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

**DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL**

**AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Duracid PW

Product type 18

Cypermethrin as included in the

Union list of approved active substances

Case Number in R4BP: BC-GV059382-15

Evaluating Competent Authority: Greece

Date: May 2022

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# CONCLUSION

**Conclusion for Physico-chemistry:**

Duracid PW is a dustable powder insecticide (PT 18), containing nominal (pure) active ingredient of 0.6% w/w cypermethrin.

Its physicochemical properties are considered acceptable for dustable powder product. The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

Acceptable data from accelerated storage stability study indicate that the product is anticipated to be stable for up to two years at ambient temperature when stored in the proposed commercial packaging.

Acceptable analytical method was provided for the determination of the four isomers of the active substance in the formulation.

**Post-authorization data requirement:** The long term storage stability study at ambient temperature should be provided, for the product Duracid PW, when completed.

**Conclusion for human health:**

Regarding human health hazards the biocidal product Duracid PW should not be classified.

Regarding risk assessment, the primary exposure of professional and non-professional users does not entail unacceptable risk for human health.

With respect to secondary exposure of the general public, a risk has been identified for infants, toddlers and children entering into treated areas and touching with their hands the contaminated surfaces. However, considering the label implication that the product should be used in areas inaccessible to infants and children, no concern arises for these populations groups.

**Conclusion for Efficacy**

Several efficacy studies (laboratory, simulated use and field studies) were submitted for Duracid PW (Ready to Use product) containing cypermethrin 0.6%. Based on the results of the submitted efficacy studies, the product was effective when applied as:

* Crack and crevice treatment indoors against crawling insects at 5 gr/ m2 and crack and crevice treatment outdoors against ants at 5 gr/ m2, by non-professionals. (Intended Use 1)
* Barrier treatment outdoors against ants (*L. niger*), at 5gr/m2, by non-professionals. All around the perimeter apply a strip not wider than 1cm. (Intended Use 2)
* Crack and crevice treatment indoors against crawling insects at 5 gr/ m2, by professionals. (Intended Use 3)
* Crack and crevice treatment indoors against bed bugs and fleas at 10 gr/ m2, by non-professionals and professionals. (Intended Uses 4&5)
* Spot application at the entrance of wasp nests at 2.5 gr/ nestindoors, by non-professionals and professionals. (Intended Uses 6&7)
* Crack and crevice treatment indoors against poultry mites at 10 gr/ m2, by non-professionals and professionals. (Intended Use 8)

**Conclusion for Environment:**

According to the environmental risk assessment, the risk for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning) is acceptable when following the label instructions of Duracid PW.

Furthermore, an acceptable risk for Duracid PW to be used in animal housing in arable lands and grasslands, for non-target organisms, is demonstrated provided that label instructions are followed.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Duracid PW | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | VEBI ISTITUTO BIOCHIMICO SRL |
| **Address** | VIA DESMAN 43, 35010 BORGORICCO (PD), Italy |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | VEBI ISTITUTO BIOCHIMICO SRL |
| **Address of manufacturer** | VIA DESMAN 43, 35010 BORGORICCO (PD), Italy |
| **Location of manufacturing sites** | 1. VIA DESMAN 43, 35010 BORGORICCO (PD), Italy 2. Sinapack s.r.l., Viale Industria e Atrigianato 7, 27049 STRADELLA (PV), Italy |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | CYPERMETHRIN TECHNICAL 40/60 |
| **Name of substance supplier (according to art. 95)** | LIMARU NV (acting for Tagros Chemicals India Ltd) |
| **Address of substance supplier (according to art. 95)** | Business Center Mezzo  Paalsesteenweg 170 Bus 7,  B-3583 BERINGEN, Belgium |
| **Name of manufacturer** | Tagros Chemicals India Private Ltd. |
| **Address of manufacturer** | “Jhaver Centre”, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, 600 008 Egmore, Chennai, India |
| **Location of manufacturing site** | A-4/1&2, Sipcot Industrial Complex,  Pachayankuppam, Cuddalore,  607 005 Tamil Nadu India  The address of the manufacturing plant for the active substance has been evaluated in the technical equivalence of Tagros Chemicals. |

### Product 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

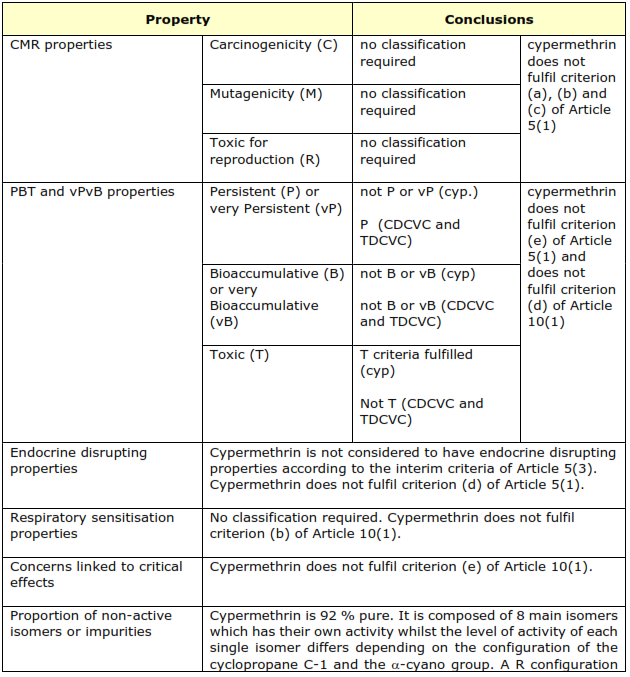
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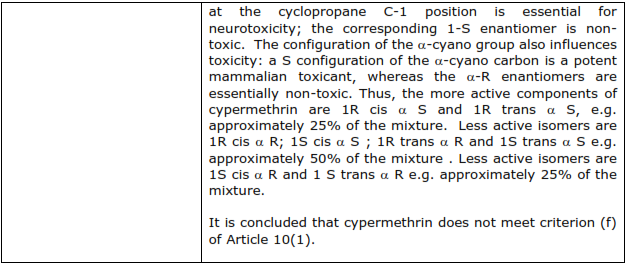
#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent** | |
| **ISO name** | CYPERMETHRIN TECHNICAL 40/60 |
| **IUPAC or EC name** | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; alphacyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cyclopropanecarboxylic acid,  3(2,2-dichloroethenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester; cypermethrin cis/trans +/-  Cis/trans 40/60; cypermethrin, technical |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 607-421-00-4 |
| **Minimum purity / content** | Minimum purity according to Commission Implementing Regulation (EU) 2018/1130: 92% w/w  Minimum purity from the technical of source used for the preparation of the product Duracid PW: 95 % w/w (Tagros) |
| **Structural formula** |  |
| **Molecular weight** | 416.3 g/mol |
| **Molecural formula** | C22H19Cl2NO3 |

#### Candidate for substitution

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

**

**

Cypermethrin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. Cypermethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

Results from Opinion on the application for approval of the active substance (ECHA/BPC/153/2017):

Cypermethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No

528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR” and in line with “Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR” agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1) (a, b, d, e and f).

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin | (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.6 % w/w (pure)  0.632 % w/w  (technical) |
| Dipropylene glycol monomethyl ether | 1-(3-methoxypro-poxy)propan-1-ol | Co-formulant | 34590-94-8 | 252-104-2 | 1.4 % w/w |
| Non-active substance | Confidential information. Please refer to the confidential information annex | | | | Up to 100 |

#### 

#### Information on technical equivalence

The source of the active substance cypermethrin in DURACID PW biocidal formulation is Tagros Chemicals India Ltd., which has been assessed to be technical equivalent to the reference source by ECHA on December 2020 (case number BC-UA059575-34, decision number TAP-D-1477453-13-00/F).

The active substance supplier LIMARU NV is the approved supplier of cypermethrin active substance in accordance with Article 95 of Regulation (EU) No. 528/2012. The respective Letter of Access/Supply has been submitted.

#### Information on the Substance(s) of Concern

The biocidal product Duracid PW contains as a Substance of Concern the co-formulant dipropylene glycol monomethyl ether (CAS No. 34590-94-8), as it has a European Union-agreed Indicative Occupational Exposure Limit Value (IOELV).

Please refer to the Confidential Annex for further details.

#### Type of formulation

|  |
| --- |
| DP - Dustable powder |

### Hazard and precautionary statements[[3]](#footnote-3)

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute category 1  Aquatic Chronic category 1 |
| Hazard statement | H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning GHS09 |
| 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 and container in accordance with national law. |
|  | |
| Special provisions: | ND |
| Contains | - |
| Note | - |

### Authorised use(s)

#### Use description #1

Table 1. Intended use # 1 – **General public- crawling insects**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of crawling insects - General public |
| Target organism (including development stage) | *Lasius niger* Ants Adults *Blatta orientalis* Oriental cockroach Adults *Blattella germanica* German cockroach Adults |
| Field of use | Indoors and only for the control of ants outdoor around the building only on balconies and terraces. |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  Apply 5 g/m2 of product in thin layers in cracks and crevices, only on restricted areas on surfaces where wet cleaning is not feasible (e.i. behind or under appliances, under the kitchen sink), voids and cavities(partition between walls, holes, etc.) where insects usually hide.  For outdoor treatment: apply 5 g/m2 of product in thin layers in cracks and crevices on paved surfaces, only on balconies and terraces. |
| Application rate(s) and frequency | The application rate is 5 g/m².​  Residual activity  Cockroaches: 8 weeks  Ants: 4 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle: LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  - bottle: HDPE  - cap: PP; LDPE |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  The product is a powder intended to be used as it is.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  5 grams of product equals to 4 teaspoons approximately. Disposable or dedicated teaspoon should be used.  For indoor treatment: apply 5 g/m2 of product in thin layers in cracks and crevices, only on restricted areas on surfaces where wet cleaning is not feasible (e.i. behind or under appliances, under the kitchen sink), voids and cavities (partition between walls, holes, etc.) where insects usually hide.  Against Oriental cockroach the product exerts no knockdown effect and mortality is expected 7 days after exposure of the insects to the treated surfaces.  For outdoor treatment: apply 5 g/m2 of product in thin layers in cracks and crevices on paved surfaces, only on balconies and terraces.  For the use indoors and outdoors against ants: the product exerts no knockdown effect and mortality is expected 7 days after exposure of the insects to the treated surfaces.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces where wet cleaning is not feasible. Do not apply to areas susceptible to routine wet cleaning.  For treatment around building: apply only on paved surfaces and roof-covered area. Do not apply near bodies of surface water or in the area of water protection zones.  Apply only in areas that are not liable to submersion or becoming wet, i.e protected from rain, floods and cleaning water.  For use only in areas that are inaccessible to infants, children, companion animals and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #2

Table 2. Intended use # 2 – **General public - ants, outdoor around the building**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of ants - General public – around building |
| Target organism (including development stage) | *Lasius niger* Ants Adults |
| Field of use | Other: Outdoor around building |
| Application method(s) | Spreading  Ready to use product  Apply 5 g/m2 as a barrier treatment all around the perimeter of the building, with a strip not wider than 1 cm. |
| Application rate(s) and frequency | The application rate is 5 g/m².​  The product has no residual activity.  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle: LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  - bottle: HDPE  - cap: PP; LDPE |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  The product is a powder intended to be used as it is.  Apply 5 g/m2 as a barrier treatment all around the perimeter of the building, with a strip not wider than 1 cm.  5 grams of product equals to 4 teaspoons approximately. Disposable or dedicated teaspoon should be used.  The product exerts no knockdown effect and mortality is expected only 7 days after exposure of the ants to fresh treated non-porous surfaces.  The product has no residual activity.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes |

#### 

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #3

Table 3. Intended use # 3 – **Professional - crawling insects - indoors**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of crawling insects - professional |
| Target organism (including development stage) | *Lasius niger* Ants Adults *Blatta orientalis* Oriental cockroach Adults *Blattella germanica* German cockroach Adults |
| Field of use | Indoors |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product.  Apply 5 g/m2 of product in thin layers in cracks and crevices, only on restricted areas on surfaces on surfaces where wet cleaning is not feasible (e.i. behind or under appliances, under the kitchen sink), voids and cavities (partition between walls, holes, under floating floors etc.) where insects usually hide. |
| Application rate(s) and frequency | The application rate is 5 g/m².​  Residual activity against *Blattella Germanica*: 8 weeks  Residual activity against *Blatta orientalis* and *Lasius niger*: 2 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | Trained professional  Professional |
| Pack sizes and packaging material | Envelope:  0,5 kg, 1kg, 1,5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 500 g  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  Codes of good practice should be followed.  Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.). Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action. Do not mix with other chemicals or products.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  The product is a powder intended to be used as it is.  Apply 5 g/m2 of product in thin layers in cracks and crevices, only on restricted areas on surfaces where wet cleaning is not feasible (e.i. behind or under appliances, under the kitchen sink), voids and cavities (partition between walls, holes, under floating floors etc.) where insects usually hide.  Μortality of the Oriental cockroaches is expected 7 days after exposure of the insects to treated surfaces.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Environmental precautions: Prevent product from entering the environment (surface and groundwater), sewerage, drainage with the construction of protective barriers and closing drains.  Inform the relevant authorities uncontrolled leaks or spills to water courses, drains, sewers.  Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor.  For use only in areas that are inaccessible to infants, children, companion animals and farm animals.  The product has to be applied only on restricted areas on surfaces where wet cleaning is not feasible. Do not apply to areas susceptible to routine wet cleaning.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes |

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #4

Table 4. Intended use # 4 – **General public - Bed bugs and fleas - indoors**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of bed bugs and fleas- General public – indoors |
| Target organism (including development stage) | *Cimex lectularius* Bed bug Adults *Ctenocephalides felis* Cat flea Adults |
| Field of use | Indoors |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  Apply 10 g/m2 of product in thin layers in cracks and crevices only on restricted areas on surfaces not regularly wet cleaned  (e.i. under furniture, corners) and in void and cavities (between partition walls, holes, etc.) where insects usually hide. |
| Application rate(s) and frequency | The application rate is 10 g/m².​  Residual activity: 2 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  - bottle: HDPE  - cap: PP; LDPE |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  Bedbugs harbour themselves in very confined areas in wall cracks, furniture joints, behind pictures and in seams of furnishings. These insects generally confine themselves to these areas and leave them only to feed during the night. Bedbugs are usually not seen outside the harbourage during the day or when the lights are on.  The product is a powder intended to be used as it is.  Fleas harbour themselves on cracks in the floor, or crevices in furniture and furnishings.  Apply 10 g/m2 of product in thin layers in cracks and crevices only on restricted areas on surfaces not regularly wet cleaned (e.i. under furniture, corners) and in voids and cavities (between partition walls, holes, etc.) where insects usually hide.  10 grams of product equals to 8 teaspoons approximately. Disposable or dedicated teaspoon should be used.  The product is effective up to 2 weeks.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  The product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  For use only in areas that are inaccessible to infants, children, companion animals and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

#### 

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #5

Table 5. Intended use # 5 – **Professional - Bed bugs and fleas - indoors**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of bed bugs and fleas – professional |
| Target organism (including development stage) | *Cimex lectularius* Bed bug Adults *Ctenocephalides felis* Cat flea Adults |
| Field of use | Indoors |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  Apply 10 g/m2 of product in thin layers in cracks and crevices only on restricted areas on surfaces not regularly wet cleaned  (e.i. under furniture, corners) and in void and cavities (between partition walls, holes, etc.) where insects usually hide. |
| Application rate(s) and frequency | The application rate is 10 g/m².​  Residual activity: 2 weeks  Treatment can be performed up to 2 times per year. |
| Category(ies) of user(s) | Trained professional  Professional |
| Pack sizes and packaging material | Envelope:  0,5 kg, 1kg, 1,5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 500 g  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  Codes of good practice should be followed.  Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.). Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action. Do not mix with other chemicals or products.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for wall cracks, furniture joints, behind pictures and in seams of furnishings. These insects generally confine themselves to these areas and leave them only to feed.  The product is a powder intended to be used as it is.  Apply 10 g/m2 of product in thin layers in cracks and crevices only on restricted areas on surfaces not regularly wet cleaned (e.i. under furniture, corners) and in voids and cavities (between partition walls, holes, etc.) where insects usually hide.  The product is effective up to 2 weeks.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  The product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor  For use only in areas that are inaccessible to infants, children, companion animals and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

#### 

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #6

Table 6. Intended use # 6 – **General public - control of wasp - indoors**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of wasp - General public – treatment of nest. |
| Target organism (including development stage) | *Vespula germanica*  German wasp  Adults and larvae |
| Field of use | Indoors  Spot application at the entrance of the nest |
| Application method(s) | Spot application by spreading into wasp nests.  Apply 2,5 g of dust into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal. |
| Application rate(s) and frequency | The application rate is 2,5 g/ nest.​  The product will destroy the entire nest 3 weeks after treatment.  Treatment can be performed up to 2 times per year. |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  - bottle: HDPE  - cap: PP; LDPE |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  The product is a powder intended to be used as it is.  Apply 2,5 g of product directly on the holes. Apply the dust such into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  2.5 grams of product equals to 2 teaspoons approximately. Disposable or dedicated teaspoon should be used.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal.  Apply the product only after locating the entrance to the tunnel, and apply the product when there is no activity of wasps (usually after the sunset or early morning). Contact a pest control if the shape of the nest does not allow to clearly identify the entrance to the nest.  The product will destroy the entire nest 3 weeks after treatment.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  The product has to be applied only on restricted areas on surfaces not regularly cleaned. Do not apply to areas susceptible to routine wet cleaning.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

#### 

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #7

Table 7. Intended use # 7 – **Professional - control of wasp - indoors**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of wasp - professional user – treatment of nest. |
| Target organism (including development stage) | *Vespula germanica*  German wasp  Adults and larvae |
| Field of use | Indoors  Spot application at the entrance of the nest |
| Application method(s) | Spot application by spreading into wasps nest.  Apply 2,5 g of dust into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal. |
| Application rate(s) and frequency | 2.5 g/nest.  Spot application.  The product will destroy the entire nest 3 weeks after treatment.  Treatment can be performed up to 2 times per year. |
| Category(ies) of user(s) | Trained professional Professional |
| Pack sizes and packaging material | Envelope:  0,5 kg, 1kg, 1,5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 500 g  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  Codes of good practice should be followed.  Take into account the life cycle and characteristics of target insects to adapt treatments.  In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.  Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.). Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action. Do not mix with other chemicals or products.  The product is a powder intended to be used as it is.  Apply  2,5 g of product direcly on the holes. Use an applicator to apply the dust such into the holes where the wasps are going in and out. The dust will help  eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal.  The product will destroy the entire nest 3 weeks after the treatment.  Remove (clean) product after residual activity.  Remove dead insects. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  The product has to be applied only on restricted areas on surfaces not regularly cleaned. Do not apply to areas susceptible to routine wet cleaning.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Use description #8

Table 8. Intended use # 8 – **Rural hygiene (animal Houses/Shelters)**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For control of poultry mites - rural indoor use – cracks and crevices, voids and cavities |
| Target organism (including development stage) | *Dermanyssus gallinae*  Poultry red mite  Adults |
| Field of use | Indoor use in poultry facilities not connected to STP.  Indoors in the following animal house sub-categories:  7.Laying hen, battery cages without treatment,  9.Laying hen, battery cages with forced drying,  10.Laying hen, compact battery cages,  13.Laying hen, free range with grating floor,  14.Parent broiler >18 weeks, free range with grating floor, 15.Parent broiler in rearing, free range with grating floor. |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  Apply 10 g of product in thin layers in cracks and crevices  (in corners and other hiding places, electrical panels and conduits) |
| Application rate(s) and frequency | 10 g/m2  Treatment can be performed up to 4 times per year with an interval of 91 days between applications.  Residual activity: 2 weeks  Efficacy is expected 1 week after application |
| Category(ies) of user(s) | Trained professional Professional  General public (non-professional) |
| Pack sizes and packaging material | General public (non-professional)  Envelope:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle: LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  - bottle: HDPE  - cap: PP; LDPE  Trained professional / Professional  Envelope:  0,5 kg, 1kg, 1,5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic: PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic: PP25+PE80  - plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle: LDPE, HDPE, PP  - cap: PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 500 g  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

#### Use-specific instructions for use

|  |
| --- |
| Comply with the instructions for use.  The product is a powder intended to be used as it is.  Clean the poultry before the treatment. Apply 10 g/m2 of insecticide. Apply the product in crack and crevices where mites may hide.  10 grams of product equals to 8 teaspoons approximately. Disposable or dedicated teaspoon should be used.  Efficacy is expected 1 week after application. |

#### Use-specific risk mitigation measures

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| --- |
| Environmental precautions: Prevent product from entering the environment (surface and groundwater), sewerage, drainage... with the construction of protective barriers and closing drains. Inform the relevant authorities uncontrolled leaks or spills to water courses, drains, sewers.  For use only in areas that are inaccessible to infants, children, companion animals and farm animals.  Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.  The product should be applied away from animals, do not apply directly on animals.  In case of product in bags/bucket to be used with an applicator: Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

|  |
| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

### General directions for use

#### Instructions for use

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| --- |
| Comply with the instructions for use.  Do not mix with other chemicals or products.  Remove (clean) product and dead insects, when the presence of live insects is stopped.  Strategies for managing the development of resistance:  For professional use:  - Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.  - Where possible, application treatments should be recommended to be combined with non-chemical measures.  - Products should always be used in accordance with label recommendations.  - Applications should always be made against the most susceptible stages in the pest life cycle.  - Where an extended period of control is required, treatments should be alternated with products with different modes of action.  - Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.  - In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.  - The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.  - Do not [use/apply] the product in areas where resistance to the active substance (s) contained in this product is suspected or established.  For non-professionals:  -Products should always be used in accordance with label recommendations.  -If the infestation persists, contact a professional. |

#### 

#### Risk mitigation measures

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes.  See use specific RMMs, as detailed in above sections. |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  The product contains: cypermethrin. May cause paraesthesia.  IF EXPOSED: Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Dispose of waste and residues in accordance with local authority requirements.  Do not allow runoff to sewer, waterway or ground. |

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

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| --- |
| Keep out of reach of children and non-target animals/pets.  Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

### Other information

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| --- |
| The label of the product shall indicate that it contains Silicon dioxide (nano). |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g | PP MAT20 + PET MET 12 + PE45 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g | PP 25+PET MET 12 +PE60 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g | PP MAT20 + PET MET 12 + PE60 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g | PP25+PE80 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g | PP25+PET12+PE60 | heat-sealed | General public (non-professional) | Yes |
| Spreader Bottle | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g | bottle: LDPE, HDPE, PP  cap: PP; LDPE | Pressure cap with spreader | General public (non-professional) | Yes |
| Bottle with applicator | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g, 500 g | bottle: HDPE  cap: PP; LDPE | Pressure cap with tip applicator | General public (non-professional) | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP MAT20 + PET MET 12 + PE45 | heat-sealed | Trained professional  Professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP 25+PET MET 12 +PE60 | heat-sealed | Trained professional  Professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP MAT20 + PET MET 12 + PE60 | heat-sealed | Trained professional  Professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP25+PE80 | heat-sealed | Trained professional  Professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP25+PET12+PE60 | heat-sealed | Trained professional  Professional | Yes |
| Spreader Bottle | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500g, 750g, 1000 g | bottle: LDPE, HDPE, PP  cap: PP; LDPE | Pressure cap with spreader | Trained professional  Professional | Yes |
| Bottle with applicator | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g | bottle: HDPE  cap: PP; LDPE | Pressure cap with tip applicator | Trained professional  Professional | Yes |
| Bucket | 5 kg, 10 kg | CPP (Copolymer Polypropylene) | Pressure cap with seal | Trained professional  Professional | Yes |

All the packaging proposed are non transparent and waterproof.

