceptable |
| Tier 2: BLACK PEARL GRAIN in sachet | Alphachloralose | 0.15 | 100 | 100 | 1.51 x 10-2 | 10 | Acceptable |

Annex 8: Residue behaviour

Alphachloralose

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

Annex 9: Efficacy of the active substance from its use in the biocidal product

| Test substance | Test organism(s) | Test system / concentrations applied / exposure time | Test results: effects, mode of action, resistance | Reference | RI |
| --- | --- | --- | --- | --- | --- |
| BLACK PEARL GRAIN  (freshly manufactured and 14 days-aged manufactured) | *Mus musculus*  10 males and 10 females albino RjOrl:Swiss (CD-1) House mice | Choice test with unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet) during a 4-day test period.  Mice received the test item from two symmetrically-placed food bowls at the front of each cage, one filled with the test product, the other with the challenge diet. The positions of the bowls were alternated daily. The contents of the food bowls were made up daily to provide an excess of the animals’ daily requirement from each bowl (approximately 5 g of rodenticide grain bait, 10 g of challenged diet in each corresponding pot).  The maximum duration of the test was 13 days: 6 days of acclimatization (including 4-days pre-test period when food intake and body weight of each animal were determined daily); 4-days test period (period of exposure to the test item) and 3-days observation period. | The study showed that, freshly and aged manufactured, chloralose grain bait are palatable, with a mean palatability against ground laboratory diet of respectively 20.8 % (S.D. 5.0 %) and 23.3 % (S.D: 8.2 %). The test item also resulted in 100 % mortality after a 4-days choice feeding period between the fresh or aged test item formulation and challenge diet. | IIIB5.10.2-01 | 1 |
| BLACK PEARL GRAIN | *Mus musculus* | The test was carried out on a farm raising calves and cows.  - first period: determination of the consumption plateau of the initial population to measure initial daily consumption (43 days)  - second period: rodenticide application (8 days)  - third period: establishment of the consumption plateau of the surviving population to measure residual consumption (6 days).When the pre-baiting consumption reached the plateau, the non-poisoned baits were replaced by the product to be tested. After the baiting period, the residual consumption was determined to be compared with the initial consumption.  During the baiting period, bait stations received 50 g baits (4 % alphachloralose). Baits were replaced daily. | Efficacy of 97.7 %. | IIIB5.10.2-02 | 2 |
| ALPHACHLORALOSE GRAIN (fresh) | *Mus musculus*  5 males and 5 females  Wild strains | Choice test with unrestricted access to the test bait and to palatable and familiar alternative food (challenge diet) during a 4-day test period.  Mice received the test item from two symmetrically-placed food bowls at the front of each cage, one filled with the test product, the other with the challenge diet. The positions of the bowls were alternated daily. The contents of the food bowls were made up daily to provide an excess of the animals’ daily requirement from each bowl (10 g of rodenticide grain bait (ALPHACHLORALOSE GRAIN), 10 g of challenged diet in each corresponding pot).  Duration of the test::4 days of acclimatization; 4-days pre-test period when food intake and body weight of each animal were determined daily; 4-days test period (period of exposure to the test item) and no-day observation period because all the rodents died. | The study showed that, freshly ALPHACHLORALOSE GRAIN bait is palatable, with a mean palatability ratio of the product of 1,7. The test item also resulted in 100 % mortality after a 3-days choice feeding period between the fresh test item formulation and challenge diet. | IIIB5.10.2-03 | 1 |
| ALPHACHLORALOSE GRAIN (fresh) | *Mus musculus*  Approximately 15 mice. | The test was carried out in a cellar of a residual house.  - first period: determination of the consumption plateau of the initial population to measure initial daily consumption (7 days)  - second period: rodenticide application (10 days)  - third period: establishment of the consumption plateau of the surviving population to measure residual consumption (8 days).When the pre-baiting consumption reached the plateau, the non-poisoned baits were replaced by the product to be tested. After the baiting period, the residual consumption was determined to be compared with the initial consumption.  During the baiting period, bait stations received 10 g baits (4 % alphachloralose) separated by 5 m. Baits were replaced daily. | Efficacy of 100 % from D8.  4 dead house mouse. | IIIB5.10.2-04 | 1 |

**Annex 10 : Addendum to the Product Assessment Report**

**Addendum to the**

**Product Assessment Report**

Biocidal product assessment reports related to product authorisation and frame formulation establishment under Directive 98/8/EC

**BLACK PEARL GRAIN**

**LODI S.A.S.**

April 2014

|  |  |
| --- | --- |
| Internal registration/file no: | PB-11-00241, PB-11-00244 |
| Authorisation/Registration no: | FR-2013-0004 (professional) and FR-2013-1003 (non-professionnal),FR-2013-0016 (professional) and FR-2013-1008 (non-professionnal), |
| Granting date/entry into force of authorisation/ registration: | 19 March 2013 |
| Expiry date of authorisation/ registration: | 30 June 2021 |
| Active ingredient: | Alphachloralose |
| Product type: | 14 - Rodenticide |

**Competent Authority in charge of delivering the product authorisation:**

French Ministry of Ecology

Department for Nuisance Prevention and Quality of the Environment

Chemical Substances and Preparation Unit

Grande Arche, Paroi Nord

92 055 La Défense cedex – FRANCE

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**Authority in charge of the efficacy and risk assessment:**

Anses – French agency for food, environmental and occupational health and safety

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1. **General information**

*This addendum relates to the submission of post-registration data by the applicant, as requested in the product assessment reports related to BLACK PEARL GRAIN product authorization and frame formulation establishment under Directive 98/8/EC.*