Please refert to IUCLID section 12 for additional details about packaging.

|  |
| --- |
| **Conclusion on the packaging of the biocidal product** |
| Accelerated storage stability test for 14 days at 54°C demonstrated compatibility with the packaging material plastic envelope from PP MAT20 + PET MET 12 + PE45. A statement has been submitted by the applicant regarding the effect of stacking for the flexible packages.  According to Guidance on the BPR (Volume I Parts A+B+C) for solid preparations extrapolation to all types of packaging is acceptable.Therefore, all the above-mentioned proposed packaging is considered acceptable for commercial use. |

### Documentation

#### Data submitted in relation to product application

Data on the active substance are available through Letter of access (IUCLID, section 13). Data on the product are available in theIUCLID dossier and are listed in Annex 3.1 to this document.

#### Access to documentation

The applicant submits the Letter of Access granted by the manufacturers of the active substance; this cover the studies owned by the companies and other information that have been used for including the active substance in the Union list of approved active substances under the Biocidal Products Regulation.

With such Letter of Access the applicant is authorized to use, refer to and rely on active substance data in order to apply for the authorization of the biocidal product.

## Assessment of the biocidal product

### Intended use(s) as applied for by the applicant

#### Table 1. Intended use # 1 – General public- crawling insects, indoor

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of crawling insects - General public |
| Target organism (including development stage) | *Lasius niger* Ants Adults *Blatta orientalis* Oriental cockroach Adults *Blattella germanica* German cockroach Adults |
| Field of use | Indoor and only for the control of ants ants outdoor around the building. |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  For indoor treatment: apply 5 g/ m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, etc.).  For around building treatment: apply 5 g/ m2 of product in thin layers in cracks and crevices only on paved surfaces, balconies and terraces. |
| Application rate(s) and frequency | The application rate is 5 g/m².​  Residual period :  Against cockroaches 8 weeks  Against ants 4 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope: 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g,300 g, 375 g, 500 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE |

##### Use-specific instructions for use

|  |
| --- |
| Always read the label or package leaflet before use and follow all instructions provided.  The product is a powder intended to be used as it is.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  Apply 5 g/ m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, etc.).  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### 

##### Use-specific risk mitigation measures

|  |
| --- |
| To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  For around building treatment: apply only on paved surfaces and roof covered area. Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

##### 

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

|  |
| --- |
| Refer to general directions for use |

#### Table 2. Intended use # 2 – General public- ants - around building

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control ants - General public - urban environment |
| Target organism (including development stage) | *Lasius niger* Ants Adults |
| Field of use | Other: Outdoor around building |
| Application method(s) | Spreading  Ready to use product  For around building treatment, apply 5 g/ m2 as a barrier treatment in the way it is considered most suitable for the building:  1) all around the perimeter apply a strip not wider than 1 cm  2) only on doors and windows apply a strip not wider than 5 cm |
| Application rate(s) and frequency | The application rate is 5 g/m².​  Residual period 3 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope: 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g,300 g, 375 g, 500 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE |

##### Use-specific instructions for use

|  |
| --- |
| Always read the label or package leaflet before use and follow all instructions provided.  The product is a powder intended to be used as it is.  For around building treatment, only for the protection of the buildings from ants.  Apply 5 g/ m2 as a barrier treatment in the way it is considered most suitable for the building:  1) all around the perimeter apply a strip not wider than 1 cm  2) only on doors and windows apply a strip not wider than 5 cm  The product is effective for 3 weeks in barrier treatments.  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

|  |
| --- |
| When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc).Do not apply to areas susceptible to routine wet cleaning.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

#### Table 3. Intended use # 3 – Professional-crawling insects- indoor

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of crawling insects - professional – urban environment |
| Target organism (including development stage) | *Lasius niger* Ants Adults *Blatta orientalis* Oriental cockroach Adults *Blattella germanica* German cockroach Adults |
| Field of use | Indoor |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product.  For indoor treatment: apply 5 g/ m2 of product in thin layers in cracks and crevices , (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, under floating floors etc.). |
| Application rate(s) and frequency | The application rate is 5 g/m².​  Residual period against *Blattella Germanica*: 8 weeks  Residual period against *Blatta orientalis* and *Lasius niger*: 2 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | Industrial  Trained professional  Professional |
| Pack sizes and packaging material | Envelope:0,5 kg; 1kg, 1,5 kg, 2.0 kg; 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

##### Use-specific instructions for use

|  |
| --- |
| Codes of good practice should be followed.  Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action.Do not mix with other chemicals or products.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  The product is a powder intended to be used as it is.  For indoor treatment: apply 5 g/ m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, under floating floors etc...)  Residual period against Blattella Germanica: 8 weeks  Residual period against Blatta orientalis and Lasius niger: 2 weeks  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

|  |
| --- |
| Use chemical resistant gloves (EN 374 ) .  Environmental precautions: Prevent product from entering the environment (surface and groundwater), sewerage, drainage... with the construction of protective barriers and closing drains. Inform the  relevant authorities uncontrolled leaks or spills to water courses, drains, sewers...The application is allowed only in areas that are not wetcleaned.  Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor  For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

#### Table 4. Intended use # 4 – General public - bed bugs and fleas- indoor

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of bed bugs and fleas- General public – indoor |
| Target organism (including development stage) | *Cimex lectularius* Bed bug Adults *Ctenocephalides felis* Cat flea Adults |
| Field of use | Indoor |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  For indoor treatment: Apply 10 g/m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition  between walls, holes, etc...) |
| Application rate(s) and frequency | The application rate is 10 g/m².​  Residual period 2 weeks  Treatment can be performed up to 2 times per year |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope: 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g,300 g, 375 g, 500 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE |

##### Use-specific instructions for use

|  |
| --- |
| Always read the label or package leaflet before use and follow all instructions provided.  Bedbugs harbour themselves in very confined areas in wall cracks, furniture joints, behind pictures and in seams of furnishings. These insects generally confine  themselves to these areas and leave them only to feed during the night. Bedbugs are usually not seen outside the harbourage during the day or when the lights are on.  The product is a powder intended to be used as it is.  Life cycle of bed bugs take four to five weeks, we recommend not to remove the product before 6 weeks.  Fleas harbour themselves on cracks in the floor, or crevices in furniture and furnishings.  Apply 10g of product in thin layers in cracks and crevices where insects hide (under furniture, corners, under pet baskets) and in void and cavity (between partition walls, holes, etc.)  The product is effective up to 2 weeks.  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

|  |
| --- |
| To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

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

|  |
| --- |
| Refer to general directions for use |

#### Table 5. Intended use # 5 – Professional- bed bugs and fleas- indoor

|  |  |
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| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of bed bugs and fleas- professional |
| Target organism (including development stage) | *Cimex lectularius* Bed bug Adults *Ctenocephalides felis* Cat flea Adults |
| Field of use | Indoor |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  For indoor treatment: apply 10 g/ m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes, etc...) |
| Application rate(s) and frequency | The application rate is 10 g/m².​  Treatment can be performed up to 2 times per year.  Residual period of the treatment 2 weeks. |
| Category(ies) of user(s) | Industrial  Trained professional  Professional |
| Pack sizes and packaging material | Envelope:0,5 kg; 1kg, 1,5 kg, 2.0 kg; 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

##### Use-specific instructions for use

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| Codes of good practice should be followed.Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action Do not mix with other chemicals or products.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for wall cracks, furniture joints, behind pictures and in seams of furnishings. These insects generally confine themselves to these areas and leave them only to feed.  The product is a powder intended to be used as it is.  Apply 10 g of product in thin layers in cracks and crevices where insects hide (under furniture, corners, etc.) and in void and cavity (between partition walls, holes, etc.)  The product is effective up to 2 weeks.  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

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| Use chemical resistant gloves (EN 374 ) .  To avoid resistance, keep the label instructions. For resistance management avoid repeated use of products containing cypermethrin and alternate with products containing active substance with different mode of action and different group.  When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor  For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

##### 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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| Refer to general directions for use |

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

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| Refer to general directions for use |

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

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| Refer to general directions for use |

#### Table 6. Intended use # 6 – General Public- control of wasp indoor, outdoor

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| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of wasp - General public – treatment of nest. |
| Target organism (including development stage) | *Vespula germanica*  German wasp  Adults and larvae |
| Field of use | Spot application indoor and outdoor on the entrance of the nest |
| Application method(s) | Spot application by spreading into wasps nest.  Apply 2,5 g of dust dust such into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal. |
| Application rate(s) and frequency | The application rate is 2,5 g nest.​  In case of outdoor use the product is intended to be treated only one nest per application.  The product will destroy the entire nest 3 weeks after treatment. |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Envelope: 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g,300 g, 375 g, 500 g, 1000 g  - bottle : LDPE, HDPE, PP  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE |

##### Use-specific instructions for use

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| Always read the label or package leaflet before use and follow all instructions provided.  The product is a powder intended to be used as it is.  Apply 2,5 g of product directly on the holes. Apply the dust such into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal.  The product will destroy the entire nest 3 weeks after treatment.  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

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| When the infestation persists contact a professional.  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc).Do not apply to areas susceptible to routine wet cleaning.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

##### 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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| Refer to general directions for use |

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

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| Refer to general directions for use |

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

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| Refer to general directions for use |

#### Table 7. Intended use # 7 – Professional- control of wasp

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| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of wasp - professional user – . |
| Target organism (including development stage) | *Vespula germanica*  German wasp  Adults and larvae |
| Field of use | Spot application indoor and outdoor on the entrance of the nest |
| Application method(s) | Spot application by spreading into wasps nest.  Apply 2,5 g of dust into the holes where the wasps are going in and out. The dust will eliminate the wasps in the nest and any other wasps returning to the nest.  For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal. |
| Application rate(s) and frequency | 2.5 g/nest.  Spot application.  In case of outdoor use the product is intended to be treated only one nest per application.  The product will destroy the entire nest 3 weeks after treatment. |
| Category(ies) of user(s) | Industrial Trained professional Professional |
| Pack sizes and packaging material | Envelope:0,5 kg; 1kg, 1,5 kg, 2.0 kg; 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  - bottle : LDPE, HDPE  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g,300 g, 375 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

##### Use-specific instructions for use

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| Codes of good practice should be followed.  Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.Adopt   integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action Do not mix with other chemicals or products.  The product is a powder intended to be used as it is.  Apply  2,5 g of product direcly on the holes. Use an applicator to apply the dust such into the holes where the wasps are going in and out. The dust will help  eliminate the wasps in the nest and any other wasps returning to the nest. For ideal results, treat the wasps nest late in the evening or early in the morning morning when insects' activity is minimal.  The product will destroy the entire nest 3 weeks after the treatments. Remove (clean) product and dead insects, when the presence of live insects is stopped. |

##### Use-specific risk mitigation measures

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| Use chemical resistant gloves (EN 374 ) .  Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor  Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc).Do not apply to areas susceptible to routine wet cleaning.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

##### 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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| --- |
| Refer to general directions for use |

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

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| Refer to general directions for use |

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

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| Refer to general directions for use |

#### Table 8. Intended use # 8 – Rural hygiene (Animal Houses/ Shelters)

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| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of crawling insects - rural indoor use - crack and crevices, voids and cavities |
| Target organism (including development stage) | Dermanyssus gallinae  Poultry red mite  Adults |
| Field of use | Indoor  Indoors in the following animal house sub-categories: Laying hen, battery cages without treatment, Laying hen, battery cages with forced drying, Laying hen, compact battery cages,  Laying hen, free range with grating floor, Parent broiler >18 weeks, free range with grating floor, Parent broiler in rearing, free range with grating floor. |
| Application method(s) | Crack and crevices treatment by dusting.  Ready to use product  Apply 10 g of product in thin layers in cracks and crevices ( in corners and other hiding places, electrical panels and conduits) |
| Application rate(s) and frequency | 10 g/m2  Treatment can be performed up to 2 times per year  Residual period 2 weeks  The product reaches the complete efficacy one week after application |
| Category(ies) of user(s) | Industrial Trained professional Professional  General public (non-professional) |
| Pack sizes and packaging material | Envelope: 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 400 g, 500 g, 1000 g  Professional user 1,5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  - plastic: PP MAT20 + PET MET 12 + PE45  - plastic PP 25+PET MET 12 +PE60  - plastic: PP MAT20 + PET MET 12 + PE60  - plastic PP25+PE80  - plastic PP25+PET12+PE60  Spreader Bottle: 50 g, 100 g, 150 g, 200g, 250 g, 500 g, 750g, 1000 g  - bottle : LDPE, HDPE,PP  - cap:PP; LDPE  Bottle with applicator: 50 g, 100 g, 150 g, 200g, 250 g, 500 g,  - bottle: HDPE  - cap: PP; LDPE  Bucket CPP: 5 kg, 10 kg |

##### Use-specific instructions for use

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| Always read the label or package leaflet before use and follow all instructions provided.  The product is a powder intended to be used as it is.  Clean the poultry before the treatment. Apply 10 g/m2 of insecticide. Apply the product in crack and crevices and or targeted spot or areas where insects may crawl and hide  The product reaches the desired efficacy one week after application |

##### Use-specific risk mitigation measures

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| Use chemical resistant gloves (EN 374 ) .  Environmental precautions: Prevent product from entering the environment (surface and groundwater), sewerage, drainage... with the construction of protective barriers and closing drains. Inform the relevant authorities uncontrolled leaks or spills to water courses, drains, sewers...The application is allowed only in areas that are not regularly wetcleaned.  For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the  damp papers used as solid wastes.  Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.  The product should be applied away from animals , do not apply directly on animals  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or thedamp papers used as solid wastes.  In case of product in bags/bucket to be used with an applicator: Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor |

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

|  |
| --- |
| Refer to general directions for use |

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

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| Refer to general directions for use |

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

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| Refer to general directions for use |

### Physical, chemical and technical properties

Test item DURACID PW (Batch no.: 0B1210, LAB01022021) has been used for the submitted experimental test. Composition of the formulation DURACID PW is reported in the confidential section.

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **GLP** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830.6303 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | Powder | CH – 0181/2020 | Yes | Acceptable |
| Colour at 20 °C and 101.3 kPa | OPPTS 830.6302 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | White | CH – 0181/2020 | Yes | Acceptable |
| Odour at 20 °C | OPPTS 830.6304 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | Characteristic odour | CH – 0181/2020 | Yes | Acceptable |
| Acidity / alkalinity | CIPAC MT 75.3 and OECD No. 122 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | 9.7 (1% w/v aqueous dispersion at 20°C; water HPLC grade)  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. | CH – 0181/2020 | Yes | Acceptable |
| bulk density | CIPAC MT 186 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | Pour density: 0.76 g/mL  Bulk density: 0.90 g/mL | CH – 0181/2020 | Yes | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days)  Please see table below for additional information on test methods. | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | From the obtained results it can be concluded that a change (about 9 % decrease) was found in the Cypermethrin active ingredient content, no change in the sample appearance, colour or odour, no loss of sample and no evidence on corrosion phenomena.  Moreover, no significant changes in physical properties (pH value, dustiness, particle size distribution by laser diffraction and sieve analysis) were found for the sample stored in the plastic composite envelope: PP MAT20 + PET MET 12 + PE45 for 14 days of storage at 54°C, comparing the obtained results at the beginning of the storage stability.  Please see table below for additional information on results.  **Substance of concern:**  Dipropyleneglycol monomethyl ether has been considered a substance of concern in the formulation Duracid PW.  No data submitted for the determination of substance of concern before and after storage in Duracid PW formulation. Furthermore, no analytical method for its determination is available.  **RefMS:** In general, analytical methods for the determination of identified substances of concern is a requirement according to Annex III Title I to the BPR. However, analytical methods are not required since SoC cannot be formed during storage and its concentration remain unchanged.  Based on the above, no further data are required. | CH – 0183/2020 | Yes | Acceptable  A significant but acceptable degradation of 9% in the active substance content occurred in the biocidal product Duracid PW when stored in its initial commercial packaging under the tested accelerated storage conditions (54°C for 14 days).  No significant variation of physicochemical and technical properties appears during storage. |
| Storage stability test – **long term storage at ambient temperature** | GIFAP Monograph No. 17, 2nd edition, June 2009: Guidelines for Specifying the Shelf Life  of Plant Protection Products  36 months of storage at ambient warehouse  Temperature  Cypermethrin a.i. content:  Method No. 0182/2020  Appearance (Colour, odour and physical state):  OPPTS 830.6302  OPPTS; 830.6303;  OPPTS 830.6304  pH value (1% w/v aqueous dilution):  MT 75.3  Acidity or alkalinity  CIPAC MT 31 or MT 191  (only if pH < 4 or pH > 10),  OECD No. 122  Weight variation (%): technical balance  Compatibility (resistance) of the packaging material (corrosion characteristics): internal and external visual examination of the packaging  Dustiness of granular products – gavimetric method: CIPAC MT 171.1  Particle size distribution  (laser diffraction): CIPAC MT 187, OECD No. 110  Particle size distribution  (sieve analysis): CIPAC MT 59.2, CIPAC MT 170, OECD No. 110 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | The study is ongoing.  Results will be added as soon as available. | Study Plan  CH – 0184/2020 | Yes | The long-term storage stability study at ambient temperature is ongoing and should be submitted when completed, to confirm the proposed shelf-life of the biocidal product  **(post authorization data requirement)**  However, the acceptable accelerated storage stability test indicates that the product is anticipated to be stable for up to two years when stored in its initial commercial packaging at ambient temperature. |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not applicable since the product is a solid |  |  | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Study waived: Packaging material is not transparent and no effect of light is expected. Furthermore envelopes are made of a coextruded material (COEXSTRUDED 20 MY  POLYESTER 12 MET MY  POLYETHYLENE 60 MY) which contains a metalized foil inside to protect the product from light. |  |  | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days) | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | From the results obtained from the accelerated storage stability study for 2 weeks at 54°C, an acceptable degradation in active ingredient content was observed and no change in the physicochemical properties of the biocidal product.  From the above reported data, it can be concluded that the formulation Duracid PW is stable in its commercial packaging under the tested accelerated storage conditions. | CH – 0183/2020 | Yes | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days) | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | From the results obtained from the accelerated storage stability study for 2 weeks at 54°C, no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena. | CH – 0183/2020 | Yes | Acceptable |
| Wettability |  |  | Not applicable. The product is a dustable powder. |  |  | - |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable. The product is a dustable powder. |  |  | - |
| Wet sieve analysis and dry sieve test | CIPAC MT 59.2 (58) and MT 170; OECD No. 110 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | Residue on the sieve:  -45 mesh (0.355 mm) 2.19 %  -60 mesh (0.250 mm) 38.13 %  -80 mesh (0.180 mm) 41.10 %  - 120 mesh (0.125 mm) 11.20 %  -200 mesh (0.075 mm) 6.23 %  -325 mesh (0.045 mm) 0.85 %  - < 0.045 mm 0.01% | CH – 0181/2020 | Yes | Acceptable |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable The product is a dustable powder not to be diluted. |  |  | - |
| Disintegration time |  |  | Not applicable. The product is not a tablet. |  |  | - |
| Particle size distribution, content of dust/fines, attrition, friability  Particle Size Analysis by Laser Diffraction | CIPAC MT 46.3 CIPAC MT 187;  OECD No. 110 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: LAB01022021 | After 14 days of storage at 54°C, the particle size analysis by laser diffraction of the Duracid PW formulation sample are comparable to the relevant values obtained in the initial characterisation.  Please see table below for additional information on results | CH – 0190/2021 | Yes | Acceptable |
| Persistent foaming |  |  | Not applicable, the product is a solid dustable powder |  |  | - |
| Dustiness of granular products | CIPAC MT 171.1 | Test item: Duracid PW  Cypermethrin: 0.60 % w/w (pure)  Batch number: 0B1210 | 19.6 mg (essential non dusty) | CH – 0181/2020 | Yes | Acceptable |
| Burning rate — smoke generators |  |  | Not applicable, the product is a solid dustable powder |  |  | - |
| Burning completeness — smoke generators |  |  | Not applicable, the product is a solid dustable powder |  |  | - |
| Composition of smoke — smoke generators |  |  | Not applicable, the product is a solid dustable powder |  |  | - |
| Spraying pattern — aerosols |  |  | Not applicable, te product is a solid dustable powder |  |  | - |
| Physical compatibility |  |  | Not applicable, the product is a solid dustable powder |  |  | - |
| Chemical compatibility |  |  | Not applicable, The product is not intended to be used with other products. |  |  | - |
| Degree of dissolution and dilution stability |  |  | Not applicable, The product is a dustable powder. |  |  | - |
| Surface tension |  |  | Not applicable. The product is a dustable powder. |  |  | - |
| Viscosity |  |  | Not applicable. The product is a dustable powder. |  |  | - |

**Storage stability test – accelerated storage details:**

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| --- | --- | --- | --- |
| **Test** | **Guidelines and Methods** | **Initial characterisation**  (study CH-181/2020) | **After 14 days of storage at 54°C** (study CH-183/2020) |
| Packaging of the test items | -- | Plastic composite: PP MAT20 + PET MET 12 + PE45 | Plastic composite: PP MAT20 + PET MET 12 + PE45 |
| Weight variation (%) | By technical balance | - | Mean of 9 packs:  -0.02% |
| Cypermethrin active  ingredient content | Method No. 0182/2020 | 0.65 ± 0.01 % w/w  Cis isomer: 0.29 ± 0.005 % w/w  Trans isomer: 0.36 ± 0.01 % w/w  (study CH-182/2020) | 0.59 ± 0.003 % w/w  Cis isomer: 0.26 ± 0.002 % w/w  Trans isomer: 0.33 ± 0.002 % w/w  **Delta** (%) from T0: -9.2 |
| Appearance  (Colour, odour and  physical state) | OPPTS 830.6302;  OPPTS 830.6303;  OPPTS 830.6304 | White  (shortcode NE 12)  powder with characteristic  odour | White  (shortcode NE 12)  powder with characteristic  odour |
| Compatibility (resistance) of the packaging material  (Visual examination of packaging both externally and internally) | Visual examination of both external and internal packaging | - | The pack didn’t present any  deformation in both bottom  and lateral layers, or loss of  sample and evident corrosion  phenomena |
| pH value  (1% w/v aqueous dispersion at 20° C; water HPLC grade) | CIPAC MT 75.3  OECD No. 122 | 9.7  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. | 9.7  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. |
| Dustiness of granular products | CIPAC MT 171.1 | 19.6 mg (essential non dusty) | 19.1 mg (essential non dusty) |
| Wet sieve analysis and dry sieve test | CIPAC MT 59.2 (58) and MT 170,  OECD No. 110 | More than 99 % of the test  item presents a particle size  higher than 0.045 mm and it  is distributed between:  the 0.355 mm sieve (2.19%),  the 0.250 mm sieve  (38.13 %),  the 0.180 mm sieve (41.10%),  the 0.125 mm sieve (11.20%),  the 0.075 mm sieve (6.23%)  and the 0.045 mm sieve  (0.85 %).  A 0.01 % of test item presents  a particle size lower than  0.045 mm. | More than 99 % of the test  item presents a particle size  higher than 0.045 mm and it is  distributed between:  the 0.355 mm sieve (4.97%),  the 0.250 mm sieve  (31.95 %),  the 0.180 mm sieve (40.62%),  the 0.125 mm sieve (15.74%),  the 0.075 mm sieve (5.82%)  and the 0.045 mm sieve  (0.67 %).  A 0.01 % of test item presents  a particle size lower than  0.045 mm |
| Particle size distribution | CIPAC MT 46.3  CIPAC MT 187  OECD No. 110 | Dv 10 (μm): 1.47  Dv 50 (μm): 6.45  Dv 90 (μm): 44.1  % < 50 μm: 91.95%  % > 75 μm: 2.79%  (Study CH – 0190/2021) | Dv 10 (μm): 1.61  Dv 50 (μm): 7.46  Dv 90 (μm): 42.6  % < 50 μm: 92.39%  % > 75 μm: 2.83%  (Study Plan CH – 0190/2021) |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Physical-chemical properties:  The preparation is a white powder with characteristic odour, containing 0.6 % w/w (pure) cypermethrin. pH value of a 1 % w/v aqueous dispersion of was 9.7 at a tempertature of 20°C. Bulk density of Duracid PW is 0.9 g/mL at 20°C. The product can be considered as essential non dusty due to a dustiness of granular products value of 19.6 mg.  Storage stability:  After storage at 54°C for 14 days (in plastic composite: PP MAT20 + PET MET 12 + PE45), the test item did not show any significant difference in terms of pH, dustiness and sieve analysis, compared to the initial conditions. The active ingredient content show a degradation of 9%, which is considered acceptable (below 10%).  The long-term storage stability study at ambient temperature (for 36 months) is ongoing and should be submitted when completed, to confirm the proposed shelf-life of the biocidal product **(post authorization data requirement).**  However, the acceptable accelerated storage stability test indicates that the product is anticipated to be stable for up to two years when stored in its initial commercial packaging.  The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **GLP** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | Assessment of the potential oxidizing and explosive behaviour using thermodynamics data obtained from the molecular structure of the main components of the formulation by the computer software CHETAH (Chemical Thermodynamic And Hazard evaluation), version 7.3 (ASTM 2002). | Duracid PW formulation (see confidential annex) | The experimental study does not need to be conducted because there are no chemical groups present in the molecules which are associated with explosive properties.  For more detailed information see confidential annex. | CH – 0185/2020 | Yes | Acceptable |
| Flammable gases |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Flammable aerosols |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Oxidising gases |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Gases under pressure |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Flammable liquids |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Flammable solids | EC No. 440/2008 A.10 | Dustable powder pure active ingredient content (Cypermethrin): 0.60 % w/w from the Certificate of Analysis supplied by the Sponsor batch number 0B1210 | Two preliminary tests were performed and the same sample behaviour was observed.  The test item, white powder solid, carbonised when the Bunsen burner flame came close, but the combustion did not propagate.  Since test item did not propagate combustion, no further testing was required.  Therefore from the experimental data, it can be concluded that the test item formulation sample is not highly flammable. | CH – 0181/2020 | Yes | Acceptable  The preliminary test performed is similar to the one of the CLP guidance. |
| Self-reactive substances and mixtures |  |  | Study waived. There are no chemical groups present in the molecule associated with explosive or self-reactive properties (CLP guidance).  The ADR states that self-reactive materials are materials that are thermically instable and that can undergo to exothermic decomposition. None of the ingredients is listed in the list of self-reactive substances in the ADR.  In the flammability study, the test item did not propagate combustion and according to the accelerated storage stability study, Duracid PW formulation was stable in its commercial packaging (14 days at 54°C).  In addition, as stated in the ADR, materials with a heat decomposition lower than 300 J/g are not considered self-reactive materials.  Therefore, the mixture is not expected to have self-reactive properties.  For more detailed information see confidential annex. |  |  | Acceptable |
| Pyrophoric liquids |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Pyrophoric solids |  |  | Study waived. Experience in manufacture or handling shows that the mixture does not ignite spontaneously on coming into contact with air at normal temperatures (CLP guidance) |  |  | Acceptable |
| Self-heating substances and mixtures |  |  | Study waived. Experience in manufacture or handling shows that the mixture does not have self-heating properties. |  |  | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Study waived.  The chemical structure of the mixture does not contain metals or metalloids and experience in handling and use shows that the mixture does not react with water (CLP guidance). |  |  | Acceptable |
| Oxidising liquids |  |  | Not applicable since the product is a dustable powder. |  |  | - |
| Oxidising solids | Assessment of the potential oxidizing and explosive behaviour using thermodynamics data obtained from the molecular structure of the main components of the formulation by the computer software CHETAH (Chemical Thermodynamic And Hazard evaluation), version 7.3 (ASTM 2002). | Duracid PW formulation (see confidential annex) | From the criteria results obtained with CHETAH software based on the molecular structure of the active substances and main co-formulants of the test item, it can be concluded that the Duracid PW should not have an oxidizing behaviours.  For more detailed information see confidential annex. | CH – 0185/2020 | yes | Acceptable |
| Organic peroxides |  |  | Study waived. There are no peroxides in the chemical structures of the substances into the mixture. |  |  | Acceptable |
| Corrosive to metals |  | Duracid PW formulation (see confidential annex) | Duracid PW is made for 97% by substances with very high melting points. Accelerate storage stability test performed at 54°C didn’t show any variation in the appearance of the product. Therefore, we propose a weight-of-evidence approach to consider the melting point of Duracid PW higher than 55°C. It should not be classified as corrosive on these basis.  For more detailed information see confidential annex. |  |  | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) |  |  | Not applicable. The product is a dustable powder. |  |  | - |
| Relative self-ignition temperature for solids |  |  | Study waived.  Most of mixture’s components flash-points are above 100°C. During normal condition of production and use of the b.p. no sources of ignition or conditions suitable for combustion will be expected. Duracid PW is not considered flammable or subject to autoignition, and the flash-point study was waived. |  |  | Acceptable |
| Dust explosion hazard |  |  | Study waived. The dust cannot ignite or explode when exposed to ignition source because the product is neither flammable nor oxidising and it has neither explosive properties (none of the component has chemical groups associated with explosive properties) nor self-reactive properties. In addition, long experience in manufacturing and handling shows that the powder does not have dust explosion hazard. |  |  | Acceptable |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not expected to have explosive or oxidising properties, nor to be self-heating, self-reactive or flammable. None of the components is known to evolve any flammable gases in contact with water/humid air or to be pyrophoric. The product is not expected to be corrosive to metals. Thus, has no classification according to CLP criteria. |

### Methods for detection and identification

**Analytical methods for the analysis of the product as such including the active substance, impurities and residues**

Scope

This method is applicable to the quantitative determination of Cypermethrin active ingredient in Duracid PW formulation samples.

The method has been validated by the analysis of reference material and test item solutions.

Principle of the method

The determination of the active ingredient was performed by HPLC using an external standard and a UV detector.

The quantification of active ingredient, as Cypermethrin, is performed by comparing the sum of the four peak areas of Cypermethrin (Cypermethrin Cis I, Cypermethrin Cis II, Cypermethrin Trans I, Cypermethrin Trans II) analytical standard versus the sum of the four peaks areas in Duracid PW test item solutions.

Preparation of the eluent (iso octane/ethyl acetate at 99.5/0.5 % v/v)

Into 2 L volumetric flask add, using volumetric pipette, 10.00 mL of ethyl acetate and make to volume with iso-octane.

Preparation of the stock reference material solution

Using an analytical balance, a volumetric flask and a volumetric pipette, prepare a stock reference material solution in eluent as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| Reference material | Stock reference material solution (SRMS) | | |
| Nominal weight (mg) (1) | Volume (mL) (2) | Nominal concentration (μg/mL) |
| Cypermethrin | 20 | 20.00 | 1000 |

(1) Reference material nominal weight

(2) Volume of the stock reference material solution.

Preparation of the working standard solutions

Using volumetric flasks and volumetric pipettes, prepare three working standard solutions for linear calibration in eluent as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Working Standard Solution | Stock reference material solution (SRMS) (mL) | Final Volume (mL) | Nominal concentration (μg/mL) | Nominal linearity range (% w/w) (1) |
| Blank | 0 | 10.00 | 0 | 0 |
| WSS 1 | 0.60 | 10.00 | 60 | 0.30 – 0.90 |
| WSS 3 | 1.20 | 10.00 | 120 |
| WSS 5 | 1.80 | 10.00 | 180 |

(1) Calculated with respect to the nominal test item weight in repeatability (2000 mg).

All the stock and working standard solutions have been stored in a refrigerator.

Preparation of the test item solutions

Using the analytical balance, weigh about 2000 mg of the test item into 100.00 mL volumetric flask, make to volume with eluent and place in an ultrasonic bath for 15 minutes.

After thermal equilibrium at room temperature, filter an aliquot of the stock test item solution using PTFE syringe filter at 0.45 μm and then, transfer an aliquot of the filtered test item solution into a vial for the HPLC analysis.

The summary of test item preparation procedure is presented in the table here below.

|  |  |  |
| --- | --- | --- |
|  | Stock test item solution (STIS) | |
| Nominal weight (mg) | Volume (mL) |
| Test item | 2000 | 100.00 |

NOTE: Perform the test item weights mixing the granular formulation contained in five commercial packaging

Test item solutions have been stored in a refrigerator.

Chromatographic conditions

|  |  |
| --- | --- |
| HPLC column | Agilent Technologies or equivalent |
|  | Zorbax RX-SIL, 150 x 4.60 mm i.d., 5.0 μm |
| Detector | UV/Vis operating at 278 nm |
| Column temperature | 35°C |
| Eluent B | iso octane/ethyl acetate = 99.5 / 0.5 % v/v |
| Eluent (isocratic) | 100% eluent B |
| Eluent flow | 2.0 mL/min |
| Volume of injection | 10 μL |
| Cypermethrin Cis I ret. time | about 12 minutes |
| Cypermethrin Cis II ret. Time | about 14 minutes |
| Cypermethrin Trans I ret. Time | about 18 minutes |
| Cypermethrin Trans II ret. time | about 20 minutes |
| Total analysis time | 30 minutes |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | | **Reference** |
| Range | Mean | RSD | |  |
| Cypermethrin (active substance in Duracid PW) | HPLC/UV  (HPLC mod. 1200 equipped with UV detector, autosampler, managed by Chemstation software).  detector wavelength 278 nm | Using the analytical balance and volumetric pipettes, the fortified placebo solutions were prepared in eluent.  Spike A:  Cypermethrin Cadded 5.85 g/kg  Spike B:  Cypermethrin Cadded 5.84 g/kg  Number of measurements: 2. | Five working standard solutions were prepared and each solution was analysed by  HPLC/UV.  The injected range and the relevant linearity range for the active ingredient were:  Cypermethrin  No. of WSS: 5  Injected range:  59.70 – 179.09 μg/mL  Linearity Range:  0.30 – 0.90 % w/w  y = 15472x - 38109  r = 0.99972  Cypermethrin Cis isomer  No. of WSS: 5  Injected range:  25.99 – 77.97  μg/mL  y = 15425x -15608  r = 0.99970  Cypermethrin Trans isomer  No. of WSS: 5  Injected range:  33.71 – 101.12 μg/mL  y = 15508x -22501  r = 0.99966 | The Cypermethrin active ingredient peaks were well separated and interferences with the Placebo peak were not evidenced.  Therefore, by using the conditions stated in the method, interferences can be avoided and the active ingredient can be reliably determined in test item samples. | Spike A:  Cypermethrin C added 5.85 g/kg  Cypermethrin C found 5.54 g/kg  Test No.: 1 det.  Cypermethrin Recovery (%) 94.71  Spike B:  Cypermethrin C added 5.84 g/kg  Cypermethrin C found 5.75 g/kg  Test No.: 1 det.  Cypermethrin Recovery (%) 98.46 | Total mean recovery (%):96.6 | - | | Not required | CH – 0182/2020 |

**Specificity**

The analytical method, using the HPLC/UV instrument with quantification by external standard, was shown to be specific for Cypermethrin active ingredient in the test item formulation samples.

**Linearity**

Five working standard solutions were prepared as described in the Experimental section and each solution was analysed by HPLC/UV.

The injected range and the relevant linearity range for the active ingredient are detailed in the table here below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Active ingredient** | **No. of**  **WSS** | **Injected range**  (μg/mL) | **Linearity Range**  (% w/w) (1) |
| Cypermethrin | 5 | 59.70 – 179.09 | 0.30 – 0.90 |
| Cypermethrin Cis isomer | 5 | 25.99 – 77.97 | - |
| Cypermethrin Trans isomer | 5 | 33.71 – 101.12 | - |

(1) Calculated with respect to the nominal test item weight and preparative in repeatability.

No significant memory signal was detected in the washing injected after the highest working standard solution and the range tested for the active ingredient was found to be linear (correlation coefficient r > 0.99).

**Precision**

The precision test was performed by five determinations of the test item (labelled A to E).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Active ingredient** | **Test No.** | **Mean**  **value**  (% w/w) (1) | **Standard deviation** (S.D.)  (% w/w) | **Relative Standard Deviation** (RSD%) | **Horwitz**  **RSDr** (2) | **Horrat value** (3) |
| Cypermethrin | 5 | 0.65 | 0.01 | 1.59 | 2.86 | 0.56 |
| Cypermethrin Cis isomer | 5 | 0.29 | 0.005 | 1.57 | 3.23 | 0.49 |
| Cypermethrin Trans isomer | 5 | 0.36 | 0.01 | 1.64 | 3.13 | 0.52 |

(1) Calculated with respect to the weighed test item.

(2) % RSDr = % RSDR x 0.67; % RSDR = 2(1-0.5 log C), based on the Horwitz equation.

(3) Horrat value = RDS% / RSDr

Cypermethrin: 0.65 ± 0.01 % w/w

Cypermethrin Cis isomer: 0.29 ± 0.005 % w/w

Cypermethrin Trans isomer: 0.36 ± 0.01 % w/w

From data obtained, the Horrat value resulted to be lower than 1 for the active ingredient and therefore the precision of the analytical method is considered acceptable.

**Recovery**

For the recovery, the mean recovery values obtained comply with the SANCO/3030/99 rev. 5 guideline’s requirement, as below:

in the range 80 to 120 % for active ingredient content between 0.1 % w/w and 1 % w/w.

Since all recovery values were in the correct range, these criteria were fulfilled and therefore recovery of the analytical method is considered acceptable.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Active ingredient** | **Level** | **Tests No.** | **Recovery value** (%) | |
| Cypermethrin | Spike A | 1 det. | 94.71 | |
| Spike B | 1 det. | | 98.46 |
| Mean value: | | | 96.6 |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The HPLC-UV analytical method was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of Cypermethrin (including its isomers), in Duracid PW formulation. |

**Analytical methods for monitoring**

Monitoring methods were reported in the Cypermethrin Assessment Report, and they are available through the Letter od Access attached to the IUCLID dossier:

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | GC with MS detection, LOQ = 0.05 mg/kg (LOQ = 0.5 μg/kg for sediment) |
| Air (principle of method and LOQ) | GC with MS detection, LOQ = 0.375 μg/m3 |
| Water (principle of method and LOQ) | GC with electron capture detection, LOQ = 0.01 μg/L |
| Body fluids and tissues (principle of method and LOQ) | Cypermethrin is not indicated to be toxic or highly toxic. Therefore, analytical methods for the determination of Cypermethrin in animal and human body fluids and tissues are not required. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | GC with electron capture detection, LOD = 0.05 mg/kg (oilseed rape) and 0.025 mg/kg (wheat) |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | GC with MS detection, LOQ = 0.05 mg/kg (bovine tissue), 0.005 mg/kg (bovine milk), 0.01 mg/kg (hen eggs). |

|  |
| --- |
| **Conclusion on the methods for monitoring** |
| Acceptable validated analytical methods for monitoring are available for the detection of cypermethrin in soil, air, water and residues in food and feeding stuff, reported in the CAR for cypermethrin (Belgium, 2017).  A letter of access covering the complete dossier of Agriphar Sprl (now Arysta LifeScience Benelux Sprl) for the active substance Cypermethrin, product type 18, is available from Limaru representing Tagros Chemicals India Ltd on the Article 95 list.  Analytical methods for the detection of Cypermethrin in animal and human body fluids and tissues or further data are not required. |

**Analytical methods for substances of concern**

Dipropyleneglycol monomethyl ether (CAS n. 34590-94-8) has been considered a substance of concern in this product. Its concentration is not expected to decrease or increase over time and no reaction with the other inert components in the formulation nor with the active substance is expected. For this reason, we propose the waiver to not include this substance in the storage stability/shelf life study. For further information refer to the production method in the confidential section.

|  |
| --- |
| **Conclusion on the methods for Substances of Concern in the product.** |
| Analytical method for the determination of Substance of Concern in the formulation DURACID PW have not been submitted, nor required since SoC cannot be formed during storage. |

### Efficacy against target organisms

#### 2.2.5.1 Function and field of use

DURACID PW is an insecticide used indoors and outdoors by non-professional and professional users.

All uses can be summarized as follow:

* Crack and crevice treatment indoors against crawling insects, for non-professional and professional use.
* Crack and crevice treatment outdoors against ants, for non-professional use.
* Barrier treatment against ants outdoors, for non-professional use.
* Crack and crevice treatment indoors against bed bugs and fleas, for non-professional and professional use.
* Spot application at the entrance of wasp nests indoors, for non-professional and professional use.
* Crack and crevice treatment indoors against poultry mites, for non-professional and professional use.

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

Efficacy of DURACID PW has been determined in knock-down and killing activity against:

* *Blattella germanica*
* *Blatta orientalis*
* *Lasius niger*
* *Ctenocephalides felis*
* *Cimex lectularius*
* *Vespula germanica*
* *Dermanyssus gallinae*

#### 2.2.5.3 Effects on target organisms, including unacceptable suffering

Efficacy of DURACID PW has been determined by the observation of these effects:

* knock-down effect
* killing effect
* population reduction

According to Cypermethrin’s CAR cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid “knockdown”. The affected insect shows uncoordinated movements and finally dies.