*Please refer to the above mentioned product assessment report for further details.*

1. **Summary of the product assessment**

*This section only refers to the post-registration data requested by Anses and submitted by the applicant. For further details regarding the initial assessment of this product, please refer to the product assessment reports related to BLACK PEARL GRAIN product authorization and frame formulation establishment under Directive 98/8/EC.*

#### Physico-chemical properties of the biocidal product

* Reminder of the risk assessment performed in the frame of the first authorisation dossier:

**Storage stability:**

Results of the accelerated storage stability studies demonstrate that the biocidal product is stable 2 weeks at 54°C in glass beaker. The Biocidal product is therefore expected to be stable 2 years at ambient temperature and a 2-year shelf-life is granted.

The on-going shelf life study does not test the content of active substance during storage.

A new shelf life study must be started including the content of active substance in biocidal product.

Results of this storage stability study are required in post registration.

Compatibility with deposited packaging material (10 g LDPE bags) is not demonstrated. A study demonstrating this compatibility is required in post registration.

**Data requirement:**

Compatibility study with deposited packaging material (10 g LDPE bags) and results of the long-term storage stability study at ambient temperature with intermediary results after 1 year (with measurements of the content of the active substance in the biocidal product).

Particle size distribution of grains according to CIPAC MT 170 with sieves adapted to biocidal product.

* Assessment of the submitted post-registration data:

Results of the long-term storage stability at ambient temperature demonstrate that the biocidal product is stable 2 years at ambient temperature when packaged in LDPE bags.

Particle size distribution and attrition are acceptable; the product is nearly dust free before and after 2 years storage at ambient temperature.

All submitted studies have been performed on the BLACK PEARL GRAIN formulation containing 4% of alphachloralose.

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Shelf life study | 6 months at ambient temperature | Chloralose paste bait (4% alphachloralose)  Batch: ER20110706 achlo | **After 6 month at ambient temperature in individual bags (material not precised):**   |  |  |  | | --- | --- | --- | |  | T0 | 6M RT | | Content of AS (ppm) | Not measured | | | Appearance of test item | Black oats in individual bag. No fat, no moisture, no hole | Black oats in individual bag. No fat, no moisture, no hole | | Appearance of secondary packaging | Dry internal wall | Dry internal wall |   Concentration of a.s was not measured in this study | Richerioux S. 2012  Evaluated in the PAR |
| Shelf life study | 24 months at ambient temperature | Chloralose grain bait (4% alphachloralose)  Batch: AB20110317 achlo | **After 24 month at ambient temperature (plastic bag):**   |  |  |  | | --- | --- | --- | |  | T0 | 24M RT | | Content of AS (ppm) | 4.21 | 4.29 | | Appearance of test item | Black oats  Color N2/0.75 | Black oats  Color N3/0 | | Dry sieve | < 250 μm  Top 0.2%  Middle 0.3%  Bottom 0.2%  < 850 μm  Top 3.9%  Middle 3.8%  Bottom 3.8%  < 2000µm  0  <4000µm  0 | < 250 μm  Top 0.5%  Middle 0.5%  Bottom 0.6%  < 850 μm  Top 4.3%  Middle 4.2%  Bottom 4.1 %  < 2000µm  Top 13.4%  Middle 12.3%  Bottom 12.6%  < 4000 μm  Top 100%  Middle 100% Bottom 100% | | Attrition resistance | 99.6% | 99.6% | | Dustiness of granular products | Nearly dust free | Nearly dust free | | Richerioux S. 2013  Post authorisation Evaluation (april 2014) |

1. **Proposal from authority in charge of the efficacy and risk assessment (ANSES) for the decision to be adopted by the competent authority in charge of the decision (French Ministry of Ecology)**

*This section is a proposal from the authority in charge of the efficacy and risk assessment (ANSES) for the decision to be adopted by the competent authority in charge of the decision (French Ministry of Ecology).*

*In case of inconsistency between the risk assessment and the decision, only the original and signed decision has a legal value. The decision specifies the terms and conditions to the making available on the market and use of the biocidal product.*

The post-registration data submitted by the applicant allow to consider the product as stable for 2 years in commercial packaging. Moreover, particle size distribution and attrition are acceptable and the product is nearly dust free before and after 2 years storage at ambient temperature.

The assessment of these data does not question the previous conclusions from the authority in charge of the efficacy and risk assessment.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. RAC: ECHA Committee for Risk Assessment. [↑](#footnote-ref-3)
3. Human exposure to biocidal products – Technical Notes for Guidance (2007). Annex 4: Human exposure to rodenticides (Product Type 14) [↑](#footnote-ref-4)
4. HEEG opinion on harmonising the number of manipulations in the assessment of rodenticides (anticoagulant), agreed at TMII2010 [↑](#footnote-ref-5)
5. Rentokil Initial plc & Physalys Competent Authority Report according to the procedure of Directive 98/8/EC, active substance in biocidal products, alphachloralose CAS n°15879-93-3, product type 14 (rodenticides), RMS Portugal, October 2007 [↑](#footnote-ref-6)
6. If the dead rodents, uneaten bait and bait fragments dragged away from the tamper-resistant bait boxes or covered bait stations are not entirely collected, primary and secondary poisoning risks remain unacceptable. [↑](#footnote-ref-7)
7. Data which have not been already submitted for the purpose of the Annex I inclusion. [↑](#footnote-ref-8)