#### 2.2.5.4 Mode of action, including time delay

The relevant critical endpoints of cypermethrin cis:trans/40:60 in the toxicological studies are identified as the effect on the central nervous system, characterised by clinical signs (CS syndrome) and peripheral nerve damage; a decrease in delayed type hypersensitivity; and the effect on the liver, characterised by increase in organ weight associated with increased microsomal enzyme activity. (Evaluation report of Cypermethrin)

#### 2.2.5.5 Efficacy data

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| **Test substance** | **Test organism** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Blattella germanica*  Development stage: adults  Laboratory strains | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied in different porous (marble) and non-porous surfaces (ceramic tiles) at a dose of 5g per 1m2.  5 batches (replicates) of 10 adults were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available.  Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks to measure the residual effect (1, 2, 3, 5, 8 weeks after the first treatment).  Untreated control was included.  5 replicates were conducted. | In all types of surfaces (porous and non-porous) knock down was 100% in 7-15 minutes and mortality was 100% after 24 hours, for fresh and 8 weeks deposits.  Mortality in untreated control: 0%. | Dr. A. Drago,  2020a  **Trial 1** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Lasius niger*  Development stage: adult workers  Laboratory strains | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied in different porous (marble) and non-porous surfaces (ceramic tiles) at a dose of 5g per 1m2.  5 batches (replicates) of 20 adult worker ants were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available.  Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks to measure the residual effect (1, 2, 3, 5, 8 weeks after the first treatment).  Untreated control was included.  5 replicates were conducted. | In all types of surfaces (porous and non-porous) knock down was 100% in 10-20 minutes and mortality was 100% after 24 hours, for fresh and 8 weeks deposits.  Mortality in untreated control: 0%. | Dr. A. Drago,  2020b  **Trial 2** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Blatta orientalis*  Development stage: adults  Laboratory strains | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied in different porous (marble) and non-porous surfaces (ceramic tiles) at a dose of 5g per 1m2.  5 batches (replicates) of 10 adults were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available.  Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks to measure the residual effect (1, 2, 3, 5, 8 weeks after the first treatment).  Untreated control was included.  5 replicates were conducted. | In all types of surfaces (porous and non-porous) knock down was 100% in 20-30 minutes and mortality was 100% after 24 hours, for fresh and 8 weeks deposits.  Mortality in untreated control: 0%. | Dr. A. Drago,  2020c  **Trial 3** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Blatta orientalis*  Development stage: adults & nymphs  Laboratory strains | Simulated use test  Choice test  C&C | Choice test.  The trial was conducted in laboratory conditions (T: 23.2-26.8oC, RH: 65-75%) in test arenas.  Plastic trays of approximately 90 cm length x 90 cm width x 20 cm height were laid flat and lined with polythene sheeting. The walls were lined with liquid PTFE (fluon) to prevent cockroaches from escaping. The arenas were then lined with either a porous (plywood) or non-porous (glazed ceramic) surfaces. In the porous tile test the base substrate was cut to measure (90 cm x 90 cm) whereas in the non-porous tile test, the base substrate comprised 36 tiles of 15 x 15 cm individually arranged.  Food and water were provided on the non-treated side. Each opposing end of the arena had a cover strip of 15cm x 90cm fitted, raised off ground height by placement of 5 cm spacers in between the base and the strip. 4 batches of 30 cockroaches (adults and nymphs) were placed in the test arenas 1 day before the treatment.  The test product was applied at a dose of 5gr for 1 m2 in a limited way in the test arena to reflect a crack and crevice treatment (9% from the total surfaces).  Assessments of knockdown and/or killing effect were performed 4 hour after exposure. Mortality was recorded 24, 72 hours and 7 days later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks to measure the residual effect (4, 8 weeks after the first treatment).  4 replications were carried out.  Untreated control was used. | Non-porous surfaces Knockdown was 100% in 4 hours in fresh and 4 weeks deposits.  Knockdown was 70.8% in 4 hours in 8 weeks deposits.  Mortality after 24 h (T0): 90%  Mortality after 72 h (T0): 97.5%  Mortality after 7 d (T0): 100%  Mortality after 24 h (T4): 86.7%  Mortality after 72 h (T4): 92.5%  Mortality after 7 d (T4): 100%  Mortality after 24 h (T8): 81.7%  Mortality after 72 h (T8): 87.5%  Mortality after 7 d (T8): 93.3%  Porous surfaces  Knockdown was 100% in 4 hours in fresh deposits.  Knockdown was 85% and 64% in 4 hours and 4 and 8 weeks deposits, respectively.  Mortality after 24 h (T0): 80.9%  Mortality after 72 h (T0): 92.5%  Mortality after 7 d (T0): 100%  Mortality after 24 h (T4): 65.8%  Mortality after 72 h (T4): 85%  Mortality after 7 d (T4): 93.3%  Mortality after 24 h (T8): 60%  Mortality after 72 h (T8): 78.3%  Mortality after 7 d (T8): 93.4%  Mortality in untreated control: 0%. | Rovetto, 2021a  **Trial 3i** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Blattella germanica* | Field test  Indoors  C&C | Field conditions in occupied public housing for the elderly with infestation of German cockroaches. The presence of cockroaches was evaluated using sticky traps for three nights before the treatment.  Then the product was applied at a dose of 5 gr of product for 1m2 in cracks and crevices (under or behind doorjambs, behind skirtings or electrical sockets, in all cracks and crevices, voids or cavities).  The presence of cockroaches was evaluated 48 hours, 7 days, 14 days and 8 weeks after the treatment.  Pre-treatment monitoring of population levels was used as control (no untreated control sites were used).  3 sites of 54 m2 (replicates) with infestation were treated. | The product was highly effective against German cockroaches in terms of population reduction over a period of 8 weeks.  Mean percentage reduction in *B. germanica*  population were 100% after treatment.  95% population reduction was recorded against German cockroaches after 8 weeks. | Dr. A. Drago,  2020d  **Trial 4** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Blatta orientalis* | Field test  Indoors  C&C | Field conditions in occupied public housing for the elderly with infestation of Oriental cockroaches. The presence of cockroaches was evaluated using sticky traps for three nights before the treatment.  Then the product was applied at a dose of 5 gr of product for 1m2 in cracks and crevices (under or behind doorjambs, behind skirtings or electrical sockets, in all cracks and crevices, voids or cavities).  The presence of cockroaches was evaluated 48 hours, 7 days, 14 days and 8 weeks after the treatment.  Pre-treatment monitoring of population levels was used as control (no untreated control sites were used).  3 sites of 54 m2 (replicates) with infestation were treated. | The product was highly effective against Oriental cockroaches in terms of population reduction over a period of 6 weeks.  Mean percentage reduction in *B. orientalis*  population were 100% after treatment.  97.1% and 79.8% population reduction was recorded against Oriental cockroaches after 6 and 8 weeks, respectively. | Dr. A. Drago,  2020e  **Trial 5** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Ctenocephalides felis* | Field test  Indoors  C&C | Field conditions in cement concrete basement of a house with infestation of fleas. The pre-treatment assessment was done counting the number of fleas in the white suit of the operator who walked in the infested room for 4 times for 4 minutes, 24, 48 and 72 hours before the treatment.  Then the product was applied at 10 gr of product for 1m2 in cracks and crevices (total area treated 1.5-2 m2).  The presence of fleas was evaluated 24 hours, 7 days and 14 days after the treatment.  Three sites of 20 m2 (replicates) with infestation were treated.  3 sites as untreated controls were used.  The areas used were not subjected to washing. | The product was highly effective against fleas in terms of population reduction over a period of 2 weeks.  Mean percentage reduction in *C. felis* population were 94.5 % after treatment.  100% and 95.7% population reduction was recorded against fleas after 7 and 14 days, respectively. | Dr. A. Drago,  2020f  **Trial 6** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Ctenocephalides felis*  Field collected | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied in different porous (wood) and non-porous surfaces (ceramic tiles) at a dose of 10g per 1m2.  5 batches (replicates) of 10 fleas were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available.  Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 and 48 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 2 weeks to measure the residual effect.  Untreated control was included.  5 replicates were conducted. | In all types of surfaces (porous and non-porous) knock down was 56-74% in 60 minutes and mortality was 100% after 24 and 48 hours, for fresh and 2 weeks deposits.  Mortality in untreated control: 0%. | Martini,  2021a  **Trial 6i** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Cimex lectularius* | Field test  Indoors  C&C | Field conditions in hotel rooms with infestation of bed bugs. The pre-treatment assessments was done counting the number of bedbugs in three sites (a, b, c) of each room.  Then the product was applied at a dose of 10 gr of product for 1m2 in cracks and crevices (including all electrical sockets).  The presence of bedbugs was evaluated 48 hours, 7 days and 14 days after the treatment.  Three rooms of 30 m2 (replicates) with infestation were treated.  3 sites as untreated controls were used. | The product was highly effective against bedbugs in terms of population reduction over a period of 2 weeks.  Mean percentage reduction in *C. reclularius* population were 100 % 48 hours after treatment.  100% population reduction was recorded against bedbugs after 7 and 14 days. | Dr. A. Drago,  2020g  **Trial 7** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Dermanyssus gallinae* | Laboratory test  Field test  Indoors  C&C | Tile test  Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied by spreading, in different porous (marble) and non-porous surfaces (ceramic tiles) at a dose of 10g per 1m2.  5 batches (replicates) of 30 mites were forced to stay in contact with the treated surfaces for 24 hours. Soon after the contact period the mites were transferred to untreated inert surfaces with a nutritious substratum and water available.  Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 6 weeks to measure the residual effect (2, 4, 6 weeks after the first treatment).  Untreated control was included.  Field test  Field conditions in domestic rearing of laying hens (chicken coops) with infestation of poultry mites. The pre-treatment assessments was done counting the number of mites in cracks and crevices, in three sites (a, b, c) of each coop measuring 5x5cm, using a magnifying glass, 24, 48 and 72 hours before the treatment.  Then the product was applied at a dose of 10 gr of product for 1m2 in cracks and crevices.  The presence of mites was evaluated 24 hours, 7 days and 14 days after the treatment.  Three chicken coops (replicates) with infestation were treated.  3 sites as untreated controls were used. | Tile test  In all types of surfaces (porous and non-porous) mortality was 96.67-100% after 24 hours, for fresh and 6 weeks deposits.  Mortality in untreated control: 0-3%.  Field test  Mean percentage reduction in *D. gallinae* population was 58.3 % 24 hours after treatment.  90.3% and 90% population reduction was recorded against poultry mites after 7 and 14 days, respectively. | Dr. A. Drago,  2020h  **Trial 8** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Dermanyssus gallinae*  Field collected | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied by spreading, in wood tiles at a dose of 10g per 1m2.  5 batches (replicates) of 30 mites were forced to stay in contact with the treated surfaces for 24 hours. Soon after the contact period the mites were transferred to untreated surfaces with a nutritious substratum and water available.  Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 2 weeks to measure the residual effect.  Untreated control was included. | Mortality was 97.3-98.7% after 24 hours, for fresh and 2 weeks deposits.  Mortality in untreated control: 0%. | Martini,  2021b  **Trial 8i** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Vespula germanica* | Field test  Indoors | Three wild wasps nests of *Vespula germanica* were found in the field in cavities.  The product was applied at the entrance of the nests at a dose of 2.5 gr/m2.  The activity of the nest was determined 3, 2 and 1 day before the treatment counting the number of the wasps entering or leaving the nest in one minute.  The same counting was done 24 hours and 48 hours, 1 week, 2 weeks and 3 weeks after the treatment.  The assessments were done at the same hour for the whole test.  Three weeks after the treatment the nest was opened to check that no wasp was alive.  3 replications were carried out (nests).  Untreated control was used (3 nests).  Climatic parameters during the tests: T: 24 oC-35oC, RH: 80-95%. | Mean percentage reduction in *V. germanica* population was 15.4%, -42.1%, 49.5%, 81.5% and 100%, 24 hours, 48 hours, 7 days, 14 days and 21 days after treatment, respectively.  Untreated control nests: before the treatment the mean number (of 3 nests) of wasps per nest was 6.7-10. Mean number of wasps per nest was 5-6, 3-9, 10-13, 9-14 and 14-21 24 hours, 48 hours, 1 week, 2 weeks and 3 weeks later, respectively. | Dr. A. Drago, 2020i  **Trial 9** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Vespula germanica* | Field test  Indoors & Outdoors | Five wild wasps nests of *Vespula germanica* were found in the field in cavities (wall voids, into the soil, attics, crawlspaces, roof gutters). 3 of them were found indoors and 2 outdoors.  One opening was identified for each nest.  The product was applied at the entrance (opening) of the nest at a dose of 2.5 gr/nest.  The activity of the nest was determined 7 days and 1 day before the treatment counting the number of the wasps entering or leaving the nest for five minutes.  The same counting was done 24 and 48 hours, one week, two weeks and three weeks after the treatment.  The assessments were done at the same hour for the whole test.  5 replications were carried out (nests).  Untreated control was used (5 nests).  Climatic parameters during the tests: T: 13 oC-36oC, 0-33mm rain/ day. | Mean percentage reduction in *V. germanica* population was 61.2%, 81.8%, 93.4%, 100% and 100%, 24 hours, 48 hours, 7 days, 14 days and 21 days after treatment, respectively.  Untreated control nests: before the treatment the mean number (of 5 nests) of wasps per nest was 39.1-40.7.  Mean number of wasps per nest was 39.4, 34, 32.9, 36.5 and 35.4 24 hours, 48 hours, 1 week, 2 weeks and 3 weeks later, respectively. | Rovetto, 2021b  **Trial 9i** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Lasius niger* | Field test  Indoors  C&C | Field conditions in hallways in a public house for elderly with infestation of ants.  The product was applied at a dose of 5 gr of product for 1m2 in the 20cm long cracks and crevices.  The pre and post treatment assessments was done counting the number of ants in three sites (a, b, c) of each hallway, which measure 35x3.5cm each, for 3 minutes.  The presence of ants was evaluated 72, 48 and 24 hours before treatment and 48 hours, 7 days and 14 days after the treatment.  The assessments were done at the same hour for the whole test.  3 hallways with infestation were treated.  Three hallways as untreated controls were used.  Climatic parameters during the tests: T: 19 oC-28oC, RH: 47-63%. | Mean population reduction was 93.5%, 95.9% and 98.2%, 48 hours, 7 days and 14 days after treatment, respectively.  Untreated control:  before the treatment the mean number of ants was 8-10.1.  Mean number of ants was 9-12.7, 9.3-12.3, 9.3-14.3, 8.3-11.7 in treatment day, 48 hours, 7 days, 14 days later, respectively. | Dr. A. Drago, 2020j  **Trial 10** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Lasius niger*  Field collected | Simulated use test  Choice test  C&C | Choice test.  The trial was conducted in laboratory conditions (T: 24.1-26.8 oC, RH: 65-77%) in test arenas.  Plastic trays of approximately 90 cm length x 90 cm width x 20 cm height were laid flat and lined with polythene sheeting. The walls were lined with liquid PTFE (fluon) to prevent ants from escaping. The arenas were then lined with either a porous (plywood) or non-porous (glazed ceramic) surfaces. In the porous tile test the base substrate was cut to measure (90 cm x 90 cm) whereas in the non-porous tile test, the base substrate comprised 36 tiles of 15 x 15 cm individually arranged.  Food and water were provided on the non-treated side. Each opposing end of the arena had a cover strip of 15cm x 90cm fitted, raised off ground height by placement of 5 cm spacers in between the base and the strip. 4 batches of 200 ants were placed in the test arenas 4 days before the treatment.  The test product was applied at a dose of 5gr for 1 m2 in a limited way in the test arena to reflect a crack and crevice treatment (9% from the total surfaces).  Assessments of knockdown and/or killing effect were performed 4 hour after exposure. Mortality was recorded 24, 72 hours and 7 days later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks in outdoor coditions to measure the residual effect (4, 8 weeks after the first treatment).  4 replications were carried out.  Untreated control was used. | Non-porous surfaces  Knockdown was 1.3-9% in fresh and 4 and 8 weeks deposits.  Mortality after 24 h (T0): 66.1%  Mortality after 72 h (T0): 100%  Mortality after 7 d (T0): 100%  Mortality after 24 h (T4): 32.2%  Mortality after 72 h (T4): 75.6%  Mortality after 7 d (T4): 100%  Mortality after 24 h (T8): 24.5%  Mortality after 72 h (T8): 44.3%  Mortality after 7 d (T8): 69%  Porous surfaces  Knockdown was 0-4.8% in fresh and 4 and 8 weeks deposits.  Mortality after 24 h (T0): 78.6%  Mortality after 72 h (T0): 100%  Mortality after 7 d (T0): 100%  Mortality after 24 h (T4): 20.6%  Mortality after 72 h (T4): 58.9%  Mortality after 7 d (T4): 93.9%  Mortality after 24 h (T8): 9%  Mortality after 72 h (T8): 14.3%  Mortality after 7 d (T8): 32.6%  Mortality in untreated control: 0-5.8%. | Rovetto, 2021c  **Trial 10i** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW | *Lasius niger*  Field collected | Simulated use test  Choice test  Barrier treatment | Choice test.  The trial was conducted in laboratory conditions (T: 24-26.5 oC, RH: 65-75%) in test arenas.  Clear plastic boxes measuring 0.6 m (L) x 0.4 m (W) X 0.4 m (H) were used as test arenas. The base of the arena was divided into two separate sections, identified as side A and side B, by applying a 2 cm thick band of non-set glue (Oecotak) across the width of the arena at the mid-point, which acted as a physical barrier to prevent ants crossing between the two sections. In the middle of the band of non-set glue, a tile (either plywood or glazed ceramic representing porous and non-porous substrate surface types) measuring 10 x 10 cm was positioned over the glue which acted as a crossing point bridging the two sections of the arena. An artificial nest chamber consisting of an open-ended plastic tube approximately 15 cm long and 2 cm in diameter, covered with a piece of paper to create a dark space, containing worker ants and brood materials was positioned in side A of the arena, and a food and water source were placed the opposing side of the divide, referred to as side B.  Nest chamber were placed in the test arenas 7 days before the treatment.  The test product was applied at the “bridge tile” at a strip, not wider than 1cm, at a dose of 5gr for 1 m2.  Assessments of knockdown and/or killing effect were performed 4 hour after exposure. Mortality was recorded 24, 48, 72, 96 hours and 7 days later.  The tests were conducted after treatment and repeated with the treated tiles stored for 3 weeks in outdoor coditions to measure the residual effect.  The position of the ants within the test arena was recorded to inform the study if the insecticide was indeed effective as a barrier to insect invasion (i.e., that ants remained within the section of the arena containing the nest chamber) or which side of the test arena that ants succumbed to treatment.  4 replications were carried out.  Untreated control was used. | Non-porous surfaces  Knockdown was 18.7% and 12.4% in fresh and 3 weeks deposits, respectively.  Mortality after 24 h (T0): 51.6%  Mortality after 48 h (T0): 72.4%  Mortality after 96 h (T0): 79.9%  Mortality after 7 d (T0): 90.2%  Mortality after 24 h (T3): 46.2%  Mortality after 48 h (T3): 62%  Mortality after 96 h (T3): 82.1%  Mortality after 7 d (T3): 88.7%  Porous surfaces  Knockdown was 11.9% and 12.8% in fresh and 3 weeks deposits, respectively.  Mortality after 24 h (T0): 17.5%  Mortality after 48 h (T0): 31.5%  Mortality after 96 h (T0): 60.6%  Mortality after 7 d (T0): 79.4%  Mortality after 24 h (T3): 45.4%  Mortality after 48 h (T3): 58.9%  Mortality after 96 h (T3): 69.1%  Mortality after 7 d (T3): 75.6%  Untreated control:  Ants were able to access both sides of the test arena. | Rovetto, 2021d  **Trial 10ii** |
| Cypermethrin 0.6 gr  (Dustable powder)  “Duracid PW” | *Cimex lectularius*  Development stage: adults  Laboratory strain | Laboratory test | Laboratory conditions.  T: 25 oC+/-1%, RH: 60%+/-5%.  No-choice test.  The product is applied in two porous (wood and back tiles) and one non-porous surfaces (ceramic tiles) at a dose of 10g per 1m2.  5 batches (replicates) of 10 bed bugs were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available.  Assessments of knockdown and/or killing effect were performed up to 1 hour after exposure. Mortality was recorded 24 hours later.  The tests were conducted after treatment and repeated with the treated tiles stored for 8 weeks to measure the residual effect (1, 2, 3, 5, 8 weeks after the first treatment).  Untreated control was included.  5 replicates were conducted. | In all types of surfaces (porous and non-porous) knock down was 100% in 10-30 minutes and mortality was 100% after 24 hours, for fresh and 8 weeks deposits.  Mortality in untreated control: 0%. | Dr. A. Drago,  2020k  **Trial 11** |

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| **Conclusion on the efficacy of the product** |
| Several efficacy studies (laboratory, simulated use and field studies) were submitted for Duracid PW (Ready to Use product) containing cypermethrin 0.6%. Based on the results of the submitted efficacy studies, the product was effective when applied as:  Crack and crevice treatment indoors against crawling insects at 5 gr/ m2 and crack and crevice treatment outdoors against ants at 5 gr/ m2, by non-professionals. (Intended Use 1)   * The product has 8 weeks residual action against cockroaches and 4 weeks residual action against ants. * Against Oriental cockroach the product exerts no knockdown effect and mortality is expected 7 days after the exposure of the insects to the treated surfaces. * For the use indoors and outdoors against ants the product exerts no knockdown effect and mortality is expected 7 days after exposure of the insects to the treated surfaces.   Barrier treatment outdoors against ants (*L. niger*), at 5gr/m2, by non-professionals. All around the perimeter apply a strip not wider than 1cm. (Intended Use 2)   * The product has no residual action. * The product exerts no knockdown effect and mortality is expected only 7 days after exposure of the ants to fresh treated non-porous surfaces.   Crack and crevice treatment indoors against crawling insects at 5 gr/ m2, by professionals. (Intended Use 3)   * The product has 8 week residual action against *B. germanica* and 2 weeks residual action against *B. orientalis* and *L. niger*.   Crack and crevice treatment indoors against bed bugs and fleas at 10 gr/ m2, by non-professionals and professionals. (Intended Uses 4&5)   * The product has 2 weeks residual action against *C. lectularius* and *C. felis*.   Spot application at the entrance of wasp nests at 2.5 gr/ nestindoors, by non-professionals and professionals. (Intended Uses 6&7)   * The product will destroy the entire nest 3 weeks after treatment.   Crack and crevice treatment indoors against poultry mites at 10 gr/ m2, by non-professionals and professionals. (Intended Use 8)   * Efficacy is expected one week after application.   Please refer to section 2.2.5.8 “Evaluation of the label claims” |

#### 2.2.5.6. Occurrence of resistance and resistance management

Cypermethrin is a pyrethroid insecticide. Some resistance to pyrethroids has been found to varying degrees, depending on the pest species and location (Anon. 1987). In Europe the main problems have occurred in some areas with pests of agricultural significance. Laboratory tests on resistant strains have shown, for Myzus persicae, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).

A review by the WHO of Vector Resistance to Pesticides (WHO, 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread (IRAC, 2000).

Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2004), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).

Management strategies

Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC (Anon. 1987). The principles of strategies for managing the development of resistance are similar for cyfluthrin and transfluthrin as they are for other synthetic pyrethroids;

For professional use:

- Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.

- Where possible, application treatments should be recommended to be combined with non-chemical measures .

- Products should always be used in accordance with label recommendations.

- Applications should always be made against the most susceptible stages in the pest life cycle

- Where an extended period of control is required, treatments should be alternated with products with different modes of action

- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.

- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.

- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

- Do not [use/apply] the product in areas where resistance to the active substance (s) contained in this product is suspected or established.

For non-professionals:

* Products should always be used in accordance with label recommendations.
* If the infestation persists, contact a professional.

#### 2.2.5.7 Known limitations

There are not limitations on efficacy of DURACID PW. Underiderable and unintended side effects during the use of the product were not observed.

#### 2.2.5.8 Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intended to be used as crack and crevice treatment indoors against crawling insects and around building against ants, for non-professional use (Intended use 1), as barrier treatment outdoors against ants, for non-professional use (Intended use 2), as crack and crevice treatment indoors against crawling insects, for professional use (Intended use 3), as crack and crevice treatment indoors against bed bugs and fleas, for non-professional use (Intended use 4), as crack and crevice treatment indoors against bed bugs and fleas, for professional use (Intended use 5), as spot application against wasp nests indoors and outdoors, for non-professional use (Intended use 6), as spot application against wasp nests indoors and outdoors, for professional use (Intended use 7) and as crack and crevice treatment indoors against poultry mites, for professional use (Intended use 8).

**Trials submitted by the applicant to substantiate label claims:**

**Intended Use 1 (non-professional use)**

**- Crack and crevice treatment indoors against crawling insects (including *B. germanica, B. orientalis* and *L. niger*) at 5gr/m2**

**- Crack crevice treatment outdoors around building against ants (*L. niger*) at 5gr/m2 (aply the product in thin layers in cracks and crevices only on paved surfaces, balconies and terraces)**

**Trial 1**

The results of the laboratory study (non-coice test) by Drago 2020a show that Duracid PW was effective as surface treatment at 5 gr product/ m2, against German cockroaches for up to 8 weeks post treatment, providing 100% knockdown in 7-15 minutes and 100% mortality 24 hours after exposure of the insects to fresh and 8-week aged porous and non-porous treated surfaces.

**Trial 2**

The results of the laboratory study (non-coice test) by Drago 2020b show that Duracid PW was effective as surface treatment at 5 gr product/ m2, against ants (*L. niger*) for up to 8 weeks post treatment, providing 100% knockdown in 10-20 minutes and 100% mortality 24 hours after exposure of the insects to fresh and 8-week aged porous and non-porous treated surfaces.

**Trial 3**

The results of the laboratory study (non-coice test) by Drago 2020c show that Duracid PW was effective as surface treatment at 5 gr product/ m2, against Oriental cockroaches for up to 8 weeks post treatment, providing 100% knockdown in 20-30 minutes and 100% mortality 24 hours after exposure of the insects to fresh and 8-week aged porous and non-porous treated surfaces.

**Trial 3i**

In the simulated use test (choice test) by Rovetto 2021a Duracid PW was applied as crack and crevice treatment at 5 gr product/m2 against Oriental cockroach in fresh and 4 and 8 weeks deposits, providing the following results:

Non-porous surfaces

100% knockdown in 4 hours in fresh and 4 weeks deposits and 70.8% knockdown in 4 hours in 8 weeks deposits.

Mortality in fresh deposits after 24 hours, 72 hours and 7 days was 90%, 97.5% and 100%, respectively.

Mortality in 4 week deposits after 24 hours, 72 hours and 7 days was 86.7%, 92.5% and 100%, respectively.

Mortality in 8 week deposits after 24 hours, 72 hours and 7 days was 81.7%, 87.5 and 93.3%, respectively.

Porous surfaces

100%, 85% and 64% knockdown in 4 hours in fresh, 4 weeks and 8 weeks deposits, respectively.

Mortality in fresh deposits after 24 hours, 72 hours and 7 days was 80.9%, 95.5% and 100%, respectively.

Mortality in 4 week deposits after 24 hours, 72 hours and 7 days was 65.8%, 85% and 93.3%, respectively.

Mortality in 8 week deposits after 24 hours, 72 hours and 7 days was 60%, 78.3 and 93.4%, respectively.

It is noted that this study supports the claimed 8 week residual action of the product when applied according to the directions for use, noting however, that the product exerts no knockdown effect to Oriental cockroaches and mortality is expected 7 days after the exposure of the insects to the treated surfaces.

**Trial 4**

The results of the field study by Drago 2020d show that Duracid PW when applied as crack and crevice treatment at 5gr of product/ m2 was effective against German cockroaches providing 95-100% cockroach population reduction for up to 8 weeks after treatment.

**Trial 5**

The results of the field study by Drago 2020e show that Duracid PW when applied as crack and crevice treatment at 5gr of product/ m2 was effective against Oriental cockroaches providing 97.1-100% cockroach population reduction for up to 6 weeks after treatment. The population reduction 8 weeks after treatment was 79.8%.

It is noted that this study does not support the claimed 8 week residual action of the product because the 79.8% population reduction is not accepted according to the guidance.

**Trial 10**

The results of the field study by Drago 2020j show that Duracid PW when applied as crack and crevice treatment at 5gr of product/ m2 was effective against ants providing 93.5-98.2% ant population reduction for up to 2 weeks after treatment.

**Trial 10i**

In the simulated use test (choice test) by Rovetto 2021c Duracid PW applied as crack and crevice treatment at 5 gr product/m2 against ants in fresh and 4 and 8 weeks deposits, providing the following results:

Non-porous surfaces

Knockdown was 1.3-9% in fresh and 4 and 8 weeks deposits.

Mortality in fresh deposits after 24 hours, 72 hours and 7 days was 66.1%, 100% and 100%, respectively.

Mortality in 4 week deposits after 24 hours, 72 hours and 7 days was 32.2%, 75.6% and 100%, respectively.

Mortality in 8 week deposits after 24 hours, 72 hours and 7 days was 24.5%, 44.3% and 69%, respectively.

Porous surfaces

Knockdown was 0-4.8% in fresh and 4 and 8 weeks deposits.

Mortality in fresh deposits after 24 hours, 72 hours and 7 days was 78.6%, 100% and 100%, respectively.

Mortality in 4 week deposits after 24 hours, 72 hours and 7 days was 20.6%, 58.9% and 93.9%, respectively.

Mortality in 8 week deposits after 24 hours, 72 hours and 7 days was 9%, 14.3% and 32.6%, respectively.

According to the study report the treated porous and non-porous surfaces used in the study were stored in outdoor conditions in order to support the outdoor use.

It is noted that this study supports the claimed 4 week residual action of the product when applied according to the directions for use indoors and outdoors, noting however that the product exerts no knockdown effect to ants, and mortality is expected 7 days after exposure of the insects to the treated surfaces. The simulated use by Rovetto (2021c) support efficacy against ants indoors for up to 4 weeks considering test with surfaces stored outdoors as worse case scenario covering the indoor use.

It is highlighted that in the efficacy evaluation for the non-professional use of the product against *B. orientalis* and *L. niger* the results of the simulated use tests by Rovetto (2021a, 2021c) with the claimed application method (cracks and crevices), were considered using the efficacy criteria set in the guidance for non-professional use as surface treatment.

Based on the results of the aforementioned efficacy studies, the intended use 1, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

* Against Oriental cockroaches the product exerts no knockdown effect and mortality is expected 7 days after exposure of the insects to the treated surfaces for up to 8 weeks post treatment.
* For the use indoors and outdoors against ants, the product exerts no knockdown effect and mortality is expected 7 days after exposure of the insects to the treated surfaces for up to 4 weeks post treatment.
* We propose to change the claim for “kill and control” to “control” as more appropriate.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

**Intended Use 2 (non-professional use)**

**Barrier treatment outdoors against ants (*L. niger*), at 5gr/m2**

**- all around the perimeter apply a strip not wider than 1cm**

**- only on doors and windows apply a strip not wider than 5 cm**

Lab study by Drago 2020b (trial 2)

(Described in intended use 1)

**Trial 10ii**

In the simulated use test (choice test) by Rovetto (2021d) Duracid PW was applied as barrier treatment on surfaces at 5 gr product/m2, when applied as a strip not wider than 1cm, against ants for up to 3 weeks post treatment, providing the following results:

Non-porous surfaces

Knockdown was 18.7% and 12.4% in fresh and 3 weeks deposits, respectively.

Mortality in fresh deposits after 24 hours, 48 hours, 96 hours and 7 days was 51.6%, 72.4%, 79.9% and 90.2%, respectively.

Mortality in 3 week deposits after 24 hours, 48 hours, 96 hours and 7 days was 46.2%, 62%, 82.1% and 88.7%, respectively.

Porous surfaces

Knockdown was 11.9% and 12.8% in fresh and 3 weeks deposits, respectively.

Mortality in fresh deposits after 24 hours, 48 hours, 96 hours and 7 days was 17.5%, 31.5%, 60.6% and 79.4%, respectively.

Mortality in 3 week deposits after 24 hours, 48 hours, 96 hours and 7 days was 45.4%, 58.9%, 69.1% and 75.6%, respectively.

It is mentioned that the treated porous and non-porous tiles used as “bridge” in the study were stored in outdoor conditions in order to support the outdoor use.

It is highlighted that in the efficacy evaluation for the non-professional use of the product against *L. niger* the results of the simulated use test by Rovetto (2021d) with the claimed application method (barrier), were considered using the efficacy criteria set in the guidance for non-professional use as surface treatment.

Based on the results of the aforementioned efficacy studies and regarding the intended use 2, from an efficacy point of view, the following are pointed out:

* Based on the results of the simulated use study by Rovetto (2021d), the product exerts no knockdown effect and mortality is expected only 7 days after exposure of the ants to fresh treated non-porous surfaces.
* The claimed application method “only on doors and windows apply a strip not wider than 5 cm” is not supported by field studies where suffient control of ants should be proven by treating limited areas (only windows and doors) around a building.
* We propose to change the claim for “kill and control” to “control” as more appropriate.

**Intended Use 3 (professional use)**

**Crack and crevice treatment indoors against crawling insects (including *B. germanica, B. orientalis* and *L. niger*) at 5gr/m2**

Lab studies (non-choice tests) by Drago 2020a, 2020b, 2020c (trials 1, 2, 3), simulated use study by Rovetto 2021a (trials 3i) and field studies by Drago 2020d, 2020e, 2020j (trial 4, 5, 10) against German and Oriental cockroaches and ants (Described in intended use 1).

It is highlighted that in the efficacy evaluation for the professional use of the product against *B. orientalis* the results of the simulated use test by Rovetto (2021a) with the claimed application method (cracks and crevices), were considered using the efficacy criteria set in the guidance for professional use as surface treatment.

Based on the results of the aforementioned efficacy studies, the intended use 3, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

* Μortality of the Oriental cockroaches is expected 7 days after exposure to treated surfaces, considering the results of simulated use study by Rovetto 2021a (trial 3i) with 4 weeks aged treated surfaces covering (worse case) the claimed 2 week residual period.
* We propose to change the claim for “kill and control” to “control” as more appropriate.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

**Intended Uses 4 & 5 (non-professional & professional use)**

**Crack and crevice treatment indoors against bed bugs (*C. lectularius*) and fleas (*C. felis*) at 5gr/m2**

**Trial 6**

The results of the field study by Drago 2020f show that Duracid PW when applied as crack and crevice treatment at 10gr of product/ m2 was effective against fleas providing 94.5-100% flea population reduction for up to 2 weeks after treatment.

**Trial 6i**

The results of the laboratory study (non-coice test) by Martini 2021a show that Duracid PW was effective as surface treatment at 10 gr product/ m2, against fleas for up to 2 weeks post treatment, providing 100% mortality 24 hours after exposure of the insects to fresh and 2-week aged porous and non-porous treated surfaces.

**Trial 7**

The results of the field study by Drago 2020g show that Duracid PW when applied as crack and crevice treatment at 10gr of product/ m2 was effective against bed bugs providing 100% bed bug population reduction for up to 2 weeks after treatment.

**Trial 11**

The results of the laboratory study (non-coice test) by Drago 2020k show that Duracid was effective as surface treatment at 10 gr product/ m2, against bed bugs for up to 8 weeks post treatment, providing 100% knockdown in 10-30 minutes and 100% mortality 24 hours after exposure of the insects to fresh and 8-week aged porous and non-porous treated surfaces.

Based on the results of the aforementioned efficacy studies, the intended uses 4 & 5, from an efficacy point of view, are acceptable as applied for by the applicant noting however the following:

* The claimed direction for use “life cycle of bed bugs take four to five weeks, we recommend not to remove the product before 6 weeks”, implies a claim for 6-week residual activity of the product against bed bugs. However, the residual activity of the product is 2 weeks based on the results of the field study by Drago (2020g) where the product was applied according to the claimed application method. Hence, the aforementrioned statement by the applicant is proposed to be removed.
* We propose to change the claim for “kill and control” to “control” as more appropriate.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

**Intended Use 6 & 7 (non-professional & professional use)**

**Spot application at the entrance of wasp nests (*V. germanica*) at 2.5gr/nest, for indoor and outdoor treatments**

**Trial 9**

The results of the field study by Drago 2020i show that Duracid PW, was effective as spot application at the entrance of the nest at 2.5gr/m2, providing no visible signs of nest activity (100% mortality) against wasps 3 weeks after treatment in all treated wasp nests.

It is noted that this study does not sufficiently support the claimed spot application against wasps, because in the study report it is stated that 3 nests were selected as treated replications, although according to the guidance for products intended for the control of wasp nests, field trial with at least 5 treated nests is required.

Hence, it seems that this study does not fulfil the requirements of the guidance, in terms of test design, to support the label claim against wasp nests.

**Trial 9i**

The results of the field study by Rovetto (2021b) show that Duracid PW, was effective as spot application at the entrance of the nest at 2.5gr/m2, providing no visible signs of nest activity (100% mortality) against wasps 3 weeks after treatment in all treated wasp nests.

Mean percentage reduction in *V. germanica* population was 61.2%, 81.8%, 93.4% and 100%, 24 hours, 48 hours, 7 days, 14 days and 21 days after treatment, respectivley.

As stated in the study report, the nest treated were found indoors and outdoors (3 indoors and 2 outdoors).

According to the guidance for products intended for the control of wasp nests, field trial with at least 5 treated nests is required, which means that 5 treated nests outdoors should have been treated in order to support the outdoor use.

Hence, it seems that this study does not fulfil the requirements of the guidance, in terms of test design, to support the label claim against wasp nests outdoors.

The sum of 5 replicates of the study (3 indoors+2 outdoors) support efficacy against wasp nests indoors considering wasp nests outdoors as worse case scenario covering the indoor use.

Based on the results of the aforementioned efficacy studies, the intended use 8, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

* The wasp nest treatment outdoors is not supported by the efficacy field study by Rovetto (2021b) considering that only 2 replicates (wasp nests) outdoors were used, not 5 as required in the guidance.
* We propose to change the claim for “kill and control” to “control” as more appropriate.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

**Intended Use 8 (non-professional and professional use)**

**Crack and crevice treatment indoors against poultry mites (D. gallinae), at a dose of 10gr/m2.**

**Trial 8**

Tile test

The results of the laboratory study (non-coice test) by Drago 2020h show that Duracid PW was effective as surface treatment at 10 gr product/ m2, against poultry mites for up to 6 weeks post treatment, providing 96.7-100% mortality 24 hours after exposure of the mites to fresh and 6-week aged porous and non-porous treated surfaces. According to the study the product applied in one porous and one non-porous surface.

Crack and crevice study

The results of the field study by Drago 2020h show that Duracid PW when applied as crack and crevice treatment at 10gr of product/ m2 was effective against poultry mites providing 100% mite population reduction for up to 2 weeks after treatment.

**Trial 8i**

The results of the laboratory study (non-coice test) by Martini (2021b) show that Duracid PW was effective as surface treatment at 10 gr product/ m2, against poultry mites for up to 6 weeks post treatment, providing 97.3-98.7% mortality 24 hours after exposure of the mites to fresh and 2-week aged treated porous surfaces.

Based on the results of the aforementioned efficacy studies, the intended use 8, from an efficacy point of view, is acceptable as applied for by the applicant, noting however the following:

* The claim “The product reaches the complete efficacy one week after application” is proposed to be changed to “efficacy is expected one week after application”, as more appropriate.
* We propose to change the claim for “kill and control” to “control” as more appropriate.
* The claim “for control of crawling insects” in the section ‘Where relevant, an exact description of the authorised use 8’ in not supported by the efficacy studies against poultry mites. Hence, it is proposed to be changed to “for control of poultry mites”.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.4.

#### 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be used in combination with other biocidal products.

### Risk assessment for human health

**General information**

The assessment of effects on human health for Duracid PW has been developed having as starting point the rules outlined in CLP Regulation. More specifically, article 11 of CLP Regulation states “*where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value. The cut-off value referred shall be determined as set out in CLP Regulation, section 1.1.2.2 of Annex I*”. This approach was deemed as appropriate also in the light of the criteria outlined in article 3.1(f) of Biocidal Products Regulation to identify the substances of concern in a biocidal product.

The biocidal product Duracid PW contains only not hazardous co-formulants. Cypermethrin is the only hazardous ingredient in the product. Available toxicological information for the active substance and all co-formulants are deemed sufficient for the hazard assessment of Duracid PW.

The toxicological risk assessment of the biocidal product was carried out taking into account what was adopted in the RAC Opinion in December 2019 for the classification of the active substance cypermethrin. According to the RAC Opinion, cypermethrin is classified H302; H332; H335; H373.

For these reasons, in the sections below the human health hazard assessment shortly summarizes the information discussed in detail in the CAR of cypermethrin (for PT18). The use of data on active substance and model formulation is covered by the Letter of Access.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritant to skin. |
| Justification for the value/conclusion | No data on skin corrosion/irritation are available for the biocidal product Duracid PW.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).  Neither the active substance nor the co-formulants of the biocidal product Duracid PW are classified for skin corrosion/irritation, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion and irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritant to eyes. |
| Justification for the value/conclusion | No data on eye damage/irritation are available for the biocidal product Duracid PW.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).  The biocidal product Duracid PW contains one co-formulant classified for Eye Damage Cat. 1 (H318). However, as its concentration in the product is well below the generic concentration limit set out in Regulation (EC) No. 1272/2008 (CLP), no classification for eye damage/irritation is triggered for the biocidal product Duracid PW.  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the conclusion | There are currently no designated tests for the determination of respiratory tract irritation.  No data on respiratory tract irritation are available for the biocidal product Duracid PW.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).  The active substance cypermethrin is the only ingredient of the biocidal product Duracid PW, classified as STOT SE Cat. 3, H335 (RAC opinion, December 2019). However, as its concentration in the product (0.632%) is below 20%, which is the generic concentration limit triggering classification of a product for STOT SE Cat. 3, no classification for respiratory tract irritation is triggered for the biocidal product Duracid PW, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitizing to skin. |
| Justification for the value/conclusion | No data on skin sensitization are available for the biocidal product Duracid PW.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).  Neither the active substance nor the co-formulants of Duracid PW are classified for skin sensitization, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitization** | |
| Value/conclusion | Not a respiratory sensitizer. |
| Justification for the value/conclusion | There are currently no standard tests and no OECD test guidelines available for respiratory sensitization and there is no testing requirement for this endpoint under the BPR.  No data on respiratory sensitization are available for the biocidal product Duracid PW.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product in respect to classification criteria of the Regulation (EC) No. 1272/2008 (CLP).  Neither the active substance nor the co-formulants of Duracid PW are classified as respiratory sensitizers, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Non-toxic *via* the oral route. |
| Justification for the selected value | Acute oral toxicity data are not available for the biocidal product Duracid PW.  For this endpoint the classification has been estimated by the application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and one co-formulant of the biocidal product Duracid PW are classified for Acute Oral Toxicity Cat. 4 (H302). However, as their concentration in the product is below 1%, no classification for acute oral toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Non-toxic *via* the inhalation route. |
| Justification for the selected value | Acute inhalation toxicity data are not available for the biocidal product Duracid PW.  For this endpoint, the classification has been estimated by the application of the criteria of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and one co-formulant of the biocidal product Duracid PW are classified for Acute Inhalation Toxicity Cat. 4 (H332). However, as their concentration in the product is below 1%, no classification for acute inhalation toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Non-toxic *via* the dermal route. |
| Justification for the selected value | Acute dermal toxicity data are not available for the biocidal product Duracid PW.  For this endpoint, the classification has been estimated by the application of the criteria of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  None of the ingredients of the biocidal product Duracid PW is classified for acute dermal toxicity hazard. Therefore, the product does not meet the criteria for classification for acute dermal toxicity according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  For further details please refer to the Confidential Annex. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute dermal toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Information on dermal absorption***

Dermal absorption data for Duracid PW is not available; therefore, default values of dermal absorption have to be used in the risk assessment, as proposed in the current EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873].

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Dermal absorption** | |
| Substance | Cypermethrin |
| Value(s) | 50% |
| Justification for the selected value | A dermal study has not been performed with the biocidal product Duracid PW, therefore a default value of dermal absorption has to be used.  According to EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration.  Duracid PW is a solid formulation and the concentration of cypermethrin in the biocidal product is 0.632%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of solid formulations. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | In the absence of relevant dermal absorption data with Duracid PW, the default value of 50% will be considered in the risk assessment for the active substance, as proposed in the current EFSA Guidance on dermal absorption for dilutions of solid formulations [EFSA Journal, 2017; 15(6): 4873].  The available information is sufficient to evaluate this endpoint and therefore no additional studies are deemed necessary. |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

The biocidal product Duracid PW contains the co-formulant dipropylene glycol monomethyl ether (CAS No.34590-94-8). Based on the submitted MSDS of the supplier and the REACH registration dossier, dipropylene glycol monomethyl ether is not classified as hazardous according to CLP Regulation, therefore there is no impact on the classification of the biocidal product Duracid PW.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health – Part B and C Risk Assessment– Version 4.0 – December 2017), dipropylene glycol monomethyl ether should be considered as a Substance of Concern (SoC), as there is available a European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit of dipropylene glycol monomethyl ether is 308 mg/m3 (<https://echa.europa.eu/el/substance-information/-/substanceinfo/100.047.353>) with a skin note (a skin notation assigned to the OEL identifies the possibility of significant uptake through the skin).

According to the BPR Guidance (p. 424), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. If the IOELV is associated with a “skin notation” and is driven by systemic rather than local effects, then a dermal quantitative risk assessment for the professional operator should be performed.

According to the submitted MSDS of the supplier, there are available dermal and inhalation DNEL values for the long-term systemic effects of dipropylene glycol monomethyl ether. However, according to the TAB for human health (August 2021), a semi-quantitative or quantitative risk assessment of a product is needed only in cases where local NOAEC or local AEC value for the co-formulant has been peer reviewed and agreed under the BPR.

In case of dipropylene glycol monomethyl ether, a dermal NOAEC value for this co-formulant has not been peer reviewed and agreed under the BPR. Therefore, a dermal quantitative risk assessment has not been performed and only an inhalation quantitative risk assessment has been undertaken for this co-formulant.

***Available toxicological data relating to a mixture***

The biocidal product Duracid PW contains only one mixture: Denatonium benzoate (CAS No. 3734-33-6). Available toxicological data relating to the mixture contained in the biocidal product Duracid PW is provided in the MSDS attached to current submission.

***Endocrine-disrupting properties for human health: screening for co-formulants***

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product Duracid PW has been performed according to the instructions described in the document agreed in the Coordination Group (CG-39-2020-11 AP 16.4 e-c ED co-formulant assessment by MS).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The sources of information, the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product Duracid PW are presented in detail in the Confidential Annex.

Overall, based on available information it is concluded that the product Duracid PW does not contain co-formulants with endocrine-disrupting properties for human health.

***Other***

Not applicable.

#### Exposure assessment

The biocidal product Duracid PW is a ready-to-use dustable powder insecticide (PT18), containing cypermethrin (CAS No. 52315-07-8) as active substance and dipropylene glycol monomethyl ether (CAS No. 34590-94-8) as Substance of Concern.

The nominal (pure) concentration of cypermethrin in the biocidal product is 0.6% w/w and the minimum purity is 95% as stated in the technical equivalence for cypermethrin and ECHA decision on chemical equivalence (No TAP-D-1477453-13-00/F). Therefore, TGAI is 0.632% w/w (i.e. 0.6% × 100/95), which is used for the risk assessment calculations.

Exposure assessment has been performed according to Biocides Human Health Exposure Methodology, version 1, October 2015 and ECHA Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 - December 2017.

The relevant uses of the biocidal product Duracid PW are reported in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Non-professional users** | | | |
| **Use** | | **a.s concentration** | **Dose** |
| Use 1 | Indoor treatment  Crack and crevice, voids and cavities  Crawling insects | 0.632% | 5 g/m2 |
| Use 2 | Outdoor treatment around building  All around the perimeter, doors and windows  Ants | 0.632% | 5 g/m2 |
| Use 4 | Indoor treatment  Crack and crevice, voids and cavities  Bed bugs and fleas | 0.632% | 10 g/m2 |
| Use 6 | Indoor treatment  Wasp nest | 0.632% | 2.5 g/nest |
| Use 8 | Indoor rural treatment: animal houses/shelters  Crack and crevice, voids and cavities  Crawling insects | 0.632% | 10 g/m2 |
| **Professional users** | | | |
| **Use** | | **a.s. concentration** | **Dose** |
| Use 3 | Indoor treatment  Crack and crevice, voids and cavities  Crawling insects | 0.632% | 5 g/m2 |
| Use 5 | Indoor treatment  Crack and crevice, voids and cavities  Bed bugs and fleas | 0.632% | 10 g/m2 |
| Use 7 | Indoor treatment  Wasp nest | 0.632% | 2.5 g/nest |
| Use 8 | Indoor rural treatment: animal houses/shelters  Crack and crevice, voids and cavities  Crawling insects | 0.632% | 10 g/m2 |

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

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

n.a: not applicable

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Application | **Primary exposure: direct**  Indoor treatment: crack and crevice, voids and cavities.  Ready to use product: scattering powder from a hand held duster. | Professional users |
| 2. | Mixing and loading | **Primary exposure: direct**  Loading of the powder into the application device. | Professional users |
| 3. | Post-application | **Primary exposure: indirect**  Adult professional users laundering work clothes at home. | Professional users |
| 4. | Application | **Primary exposure: direct**  Indoor treatment: crack and crevice, voids and cavities.  Ready to use product: scattering powder from a hand held duster against ants. | Non-professional users |
| 5. | Post-application | **Secondary exposure**  Secondary exposure is relevant to the general public entering to treated areas after the product application and is derived *via* inhalation, dermal and oral route. | General public: infants, toddlers, children, adults |

***Industrial exposure***

BPR is not applied to the industrial formulation phase; therefore, risk assessment has not been performed for this use.

***Professional exposure***

Duracid PW is a ready-to-use dustable powder insecticide for use against crawling insects.

The biocidal product may be used by professionals indoors by dusting in crack and crevice (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes, etc...). The recommended application rate of the product is 5 g product/m2 for ants and cockroaches and 10 g product/m2 for bed bugs and fleas.

The product may also be used by professionals indoors *via* spot application on the entrance wasp nests. The recommended application rate of the product is 2.5 g/nest.

The model taken into consideration in Scenario 1 (application in crack and crevice, voids and cavities/indoor) for the assessment of primary human exposure does not take into account the actual application rate of the product, nor the surface treated, but only has the concentration of the active substance in the product as input value; therefore, although the uses have different usage doses, the model used is not affected by this difference. Model used in Scenario 1 (cracks and crevices, voids and cavities) is based on a quantity of applied biocidal product that is higher than the quantity of biocidal product used for wasp nest; therefore, exposure assesssment performed for Scenario 1 is conservative and is considered as worst case.

Primary exposure of professional users will be *via* inhalation and dermal route. The exposure is anticipated to be chronic in nature.

The model and the parameters used for the professional exposure to Duracid PW are summarised below, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 1*

| **Description of Scenario 1:** **Application of Duracid PW by professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professionals | - |
| Scenario | Application | - |
| Application rate | 10 g/m2 | Product label claim.  The recommended application rate of the product for bed bugs and fleas is used as worst case. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin (TGAI) in the biocidal product. |
| Application duration | 60 minutes | The application duration default value for spreading/scattering a granule formulation is 60 min, according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Penetration to skin (Tier 1) | 100% | As a worst-case scenario, it is assumed that no protective equipment is worn.  Tier 1 human exposure assessments ‘must not take account of exposure reduction measures such as personal protective equipment’, according to TNsG, January 2008, p. 27. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

*Scenario 2*

| **Description of Scenario 2: Loading of the powder into the application device.** | | |
| --- | --- | --- |
| Model: Mixing and loading model 5 ”Professional pouring formulation from a container into a fixed receiving vessel” (TNsG part 2, p 137). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professionals | - |
| Scenario | Loading | - |
| Application rate | 10 g/m2 | Product label claim.  The recommended application rate of the product for bed bugs and fleas is used as worst case. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin in the biocidal product. |
| Area treated/day | 100 m2 | It is assumed that the professional user treats approximately 1000 m of 10 cm crack/crevice per day, therefore the surface of the treated area is 100 m2. The selection of this value is considered precautionary given that the product is a crack and crevice, voids and cavities treatment. |
| Amount of a.s. handled/day | 0.00632 kg a.s/day | The amount of a.s. handled per day is calculated as follows:  10 g product/m2 x 100 m2 x 0.632% a.s./product = 6.32 g a.s. per day = 0.00632 kg a.s/day. |
| Tier 1: no PPE | Penetration to skin: 100% | As a worst-case scenario, it is assumed that no protective equipment is worn.  Tier 1 human exposure assessments ‘must not take account of exposure reduction measures such as personal protective equipment’, according to TNsG, January 2008, p. 27. |
| **Dermal exposure** | | |
| Indicative dermal exposure | Hands: 10.2 mg a.s./kg a.s. | Default value for dermal exposure according to Mixing and loading model 5” (TNsG part 2, p 137). |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Dermal uptake | 0.0005372 mg/kg bw/day | The dermal uptake is calculated as follows: 10.2 mg a.s./kg a.s x 0.00632 kg a.s/day x 50% / 60 kg = 0.0005372 mg/kg bw/day. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 0.66 mg a.s./kg a.s. | Default value for inhalation exposure according to Mixing and loading model 5” (TNsG part 2, p 137). |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation uptake | 0.00007 mg/kg bw/day | The inhalation uptake is calculated as follows: 0.66 mg a.s./kg a.s x 0.00632 kg a.s/day x 100% / 60 kg = 0.00007 mg/kg bw/day. |

*Scenario 3*

| **Description of Scenario 3:** **Adult professional users – laundering work clothes at home.** | | |
| --- | --- | --- |
| Exposure of adult professional users to the product Duracid PW can potentially occur *via* contact with the contaminated coveralls, during laundering at home. The worst-case exposure is *via* the dermal route – mainly to the hands – from handling the contaminated clothing prior to introduction into the washing machine.  The amount of product contaminating the coverall is considered to be equivalent to the potential dermal exposure estimated by the scenario “Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals (TNsG 2007, p. 63). The indicative exposure value for the total body of the adult user is 5.47 mg/min. With an estimated duration of the application of 60 minutes for professional users and a.s. concentration in the product of 0.632%, the potential contamination is 2.074 mg a.s./day. It is assumed that the coverall is washed weekly, after 5 days wear.  Please refer to Annex 3.2 for the detailed calculations. | | |
| Parameters | Value | Comments |
| Exposed group | Professionals users | - |
| Scenario | Laundering work clothes | - |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin (TGAI) in the biocidal product. |
| Application duration | 60 minutes | The application duration default value for spreading/scattering a granule formulation is 60 min, according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Total outer surface area of a medium sized coverall | 22700 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Total area of both hands of an adult | 820 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Dislodgable fraction | 30% | The default value for the dislodgeable fraction is set at 30%, according to RIVM report 320005002 (p.71). |

**Calculations for Scenarios 1 - 2 - 3 for cypermethrin**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | | |
| Scenario 1 | 1/no PPE | 0.000325 | 0.0173 | - | **0.01763** |
| Scenario 2 | 1/no PPE | 0.00007 | 0.00054 | - | **0.00061** |
| Scenario 3 | 1/no PPE | - | 0.000187 | - | **0.000187** |

**Further information and considerations on Scenarios 1&2**

The biocidal product Duracid PW contains as Substance of Concern the co-formulant dipropylene glycol monomethyl ether (CAS No.34590-94-8), which has a European Union-agreed IOELV (308 mg/m3).

A quantitative inhalation risk assessment for the professional operator against the IOELV has been conducted. Therefore, for Scenarios 1 and 2, the inhalation exposure of professional users to dipropylene glycol monomethyl ether has been calculated.

The parameters used for the inhalation exposure of professional users to dipropylene glycol monomethyl ether during the application (Scenario 1) and loading (Scenario 2) of Duracid PW are presented in the Confidential Annex, while the estimated inhalation exposures are summarized in the following tables.

**Calculations for Scenarios 1&2 for dipropylene glycol monomethyl ether**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | | |
| Scenario 1 | 1 | 0.00072 | - | - | **0.00072** |
| Scenario 2 | 1 | 0.000154 | - | - | **0.000154** |

**Additional considerations on scenarios**

Combined exposure (combined scenarios 1+2+3 for cypermethrin and combined scenarios 1+2 for dipropylene glycol monomethyl ether) has been assessed for the professional user, who is exposed to the active substance cypermethrin and the SoC dipropylene glycol monomethyl ether during the application of the product (primary direct exposure – Scenario 1), during the loading of the powder into the application device (primary direct exposure – Scenario 2) and during the laundering of the contaminated work clothes at home (primary indirect exposure – Scenario 3).

*Combined scenarios*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | **mg/kg bw/day** | | | |
| Scenarios [1,2,3]  Tier 1  Cypermethrin | 0.000325  +  0.00007  =  0.000395 | 0.0173  +  0.00054  +  0.000187  =  0.018 | - | **0.0184** |
| Scenarios [1,2]  Tier 1  Dipropylene glycol monomethyl ether | 0.00072  +  0.000154  =  0.000874 | - | - | **0.000874** |

***Non-professional exposure***

Duracid PW is a ready-to-use dustable powder insecticide for use against crawling insects.

The biocidal product may be used by non-professionals indoors by dusting in crack and crevice (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes, etc...). The recommended application rate of the product is 5 g product/m2 for ants and cockroaches and 10 g product/m2 for bed bugs and fleas.

The product may also be used by non-professionals by spreading outdoors around buildings against ants. The recommended application rate of the product is 5 g product/m2.

In addition, the product may be used by non-professionals indoors *via* spot application on the entrance of wasp nests. The recommended application rate of the product is 2.5 g/nest.

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor treatments (i.e., it is considered to be within the ‘risk envelope’ as defined by the indoor use).

The model taken into consideration in Scenario 4 (application in crack and crevice, voids and cavities/indoor) for the assessment of primary human exposure does not take into account the actual application rate of the product, nor the surface treated, but only has the concentration of the active substance in the product as input value; therefore, although the uses have different usage doses, the model used is not affected by this difference. Model used in Scenario 4 (crack and crevice, voids and cavities) is based on a quantity of applied biocidal product that is higher than the quantity of biocidal product used for wasp/ant nest eradication; therefore, exposure assesssment performed for Scenario 4 is conservative and is considered worst case.

Primary exposure of non-professional users will be *via* inhalation and dermal route.

The model and the parameters used for the non-professional exposure to Duracid PW are summarised below, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 4*

| **Description of Scenario 4:** **Application of Duracid PW by non-professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non-professionals | - |
| Scenario | Application | - |
| Application rate | 10 g/m2 | Product label claim.  The recommended application rate of the product for bed bugs and fleas is used as worst case. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632 % | Concentration of cypermethrin in the biocidal product. |
| Application duration | 5 min | According to RIVM report 320005002/2006; Pest Control Products Fact Sheet (p. 72), for dusting powders against crawling insects, indoors the application duration is considered to be 5 minutes. |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

**Calculations for Scenario 4**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | | |
| Scenario 4 | Tier 1/no PPE | 0.00003 | 0.00144 | - | **0.00147** |

***Exposure of the general public***

Subsequent to the use of the biocidal product, indirect secondary exposure of general public could occur in the residential environment. Secondary exposure is derived *via* inhalation, dermal and oral route.

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocide on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time.

It is noted that the biocidal product Duracid PW contains a bittering agent that prevents it from being ingested by the children. Therefore, the oral exposure of infants and toddlers from hand-to-mouth contact would be negligible.

It is assumed that infants, toddlers and children would not be permitted to be present during the application operation and therefore, there would be no acute exposure.

Secondary exposure for the general puclic is considered as a medium-term event, because it is estimated that the duration of exposure is more important than a single event, among others considering inhalation exposure. The exposure time would be high, 8 hours for inhalation of the residues and a dermal contact of one hour for infants, toddlers and children.

The models used for the secondary exposure assessment for the general public are summarized in the following table.

|  |  |  |
| --- | --- | --- |
| **Overview of models used for secondary human health exposure assessment.** | | |
| **Inhalation route** | **Models** | **Population** |
| Vapours (volatilised residues) | HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active substances. | Infant  Toddler  Child  Adult |
| **Dermal route** | **Model** | **Population** |
| Dermal contact with treated surfaces | ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off. | Infant  Toddler  Child |

**Assessment of Inhalation Exposure of Volatilised Biocidal Active Substance**

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Volatization of cypermethrin is expected to be minimal due to low vapour pressure, low Henry’s Law constant and high adsorption potential. Therefore, inhalation exposure due to evaporation is considered to be negligible. However, the assessment of inhalation exposure of volatilised residues of active substances was performed for completeness.

*Tier-1 screening tool*

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m3/24 hr and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d,

if 0.328 × [(mw x vp) / AELlong-term] ≤ 1

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is

negligible, then the inhalation risk for the infant, child and adult can also be considered to be negligible.

Tier-1 screening tool has been applied for cypermethrin as detailed in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Screening tool of inhalation exposure of volatilised biocidal active substance** | | | | | |
| **Active substance** | **MW (g/mol)** | **vp**  **(Pa)** | **AELlong-term**  **(mg/kg bw/d)** | **0.328 × mw x vp/AELlong-term** | **Result** |
| cypermethrin | 416.3 | 6 x 10-7 | 0.022 | 0.0037 | <1  risk from inhalation exposure for the toddler is negligible |

As a result of the application of Tier-1 screening tool, the risk from the inhalation exposure for toddlers is negligible in long-term exposure. Therefore, the inhalation risk for infants, children and adults is also considered negligible.

**Dermal exposure to residues on the floor – infants, toddlers and children**

Secondary dermal exposure due to the entering in areas treated with the product is not expected for the general public, as the product is applied in crack and crevice, voids and cavities. In addition, secondary exposure of children, toddlers and crawling infants is not expected as the product is used in areas that are inaccessible to infants, toddlers and children, according to the product label.

However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and children has been included in the risk assessment.

The models and the parameters used to calculate the secondary exposure assessment for the general public are described in detail in the following table, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 5*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 5: Secondary dermal exposure of the general public.** | | |
| The assessment for the dermal exposure of the general public has been performed using ConsExpo Web, version 1.0.6, considering the application rate of the product for bed bugs and fleas as worst case (10 g/m2). The parameters used were from the RIVM report 320005002/2006, Chapter 7, Dusting powders, Exposure after application (p. 71-73). | | |
| **Parameter** | **Value** | **Comments** |
| Exposed group | General public:  infant, toddler, child | - |
| Product database | Pest control products | - |
| Product category | Dusting powders | - |
| Product | Dusting powders | - |
| Scenario | Post-application (child) | - |
| Application rate | 10 g/m2 | Product label claim.  The recommended application rate of the product for bed bugs and fleas is used as worst case. |
| Body weight | Infant: 8 kg  Toddler: 10 kg  Child: 23.9 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction substance | 0.632% | Concentration of cypermethrin in the biocidal product. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Rubbing off | - |
| Exposure frequency | 70 per year | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Exposed area  (palms and backs of both hands) | Infant: 196.8 cm2  Toddler: 230.4 cm2  Child: 427.8 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Transfer coefficient | Infant/toddler/child: 0.2 m2/hr | Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: “New default values for indoor Transfer Coefficient” (agreed at the Human Health Working Group V on 22 November 2016). |
| Dislodgeable amount  (product) | 2.55 g/m2 | Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 71), using the application rate of Duracid PW for bed bugs and fleas (10 g/m2).  According to RIVM report 320005002 (p.71), “the default value for the dislodgeable fraction is set at 30%. The airborne fraction is taken to be 15%, so 85% of the powder is sprinkled onto 1 m2”.  Therefore, the dislodgeable amount for Duracid PW is calculated as follows:  10 g/m2 x 0.85 x 0.3 = 2.55 g/m2 |
| Contact time | 60 min/day | Default value for contact time, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Rubbed surface | 1 m2 | Default value for rubbed surface, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |

**Calculations for Scenario 5**

| **Summary table: systemic exposure for general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Exposed group** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | | |
| Scenario 5 | Infant | - | 0.2 | - | **0.2** |
| Scenario 5 | Toddler | - | 0.16 | - | **0.16** |
| Scenario 5 | Child | - | 0.067 | - | **0.067** |

***Monitoring data***

Not available.

***Dietary exposure***

Not applicable, due to the intended use.

*Information of non-biocidal use of the active substance*

Not applicable.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

Not relevant, in normal conditions of use the product does not come into contact with food.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Not relevant, in normal conditions of use the product does not come into contact with food.

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

Not relevant.

***Aggregated exposure***

Not relevant.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Substance** | **Estimated total uptake**  (mg/kg bw/day) |
| 1. | Professional users | 1/no PPE | Cypermethrin | **0.01763** |
| Dipropylene glycol monomethyl ether | **0.00072** |
| 2. | Professional users | 1/no PPE | Cypermethrin | **0.00061** |
| Dipropylene glycol monomethyl ether | **0.000154** |
| 3. | Professional users | 1/no PPE | Cypermethrin | **0.000187** |
| 4. | Non-professional users | 1/no PPE | Cypermethrin | **0.00147** |
| 5. | Infant | 1/no PPE | Cypermethrin | **0.2** |
| 5. | Toddler | 1/no PPE | Cypermethrin | **0.16** |
| 5. | Child | 1/no PPE | Cypermethrin | **0.067** |
| 1+2+3 | Professional users | 1/no PPE | Cypermethrin | **0.0184** |
| 1+2 | Professional users | 1/no PPE | Dipropylene glycol monomethyl ether | **0.000874** |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute delayed neurotoxicity | 20 mg/kg bw/day | 100 | 44% | 0.088 mg/kg bw/day |
| AELmedium-term | Dog, 90-days | 12.5 mg/kg bw/day | 100 | 44% | 0.055 mg/kg bw/day |
| AELlong-term | Rat, 2-year | 5 mg/kg bw/day | 100 | 44% | 0.022 mg/kg bw/day |

The following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005):

ADI = 0.05 mg/kg bw/day

ARfD = 0.2 mg/kg bw/day

**Reference values to be used in Risk Characterisation for dipropylene glycol monomethyl ether**

|  |  |  |
| --- | --- | --- |
| European IOELV according to Commission Directive (EU) 2017/164: | | Skin notation |
| 8 hours | |
| mg/m3 | ppm |
| 308 | 50 | yes |

The European IOELV (308 mg/m3) of dipropylene glycol monomethyl ether (CAS No. 34590-94-8) has been converted in the systemic inhalation uptake of 6.417 mg/kg bw/day, considering an inhalation rate of 1.25 m3/h, body weight of 60 kg, 100% inhalation absorption and 1 h duration of exposure for the professional user:

308 mg/m3 x 1.25 m3/h x 1 h x 100% / 60kg = 6.417 mg/kg bw/day

**Maximum residue limits or equivalent**

Not applicable

**Specific reference value for groundwater**

Not applicable

***Risk for industrial users***

BPR is not applied to the industrial formulation phase; therefore, risk assessment has not been performed for this use.

**Conclusion**

It is possible to conclude that occupational health risk is minimal.

***Risk for professional users***

**Systemic effects for cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELlong-term**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Application Professional users Scenario 1 | 1 | 0.022 | 0.01763 | 80.14% | yes |
| Loading Professional users Scenario 2 | 1 | 0.022 | 0.00061 | 2.8% | yes |
| Laundering work clothes  Professional users Scenario 3 | 1 | 0.022 | 0.000187 | 0.85% | yes |

**Systemic effects for dipropylene glycol monomethyl ether**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **IOELV (mg/m3/8h)** | **Converted reference value**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ reference value** | **Acceptable**  **(yes/no)** |
| Application Professional users Scenario 1 | 308 | 6.417 | 0.00072 | 0.011% | yes |
| Loading Professional users Scenario 2 | 308 | 6.417 | 0.000154 | 0.0024% | yes |

**Combined scenarios for cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AELlong-term**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Loading, application, laundering Professional users Scenarios 1, 2, 3 | 1 | 0.022 | 0.0184 | 83.64% | yes |

**Combined scenarios for dipropylene glycol monomethyl ether**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **IOELV mg/m3/8h** | **Converted reference value**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ reference value** | **Acceptable**  **(yes/no)** |
| Loading and application Professional users  Scenarios 1, 2 | 308 | 6.417 | 0.000874 | 0.014% | yes |

**Local effects**

Local effects are not expected for this product.

**Conclusion**

For scenarios 1, 2 and 3 the primary exposure of professional users is considered acceptable, as the total internal dose is below the long-term AEL. Also combined exposure of scenarios 1, 2 and 3 is considered acceptable. Therefore, there is no concern for the professionals using the biocidal product Duracid PW.

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

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Application  Non-professional users  Scenario 4 | 1 | 0.055 | 0.00147 | 2.67% | yes |

**Combined scenarios**

Not relevant.

**Local effects**

Local effects are not expected for this product.

**Conclusion**

Regarding the primary exposure of non-professional users, for scenario 4 the total internal dose is well below the medium-term AEL. Therefore, there is no concern for non-professional users, using the biocidal product Duracid PW.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Infant  Scenario 5 | 1 | 0.055 | 0.2 | 364% | **no** |
| Toddler  Scenario 5 | 1 | 0.16 | 291% | **no** |
| Child  Scenario 5 | 1 | 0.067 | 122% | **no** |

**Local effects**

Local effects are not expected for this product.

**Conclusion**

Secondary inhalation exposure due to evaporation of the active substance is considered to be negligible for the general public.

Secondary dermal exposure due to the entering in areas treated with the product is not expected for the general public, as the product is applied in cracks and crevices, voids and cavities. In addition, secondary exposure of children, toddlers and crawling infants is not expected as the product is used in areas that are inaccessible to infants, toddlers and children, according to the product label. However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and childeren has been performed.

A risk has been identified for infants, toddlers and children. However, considering the label implication that the product should be used in areas inaccessible to infants and children, no concern arises for these populations groups.

***Risk for consumers via residues in food***

Not applicable, due to the intended use.

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

No combined exposure is foreseen.

### Risk assessment for animal health

In and around buildings application

Terrestrial fauna:

Cypermethrin cis:trans/40:60 has limited acute effect on terrestrial organisms such as earthworms. The EC50 is found >100mg/Kg.

In a chronic test on earthworms, a NOEC mortality > of 100mg/Kg was determined. A NOEC biomass of 30.8 mg/Kg and a NOEC reproduction of 5.2 mg/Kg where determined in the same study. Based on the measured concentration the NOEC (reproduction) for earthworms is 4mg/kgdw.

In addition to these tests on earthworms, field trials provided information on the effect of 14d apart applications of cypermethrin 100g/L (250ml/ha) on non-target arthropod fauna. No adverse effects were identified on Linyphiidae; Collembolla; Diptera; Braconidae/ Ichneumonidae+ Aphidius Sp.; Gamebird-chick food populations. The observed effects on Carabid and Staphilinid populations were only transient allowing populations to recover within a crop season. (Evaluation Report of AS)

Terrestrial micro organisms:

Cypermethrin has moderate effect on soil microorganisms on mineralisation process. A NOEC of 52.0 mg/Kg dry soil was determined. (Evaluation Report of AS)

Toxicity to birds:

Cypermethrin cis:trans/40:60 shows oral acute toxicity to bird a dose above 1376mg a.i. /Kg/d or 5620 mg/Kg feed. Chronic effects (21d) investigated up to 1000mg/Kgfood don’t show any significant results up to 92.0 mg as/Kgbw. There were no treatment-related effects upon reproductive performance at any of the concentrations tested and no treatment-related macroscopic abnormalities were observed in any birds examined at autopsy. The NOEC was set to 1000 mg/Kgfoodor 92.0 mg as/Kgbw. (Evaluation Report of AS)

### Risk assessment for the environment

#### Effects assessment on the environment

The results of the mesocosm study cannot be used to derive the PNEC water. The value of the assessment factor (10) was chosen according to the TGD based on the available dataset. The lowest NOEC calculated is 0.04 μg/l for daphnia. Therefore, using the AF of 10, the PNEC water is 0.004 μg/L.

**PNECwater = 0.004 μg/L**

No study allow for the derivation of a PNEC sed.

Using the equilibrium partitioning method and a value of koc of 575000 to calculate Ksusp-water.

PNECsed= 0.050 mg/kg

Using the equilibrium partitioning method (epm) with a Koc of 575000, the highest Koc within those derived (see doc IIA), and an additional Af of 10 necessary due to the strong biding of the active to the sediment particles, no risk is identified for the sediment.

**PNECsed= 0.005 mg/kg**

The result of the microbial activity inhibition test is provided as an EC50. According to the TGD, an assessment factor of 100 is applied to the 163mg/l EC50 to derive the PNEC.

**PNECstp= 1.63mg/L**

Two acute tests on earthworms was provided, which both presented small deficiencies. The study presenting the most conservative value for the earthworms was kept as key study with an LC50 of 100mg/Kg dry soil . A reproduction study with earthworms provided a NOEC of 4.0mg/Kg dry soil based on measured concentration.

The field trial on mineralization of nitrogen in soil performed by Servajean, provided a NOEC of 52.0mg/Kg ww.

Additional studies on plant and non-target arthropods indicated that cypermethrin has minor and transient effect on the evaluated organisms at PPP application rate (250ml/ha) following two sequential applications (14 or 19 days).

According to the TGD, an assessment factor of 50 can be used from the earthworm’s acute test, the chronic earthworms test and microbial inhibition test (two NOEC from two trophic levels). However, the result from the study on plant and the tests on non target arthropod which are non key studies does not normally allowed to further lower the AF. However the results of the tests enhance the confidence on the overall picture of the toxicity of cypermethrin on soil and terrestrial organisms. The resulting Pnec is 0.08 mg/Kg dw (equivalent to 0.07 mg/kg ww) soil from the chronic earthworm NOEC reproduction using and AF of 50.

**PNECsoil = 0.08mg/Kgsoil dw (equivalent to 0.0708 mg/Kg wwt)**

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

The product contains 0.6% of a.s. (cypermethrin, pure a.i.) which is classified for the environmental hazards as Aquatic Acute 1, H400 (M = 100) and Aquatic Chronic 1, H410 (M = 1000). Therefore according to Regulation (EC) n. 1272/2008 (CLP), the product is classified as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410.

***Further Ecotoxicological studies***

No data available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further Ecotoxicological studies |
| Justification | No further information is required.  Data available through letter of access. |

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms |
| Justification | Refer to 2.2.7 paragraph |

***Supervised trials to assess risks to non-target organisms under field conditions***

No data available.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No data available.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No data available.

***Further studies on fate and behaviour in the environment (ADS)***

Data available through letter of access.

***Leaching behaviour (ADS)***

Not applicable.

***Testing for distribution and dissipation in soil (ADS)***

Data available through letter of access.

***Testing for distribution and dissipation in water and sediment (ADS)***

Data available through letter of access.

***Testing for distribution and dissipation in air (ADS)***

Data available through letter of access.

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not applicable.

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

Not applicable.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | **Scenario 1**: non-professional indoor insecticide against crawling insects  **Scenario 2**: professional indoor insecticide against crawling insects  **Scenario 3**: non-professional outdoor around buildings barrier treatment insecticide against ants  **Scenario 4**: non-professional outdoor around houses on paved ways, balconies and terraces treatment insecticide against ants.  **Scenario 5**: non-professional indoor insecticide against bedbugs and fleas  **Scenario 6**: professional indoor insecticide against bedbugs and fleas  **Scenario 7**: professional and non-professional indoor insecticide against wasps  **Scenario 8**: professional and non-professional outdoor insecticide against ground wasps  **Scenario 9**: professional and non-professional indoor insecticide against Poultry red mite. |
| ESD(s) used | Emission Scenario Document for Product Type 18:  OECD SERIES ON EMISSION SCENARIO DOCUMENTS  Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses  OECD SERIES ON EMISSION SCENARIO DOCUMENTS  Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems |
| Approach | All scenarios: Average consumption |
| Distribution in the environment | According to EDSs for PT18 |
| Groundwater simulation | none |
| Confidential Annexes | Not applicable |
| Life cycle steps assessed | Scenarios n:1 to 9  Production: No  Formulation No  Use: Yes  Service life: Yes |
| Remarks | none |

The following table summarizes the relation between the intended uses and the assessed scenarios.

|  |  |
| --- | --- |
| **Scenario** | **Intended uses** |
| Scenarios 1 and 4 | #1 |
| Scenario 2 | #3 |
| Scenario 3 | #2 |
| Scenario 5 | #4 |
| Scenario 6 | #5 |
| Scenarios 7 and 8 | #6 and #7 |
| Scenario 9 | #8 |

***Emission estimation***

**Scenario 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide, acaricides and products to control other arthropods. Indoor, powders/dusting. Non-professional use. Dust/powders – crack and crevices. The product has to be applied in thin layers in cracks and crevices where insects hide (under furniture, corners, etc.) and in void and cavity (between partition walls, holes, etc.). | | | |
| Application rate of biocidal product | 5 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - | Only ready to use packaging are proposed. No operation of loading are expected. |
| Number of emission days | 90 |  | Season treatment |
| Area treated in a standard house | 2 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Cleaning efficiency | 0.25 | - | (Dust/powders – crack and crevice; TAB ENV 149) |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning | - |  |

Calculations for Scenario 1

For calculations of scenario 1 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario for dusting powders indoor, application in crack and crevices, spot treatment (as defined in TABs, ENV 144). Non-professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 2.32E-05 | Local emission to wastewater entering the STP |
| Air | 1.03E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide, acaricides and products to control other arthropods. Indoor, powders/dusting. Professional use. Dust/powders – crack and crevices. | | | |
| Application rate of biocidal product | 5 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - | Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor |
| Number of emission days | 90 |  | Season treatment |
| Area treated in a standard house | 2 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Area treated in a large building | 9.3 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Frequency of application in large buildings | 1-2 times a year |  |  |
| Cleaning efficiency | 0.25 | - | (Dust/powders – crack and crevice; TAB ENV 149) |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning | - |  |

Calculations for Scenario 2

For calculations of scenario 2 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario for dusting powders indoor, application in crack and crevices, spot treatment (as defined in TABs, ENV 144). Professional use.

For the application indoor of voids and cavities under floating floors, no specific scenario was developed as no release into the environment is expected.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 3.13E-05 | Local emission to wastewater entering the STP |
| Air | 1.39E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide contributing to reduce invasion of ants. Outdoor around buildings. Urban and rural areas. Non-professional use. Outdoor around buildings barrier treatment insecticide against ants.  Emission scenario for crawling insects, barrier treatment along the perimeter of houses. 1 cm wide strips. | | | |
| Application rate of biocidal product | 5 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Location of the treated surface | Urban area / rural area |  |  |
| Cover mixing and loading | no | - |  |
| Number of emission days | 90 |  | Season treatment |
| Area treated | Foundations and soil around the building | - |  |
| Area of foundation treated per day | 0 | m2/day | As the product is a powder, the part of foundations treated is not relevant (the powder cannot be applied on vertical surfaces). |
| Area of soil treated per day | 0.5 | m2/day | Barrier treatment; TAB ENV 204: perimeter of 50 m.  Considering that 5 g of product are sufficient to treat 1 m2, the width of the strip of powder can be, i.e. 1 cm (50m\*0.01m). This is consistent with the applicator tools.  The width of the strip is compatible with the dimensions of the proposed applicators |
| Area of untreated zone | 0 | m2/day | The product is has a low dustability and the application method and tools are not compatible with the phenomenon of spray drift which is typical instead of spray products. |
| Frequency of application in standard houses | 1-2 times a year |  |  |

Calculations for Scenario 3

For calculations of scenario 3 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario outdoor for crawling insects. Non-professional use. This scenario was developed for spray products and in this case has been adapted for powder. Therefore, considering that a powder cannot be applied on vertical surfaces, the area of foundation treated was considered negligible and as the product has to be applied in thin layers around buildings and it is to be applied at an application rate of 5 g/m2, this extremely targeted application of a powder was considered inconsistent with the phenomenon of spray drift. Therefore also the area of untreated zone was considered negligible.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 7.99E-05 | Local emission to wastewater entering the STP |
| Air | 0 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

| **Resulting local emission to relevant environmental compartments (rural areas)**  **Direct emission to soil** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 |  |
| Air | 0 |  |
| Soil | 7.99E-05 | (standard houses) |
| Groundwater | 0 |  |

**Scenario 4**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: non-professional outdoor around houses on paved ways, balconies and terraces treatment insecticide against ants. Apply the product in crack and crevices in ant frequented areas.  In case of spot application on paved surfaces around domestic premises the terrace scenario has been selected (no release to sewer/STP is assumed, only releases to soil compartment around a terrace; ENV 159).  Bait boxes scenario in terrace is used.  According to ENV 154, it was agreed to use a default area for the terrace of 30 m2 and assume a receiving area of 8.5 m2 (taking into account three sides of a terrace). In addition, a default value of 4 application sites should be used if no data on the application is provided by the applicant, substantiated with efficacy tests.  This can be considered a worst case, as powder are not expected to spread away from the site of application and the treated zone is covered by roof, which prevents the washout on the surrounding soil.  According to ENV 153, the soil depth is set to 0.5 m.  5g/m2 = 5g/application site. | | | |
| Quantity of commercial product applied/nest | 5 | g |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Fraction emitted to soil during application | 0.9 |  | Worst case (as for powder in outdoor spot application) |
| Number of application sites | 4 | - | The default value for of 4 bait boxes per terrace was considered representative also for this use. |
| Number of applications during a campaign | 1 | - |  |
| Area exposed to the insecticide | 8.5 | m2 | See explanation above. |

Calculations for Scenario 4

For calculations of scenario 4 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: outdoor spot application and according to ENV TABs. Non-professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 |  |
| Air | 0 |  |
| Soil | 1.14E-04 | Kg (direct emission to soil) |
| Groundwater | 0 |  |

**Scenario 5**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide against bedbugs and fleas. Indoor. Non-professional use. Insecticides, acaricides and products to control other arthropods. Indoor, powders/dusting. Dust/powders - voids/cavities (cracks and crevices). | | | |
| Application rate of biocidal product | 10 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - |  |
| Number of emission days | 365 |  |  |
| Area treated in a standard house | 2 | m2 | Based on TAB ENV204, the classical barrier treatment should be calculated as default worst case scenario. However, based on WG-IV-2020 conclusion, a refinement in default treatment areas is applicable, provided information is available to justify doing so.  Since in use-spesific instructions for use, it is detailed that limited areas are treated and this can be justified with efficacy evaluation, a deviation from the default scenario is considered possible.  Thus, the targeted application is considered as a spot treatment. |
| Number of applications per day in a standard house | 1 |  |  |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | TAB ENV 149 |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning of treated surfaces | - |  |

Calculations for Scenario 5

For calculations of scenario 5 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario indoor for dusting powders, spot application (crack and crevice). Non-professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 4.65E-05 | Local emission to wastewater entering the STP |
| Air | 2.06E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 6**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide against bedbugs and fleas. Indoor. Professional use. Insecticides, acaricides and products to control other arthropods. Indoor, powders/dusting. Dust/powders - voids/cavities (cracks and crevices). | | | |
| Application rate of biocidal product | 10 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - | Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor |
| Number of emission days | 365 |  |  |
| Area treated in a standard house | 2 | m2 | Based on TAB ENV204, the classical barrier treatment should be calculated as default worst case scenario. However, based on WG-IV-2020 conclusion, a refinement in default treatment areas is applicable, provided information is available to justify doing so.  Since in use-spesific instructions for use, it is detailed that limited areas are treated and this can be justified with efficacy evaluation, a deviation from the default scenario is considered possible.  Thus, the targeted application is considered as a spot treatment. |
| Area treated in a large building | 9.3 | m2 | TAB ENV 142 |
| Number of applications per day in a standard house | 1 |  |  |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Number of applications per day in a large building | 1 |  |  |
| Frequency of application in large buildings | 1-2 times a year |  |  |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | TAB ENV 149 |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning of treated surfaces | - |  |

Calculations for Scenario 6

For calculations of scenario 6 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario indoor for dusting powders, spot application (crack and crevice). Professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 6.27E-05 | Local emission to wastewater entering the STP |
| Air | 2.78E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 7**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: non-professional and professional indoor insecticide against wasps. The product is applied in non-wet cleaned domestic premises as spot application on the entrance of the nest. | | | |
| Application rate of biocidal product | 2.5 | g/nest |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - | Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor\* |
| Number of emission days | 365 - Private use  300- Industrial use |  |  |
| Area treated in a standard house | 2 | m2 | TAB ENV 142 |
| Area treated in a large building | 9.3 | m2 | TAB ENV 142 |
| Number of applications per day in a standard house | 1 |  |  |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Number of applications per day in a large building | 1 |  |  |
| Frequency of application in large buildings | 1-2 times a year |  |  |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | TAB ENV 149 |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning of treated surfaces | - |  |

\*Since this is a Ready to Use product, emissions from mixing and loading step were not considered for the environmental exposure. The following use-spesific RMM will be included in case the product is loaded to an application tool "Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor".

Calculations for Scenario 7

The environmental exposure of attics and void is negligible (TAB ENV A21), while the spot application can be evaluated with the scenario indoor for dusting powders, spot application (crack and crevice).

For calculations **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario indoor for dusting powders, spot application (crack and crevice).

| **Resulting local emission to relevant environmental compartments (spot application)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 1.16E-05 – Private use | Local emission to wastewater entering the STP |
| 1.57E-05 -Industrial use |
| Air | 5.16E-06 – Private use |  |
| 6.96E-06-Industrial use |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 8**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: non-professional and professional outdoor insecticide against wasps. The product is to be applied directly into the holes of soil, where wasps are going in and out. | | | |
| Quantity of commercial product applied/nest | 2.5 | g |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Type of spot application | powder | - |  |
| Number of application sites | 1 | - | The product is intended to treated just one wasp nest per application |
| Number of applications during a campaign | 1 | - | Usually one application is sufficient to eradicate the ground wasp nest |

Calculations for Scenario 8

As the product is to be applied in spot application in soil and it is not to be applied on hanging nests, the outdoor scenario for spot application has been used as the most representative of the use of the product. Indeed the adaptation of the scenario for the treatment by spray of wasp and hornet’s nest would be representative of a powder applying pressurised dust applicator or powder spray. In this case, instead, the product has to be applied directly into soil nest using the applicator spout.

The application rate will be assessed according to the calculations of the outdoor spot application scenario once the efficacy study will be concluded.

As in this scenario it is assumed the application of 2.5 g/nest directly on the ground, and considering that the model assumes an area exposed to insecticide of 0.25 m2, the risk assessment is supported for an application rate up to 2.5 g/0.25m2 = 0.625 g/m2.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 | Local emission to wastewater entering the STP |
| Air | 0 |  |
| Soil | 0.067 | Direct emission to soil |
| Groundwater | 0 |  |

**Scenario 9**

Insecticide against poultry red mite. Indoor treatment for

* 9A: Laying hens in battery cages without treatment
* 9B: Laying hens in battery cages with forced drying (deep pit, high-rise)
* 9C: Laying hens in compact battery cages
* 9D: Laying hens in free range with grating floor (aviary system)
* 9E: Parent broilers in free range with grating floor
* 9F: Parent broilers in rearing with grating floor

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9A: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Laying hens in battery cages without treatment (7)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1,73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 21000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 3210 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=750m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 1200 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 2810 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0.9 | [5.4] in slurry |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.203 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.183 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0,1193 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.420 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2.3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0.00122 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0.00202 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 9351.3 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 1357.9 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 15483.3 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 2248.26 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9B: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Laying hens in battery cages with forced drying (deep pit, high-rise) (9)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1.73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 21000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 3210 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=750m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 600 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 2810 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0,8 | [5.4] in slurry |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.2029 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.1623 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0.1623 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.3733 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2,3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0,0011 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0,00181 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 8508.2 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 1235.4 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 13873,65 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 2014,53 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9C: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Laying hens in compact battery cages (10)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1,73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 21000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 3210 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=750m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 300 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 2810 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0,9 | [5.4] |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.2029 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.1826 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0.1826 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.4199 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2,3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0,00111 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0,00181 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 8508,15 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 1235,43 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 13873,65 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 2014,53 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9D: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Laying hens in free range with grating floor (aviary system) (13)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1,73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 20000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 3392 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=1270m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 1600 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 4780 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0,9 | [5.4] |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.2144 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.1929 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0.193 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.444 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2,3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0,0011 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0,00171 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 8103 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 1177 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 12483 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 1812,6 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | ~~[5.9]~~ TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9E: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Parent broilers in free range with grating floor (14)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1,73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 7000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 1290 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=750m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 0 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 1458 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0,9 | [5.4] |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.0815 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.0734 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0.0734 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.169 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2,3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | ~~[5.8]~~ (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0,00188 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0,00298 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 4803,4 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 697,48 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 7613,9 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 1105,58 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

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| **Input parameters for calculating the local emission** | | | |
| **Input and unit** | | **Value** | **Remarks** |
| Scenario 9F: Insecticide against poultry red mite. Indoor. Non-professional and professional use. Insecticide against Poultry red mite.  **Parent broilers in rearing with grating floor (15)** | | | |
| Content of active ingredient in formulation (%) | Fbioc% | 0.632 | % w/w (technical) |
| Area to be treated with amount prescribed (m2) for application m | AREAuii1,i2,i3 | 1 | application 10 g/m2 |
| Amount of product prescribed to be used for area specified (g) for application m | Qprod-uinsi1,i2,i3 | 10 | application 10 g/m2 |
| Fresh surface water (-) | DILUTION | 10 |  |
| Soil water partition coefficient (Kpsoil = Koc \* Foc) (l.kg-1) | Kpsoil | 1.15E-+04 | from EUSES |
| Organic carbon-water partition coefficient (-) | Koc | 5,75E+05 | from EUSES |
| Fraction organic carbon in soil (-) | Foc | 0,02 | tab 6.1 |
| Fraction air in soil (-) | Fair | 0,2 | tab 6.1 |
| Fraction water in soil (-) | Fwater | 0,2 | tab 6.1 |
| Fraction solid in soil (-) | Fsolid | 0,6 | tab 6.1 |
| Bulk density of solids (kg.m-3) | RHOsolid | 2500 | tab 6.1 |
| Air-water equilibrium distribution coefficient (m3.m-3) | Kair-water | 6.93E-06 | from EUSES |
| Soil-water equilibrium distribution coefficient (m3.m-3) | Ksoil-water | 1,73E+04 | from EUSES |
| suspended water equilibrium partitioning coefficient (m3.m-3) | Ksusp-water | 1,44E+04 | from EUSES |
| Bulk density of suspended matter (kg.m-3) | RHOsusp | 1150 | from EUSES |
| Number of animals | Ni1 | 9000 | [5.2]/[5.3] |
| Area of the housing for application m (m2) | AREAi1,i2,i3 | 1640 | [5.2]/[5.3] Worst case. Refinement: for the type of application, just floor (=500 m2) |
| Surface area of the manure storage (m2) | AREAmanure i1,i2,i3 | 0 | [5.3]/[A5 ] |
| Volume of the housing (m3) | VOLUME i1,i2,i3 | 1880 | [5.2] |
| Fraction of active ingredient released (-) | Fi1,i2,i3,i4 | 0,9 | [5.4] |
| Qai-prescri1,i2,i3 = 1E-05\*Qprod-uinsi1,i2,i3\*Fbioc% \*AREAi1/AREAuii1 | Qai-prescri1,i2,i3 | 0.1036 |  |
| Qaii1,i2,i3,i4 = Fi1,i2,i3,i4 \* Qai-prescri1,i2,i3 (g/m2) | Qaii1,i2,i3,i4 | 0.0933 |  |
| Qai - grassi1,i2,i3,i4 = Qaii1,i2,i3,i4\*Napp-manuregr (g/m2) | Qai - grassi1,i2,i3,i4 | 0.0933 |  |
| Qai - arabi1,i2,i3,i4= Qaii1,i2,i3,i4\*Napp-manurear (g/m2) | Qai - arabi1,i2,i3,i4 | 0.215 |  |
| Number of repeated treatments prescribed (-) | Napp-prescr  (Napp-bioc) | 4 | (note below tab. 2 of addendum env 89) |
| Maximum number of insecticide applications (-) | Napp-manuresoil | 4 | [5.7] |
| number of biocide applications during storage period for application on grassland (-) | Napp-manuregr | 1 | addendum env 89 |
| number of biocide applications during storage period for application on arable land (-) | Napp-manurear (Napp-biomanure\_ar2) | 2,3 | addendum env 89 |
| manure storage time arable land in new scenario (d) | Tmanure-intar2 | 212 | addendum env 89 |
| Insecticide application interval (d) | Tbioc-int | 91 | [5.7] |
| Number of land applications for grassland (-) | Nlapp-grass | 4 | [5.10] |
| Number of land application for arable land (-) | Nlapp-arab | 1 | [5.10] (also as the addendum) |
| period used for calculation of the amount of manure produced for grassland (d) | Tgr-int | 53 | [5.8] |
| period used for calculation of the amount of manure produced for arable land (d) | Tar-int | 365 | ~~[5.8]~~ (as for the addendum) |
| Amount of phosphate per animal for every relevant category/subcategory i1 (kg.d-1) | Qphosoh | 0,00077 | [5.5] |
| Amount of nitrogen per animal for every relevant category/subcategory i1 (kg.d-1) | Qnitrog | 0,00137 | [5.5] |
| Qphosoh-arab = Ni1\*Qphosoh\*Tar-int | Qphosoh-arab | 2529,45 | (pag. 56 EDS) |
| Qphosoh-grass = Ni1\*Qphosoh\*Tgr-int | Qphosoh-grass | 367,29 | (pag. 56 EDS) |
| Qnitrog-arab = Ni1\*Qnitrog\*Tar-int | Qnitrog-arab | 4500,45 | (pag. 57 EDS) |
| Qnitrog-grass = Ni1\*Qnitrog\*Tgr-int | Qnitrog-grass | 653,49 | (pag. 57 EDS) |
| Phosphate immission standard for one year on arable land (kg.ha-1) | QP2O5,arable\_land | 85 | [5.9] |
| Phosphate immission standard for one year on grassland (kg.ha-1) | QP2O5,grassland | 110 | [5.9] |
| If nitrogen immission standards are applied: |  |  | NB) At least one of the immission standards should be applied; if none is specified the phosphate immission standard is used with the default values in Table 5.9 |
| Nitrogen immission standard for one year on grassland (kg.ha-1) | QN,grassland | 170 | TAB ENV 160 |
| Nitrogen immission standard for one year on arable land (kg.ha-1) | QN,arable\_land | 170 | TAB ENV 160 |
| Mixing depth with soil (m) | DEPTHgrassland | 0,05 | [5.10] |
| Mixing depth with soil (m) | DEPTHarable\_land | 0,2 | [5.10] |
| Density of wet bulk soil (kg.m-3) | RHOsoilwet | 1700 | [5.10] |

Calculations for Scenario 9

The environmental exposure assessment has been undertaken in accordance witt Emission Scenario Document (ESD) Number 14: Emission scenario document for insecticides in stables and manure storage systems (2006), with the addendum OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (August 2020).

Additional calculations were performed according to the Guidance on the BPR, Vol. IV, Part B+C (2017), as well as from output values given by EUSES 2.2.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Concentration of Cypermethrin in soil** | | | | | | | |
|  | **[mg/kgww]** | **Scenario** | | | | | |
| **9A** | **9B** | **9C** | **9D** | **9E** | **9F** |
| **Initial concentration in soil for arable land, 1 manure application** | **PIECarab-Ni1,i2,i3,i4** | 1.36E-03 | 1.35E-03 | 1.51E-03 | 1.78E-03 | 1.11E-03 | 2.38E-03 |
| **PIECarab-P2O5i1,i2,i3,i4** | 1.12E-03 | 1.10E-03 | 1.23E-03 | 1.37E-03 | 8.78E-04 | 2.12E-03 |
| **Initial concentration in soil for grassland, 4 manure applications** | **PIECgrs4-Ni1,i2,i3,i4** | 1.62E-02 | 1.61E-02 | 1.81E-02 | 2.13E-02 | 1.33E-02 | 2.85E-02 |
| **PIECgrs4-P2O5i1,i2,i3,i4** | 1.74E-02 | 1.70E-02 | 1.91E-02 | 2.12E-02 | 1.36E-02 | 3.29E-02 |
| **Initial concentration in soil for grassland – after the last of four manure application and degradation assumed** | **PIECgrs4\_degr-P2O5i1,i2,i3,i4** | 4.93E-03 | 4.82E-03 | 5.42E-03 | 6.01E-03 | 3.86E-03 | 9.32E-03 |
| **PIECgrs4\_degr-Ni1,i2,i3,i4** | 4.60E-03 | 4.57E-03 | 5.14E-03 | 6.03E-03 | 3.76E-03 | 8.09E-03 |
| **Initial concentration in soil for grassland (after the last of four manure applications per year), after 10 years of manure application, taking degradation into account** | **PIECgrs10\_degr- P2O5i1,i2,i3,i4** | 4.93E-03 | 4.82E-03 | 5.42E-03 | 6.01E-03 | 3.86E-03 | 9.32E-03 |
| **PIECgrs10\_degr-Ni1,i2,i3,i4** | 4.60E-03 | 4.57E-03 | 5.14E-03 | 6.03E-03 | 3.76E-03 | 8.09E-03 |
| **Initial concentration in soil for arable land after 10 years of manure application, taking degradation into account** | **PIECarab10\_degr-P2O5i1,i2,i3,i4** | 1.12E-03 | 1.10E-03 | 1.23E-03 | 1.37E-03 | 8.78E-04 | 2.12E-03 |
| **PIECarab10\_degr-Ni1,i2,i3,i4** | 1.36E-03 | 1.35E-03 | 1.51E-03 | 1.78E-03 | 1.11E-03 | 2.38E-03 |

***Fate and distribution in exposed environmental compartments***

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Calculation tool: |  | EUSES 2.2.0 |  |
| Input | Value | Unit | Remarks |
| Molecular weight | 416.3 | [g.mol-1] |  |
| Melting point | 41.2 | °C |  |
| Vapour pressure at 20 [oC] | 2.3E-07 | [Pa] |  |
| Vapour pressure at 25 [oC] | 6E-07 | [Pa] |  |
| Water solubility at 20 [oC] | 4 | [µg.l-1] |  |
| Water solubility at 25 [oC] | 4.2849E-03 | [mg.l-1] |  |
| Log Octanol/water partition coefficient | 5.45 | Log 10 |  |
| Chemical class for Koc-QSAR | Predominantly hydrophobic |  |  |
| Organic carbon/water partition coefficient (Koc) | 5.75E+05 | [l.kg-1] |  |
| Henry's law constant at test temperature (at 20 °C) | 0.024 | [Pa.m3.mol-1] |  |
| Bioconcentration factor for fish | 373.4 | [l.kgwwt-1] |  |
| Biodegradability | Not biodegradable |  |  |
| Rate constant for hydrolysis in surface water | 98.9 | [d] (DT50,12[oC]) |  |
| Rate constant for photolysis in surface water | 0.0469 | [d-1] |  |
| Total rate constant for degradation in bulk soil | 17.2 | [d] (DT50; 12[oC]) |  |

Distribution in STP is foreseen for all scenario with the exception of the outdoor ground wasp nest treatment in which direct emission to soil is foreseen and of the rural hygiene scenario, in which both direct emission to soil (main pathway) and emission in Waste Water Treatment Plant (minor pathway) are foreseen.

The distribution is STP followed the standard inputs as for the OECD Emission Scenario for PT18 and EUSES 2.2, which includes in this latest release SimpleTreat 4.0.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | | | | | | | |
| Compartment | Percentage [%] | | | | | | | | |
| Scenario 1 | Scenario 2 | Scenario 3 | Scenario 4 | Scenario 5 | Scenario 6 | Scenario 7 | Scenario 8 | Scenario 9\* |
| Air | 5.44E-04 | 5.44E-04 | 5.44E-04 | N.A. | 5.44E-04 | 5.44E-04 | 5.44E-04 | N.A. | N.A. |
| Water | 8.356 | 8.356 | 8.356 | N.A. | 8.356 | 8.356 | 8.356 | N.A. | N.A. |
| Primary settler | 66.15 | 66.15 | 66.15 | N.A. | 66.15 | 66.15 | 66.15 | N.A. | N.A. |
| Sludge | 25.5 | 25.5 | 25.5 | N.A. | 25.5 | 25.5 | 25.5 | N.A. | N.A. |
| Degraded in STP | 0 | 0 | 0 | N.A. | 0 | 0 | 0 | N.A. | N.A. |

\*Based on TAB ENV194, emissions to the sewer system should only be considered for poultry stables (animal (sub) categories 8,11, 12, 16-18). Since the product is intended to be used in poultry facilities not connected to STP (animal (sub) categories 7,9,10,13-15), only direct emissions to soil are evaluated.

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | **Identification of relevant receiving compartments based on the exposure pathway** | | | | |
| **Soil** | **Water/**  **sediment** | **STP** | **Ground water** | **Air** |
| Use # 1 – General public- crawling insects, indoor | Yes | Yes | Yes | Yes | Not relevant |
| Use # 2 – General public- ants - around building treatment | Yes | Yes | Yes | Yes | Not relevant |
| Use # 3 – Professional-crawling insects- indoor | Yes | Yes | Yes | Yes | Not relevant |
| Table 4. Use # 4 – General public - bed bugs and fleas- indoor | Yes | Yes | Yes | Yes | Not relevant |
| Use # 5 – Professional- bed bugs and fleas- indoor | Yes | Yes | Yes | Yes | Not relevant |
| Use # 6 – General Public- control of wasp indoor, outdoor | Yes | Yes | No | Yes | Not relevant |
| Use # 7 – Professional- control of wasp | Yes | Yes | Yes | Yes | Not relevant |
| Use # 8 – Rural hygiene (Animal Houses/ Shelters) | Yes | Yes | No | Yes | Not relevant |

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt] | [mg/L] | [mg/m3] |
| Scenario 1(indoor, crack and crevice, spot treatment, non-professional) | 9.71E-07 | 5.21E-08 | 6.51E-04 | 2.23E-05 | 5.22E-10 | 7.08E-10 |
| Scenario 2 (indoor, crack and crevice, spot treatment, professional) | 1.31E-06 | 7.03E-08 | 8.79E-04 | 3.01E-05 | 7.04E-10 | 9.55E-10 |
| Scenario 3 (outdoor around building, contributing to reduce the ant invasion, non-professional; urban areas) | 3.34E-06 | 1.79E-07 | 2.24E-03 | 7.66E-05 | 1.79E-09 | 2.98E-14 |
| Scenario 3 (outdoor around building, contributing to reduce the ant invasion, non-professional; rural areas) | N.A. | N.A. | N.A. | 7.08E-04 | 6.98E-08 | N.A. |
| Scenario 4 (non-professional outdoor around houses on paved ways, balconies and terraces treatment insecticide against ants) | N.A. | N.A. | N.A. | 1.60E-02 | 1.55E-06 | N.A. |
| Scenario 5 (indoor, crack and crevice, spot treatment, bedbugs and fleas, non-professional) | 1.94E-06 | 1.04E-07 | 1.30E-03 | 4.46E-05 | 1.04E-09 | 5.74E-09 |
| Scenario 6 (indoor, crack and crevice, spot treatment, bedbugs and fleas, professional) | 2.62E-06 | 1.41E-07 | 1.76E-03 | 6.02E-05 | 1.41E-09 | 7.74E-09 |
| Scenario 7 (non-professional and professional indoor insecticide against wasps. Worst case) | 4.85E-07  (Private use)  6.55E-07 (Industrial use) | 2.61E-08  (Private use)  3.51E-08 (Industrial use) | 3.26E-04  (Private use)  4.39E-04 (Industrial use) | 1.11E-05  (Private use)  1.5E-05 (Industrial use) | 2.61E-10  (Private use)  3.52E-10 (Industrial use) | 1.44E-09  (Private use)  1.59E-09 (Industrial use) |
| Scenario 8 (non-professional and professional outdoor insecticide against wasps) | n.a. | n.a. | n.a. | 0.067 | 6.59E-06 | n.a. |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
| Scenario 9 | A | B | C | D | E | F |
|  | Laying hens in battery cages without treatment (7) | Laying hens in battery cages with forced drying (deep pit, high-rise) (9) | Laying hens in compact battery cages (10) | Laying hens in free range with grating floor (aviary system) (13) | Parent broilers in free range with grating floor (14) | Parent broilers in rearing with grating floor (15) |
| PIECars-P2O5 (mg/kg) | 1.12E-03 | 1.10E-03 | 1.23E-03 | 1.37E-03 | 8.78E-04 | 2.12E-03 |
| PIECgrs-P2O5 (mg/kg) | 4.93E-03 | 4.82E-03 | 5.42E-03 | 6.01E-03 | 3.86E-03 | 9.32E-03 |
| PIECars-N (mg/kg) | 1.36E-03 | 1.35E-03 | 1.51E-03 | 1.78E-03 | 1.11E-03 | 2.38E-03 |
| PIECgrs-N (mg/kg) | 4.60E-03 | 4.57E-03 | 5.14E-03 | 6.03E-03 | 3.76E-03 | 8.09E-03 |
| PIECgrs-gw-N (mg/L) | 4.52E-07 | 4.49E-07 | 5.05E-07 | 5.93E-07 | 3.70E-07 | 7.95E-07 |
| PIECgrs-water-N (mg/L) | 4.52E-08 | 4.49E-08 | 5.05E-08 | 5.93E-08 | 3.70E-08 | 7.95E-08 |
| PIECgrs-sediment-N (mg/L) | 5.66E-04 | 5.62E-04 | 6.32E-04 | 7.42E-04 | 4.63E-04 | 9.96E-04 |
| PIECars-gw-N (mg/L) | 1.33E-07 | 1.32E-07 | 1.49E-07 | 1.75E-07 | 1.09E-07 | 2.34E-07 |
| PIECars-water-N (mg/L) | 1.33E-08 | 1.32E-08 | 1.49E-08 | 1.75E-08 | 1.09E-08 | 2.34E-08 |
| PIECars-sediment-N (mg/L) | 1.67E-04 | 1.66E-04 | 1.86E-04 | 2.19E-04 | 1.36E-04 | 2.93E-04 |
| PIECgrs-gw-P2O5 (mg/L) | 4.85E-07 | 4.74E-07 | 5.33E-07 | 5.91E-07 | 3.79E-07 | 9.15E-07 |
| PIECgrs-water-P2O5 (mg/L) | 4.85E-08 | 4.74E-08 | 5.33E-08 | 5.91E-08 | 3.79E-08 | 9.15E-08 |
| PIECgrs-sediment-P2O5 (mg/L) | 6.07E-04 | 5.93E-04 | 6.67E-04 | 7.40E-04 | 4.75E-04 | 1.15E-03 |
| PIECars-gw-P2O5 (mg/L) | 1.10E-07 | 1.08E-07 | 1.21E-07 | 1.35E-07 | 8.63E-08 | 2.08E-07 |
| PIECars-water-P2O5 (mg/L) | 1.10E-08 | 1.08E-08 | 1.21E-08 | 1.35E-08 | 8.63E-09 | 2.08E-08 |
| PIECars-sediment-P2O5 (mg/L) | 1.38E-04 | 1.35E-04 | 1.52E-04 | 1.68E-04 | 1.08E-04 | 2.61E-04 |
| Amount reaching STP (mg/L) | 0  No release in STP | 0  No release in STP | 0  No release in STP | 0  No release in STP | 0  No release in STP | 0  No release in STP |

***Primary and secondary poisoning***

Regarding the bioaccumulation by terrestrial organisms, Cypermethrin has a high Koc value which ranges from 80653 to 574360, which indicate that the active would adhere to soil/sediment making it very difficult for organisms to uptake and accumulate it. Conversely, the active may also absorbe to biological surface such as skin which may lead to toxic effects in higher organisms after biomagnification.

Primary poisoning

According to the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional use, it is not believed that insecticide powders are in a form that could be sufficiently appetent to birds or mammals so they would be at risk. Indeed this dustable products is not in granular form and it is not applied together with food attractant.

The product is instead formulated with a bittering agent and, in addition, label states that it should not be applied in areas where pets or other animals can access.

Therefore there is no concern for primary poisoning.

Secondary poisoning

Secondary poisoning is concerned with toxic effects in the higher members of the food chain, either living in the aquatic or terrestrial environment, which result from ingestion of organisms from lower trophic levels that contain accumulated substances.

Since the PECwater and the PECporewater are not negligible, and as cypermethrin tends to bioaccumulate in water organisms (although it has nor B neither vB properties) and as the substance has the potential to cause toxic effects (it is classified as STOT RE 2, H273 for neurotoxicity and liver toxicity), secondary exposure assessment has been carried out according to Guidance on BPR: Vol IV Environment Parts B+C (Version 2.0 October 2017).

Outdoor scenarios (i.e. non-professional outdoor application and professional outdoor wasp nest application) and rural hygiene scenatio were considered for secondary poisoning for fish-eating predators (scenarios 3 and 9 while no emission in water is expected for scenario 4 and 8) and for earthworm-eating predators (scenarios 3, 4, 8 and 9).

Regarding scenario 9, the worst case PECs are achieved in Scenario 9F.

The following calculations and inputs where used.

*PECoral, fish-eating predator=PECwater x BCFfish x BMF*

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter (unit)** | **Symbol** | **Unit** | **Value** | **Source** |
| Predicted Environmental Concentration in fish-eating predators | *PECoral, fish-eating predator* | [mg.kgwet fish-1] | X | Output |
| Predicted Environmental Concentration in water Scenario 3 | *PECwater* | [mg.L-1] | 1.79E-071 | Input |
| Predicted Environmental Concentration in water Scenario 9F | *PECwater* | [mg.L-1] | 7.95E-081 | Input |
| Bioconcentration Factor for fish on wet weight basis | *BCFfish* | [L.kgwet fish-1] | 4172 | Input |
| Biomagnification factor in fish | *BMF* | [-] | 10 3 | Default |

1 PECwater 1.79E-07 mg.L-1 for Scenario 3 (urban areas). In Scenario 4 and 8 no emission to water is expected. PECwater 7.95E-08 mg.L-1 for Scenario 9F (worst case PEC).

2 According to cypermethrin AR.

3 According to cypermethrin AR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

*PECoral, earthworm-eating predator=*

*Cearthworm = (BCFearthworm x Cporewater + Csoil x Fgut x CONVsoil) / (1 + Fgut x CONVsoil)*

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter (unit)** | **Symbol** | **Unit** | **Value** | **Source** |
| Predicted Environmental Concentration in earthworm-eating predators | *PECoral, earthworm-eating predator* | [mg.kgwet earthworm-1] | X | Output |
| Concentration in earthworm on wet weight basis | *Cearthworm* | [mg.kgwet earthworm-1] | X | Output |
| Bioconcentration Factor for earthworms on wet weight basis | *BCFearthworm* | [mg.kgwet earthworm-1] | 3382.9 1 | Input |
| Concentration in porewater scenario 3 | *Cporewater* | [mg.L-1] | 6.98E-08 2 | Input |
| Concentration in porewater scenario 4 | *Cporewater* | [mg.L-1] | 1.55E-062 | Input |
| Concentration in porewater scenario 8 | *Cporewater* | [mg.L-1] | 6.59E-06 2 | Input |
| Concentration in porewater scenario 9F | *Cporewater* | [mg.L-1] | 7.95E-072 | Input |
| Concentration in soil scenario 3 | *Csoil* | [mg.kg wwt-1] | 7.08E-04 3 | Input |
| Concentration in soil scenario 4 | *Csoil* | [mg.kg wwt-1] | 1.60E-023 | Input |
| Concentration in soil scenario 8 | *Csoil* | [mg.kg wwt-1] | 6.70E-02 3 | Input |
| Concentration in soil scenario 9F | *Csoil* | [mg.kg wwt-1] | 8.09E-033 | Input |
| Fraction of gut loading in worm | *Fgut* | [kgdwt.kgwwt-1] | 0.14 | Default |
| Conversion factor for soil concentration wet-dry weight soil | *CONVsoil* | [kgwwt.kgdwt-1] | 1.134 | Default |

1 Calculated according to ECHA Guidance on the BPR (October 2017) equation 104d.

2 To consider the worst case, for Scenarios 3, application in rural areas was considered for calculations. Therefore, considering that Scenario 3 for rural areas, and Scenario 4, 8 and 9F (worst case PECs) have a direct release to soil, PECgw was used instead of PECporewater.

3 To consider the worst case, for Scenarios 3, application in rural areas was considered for calculations. Therefore, considering that Scenario 3 for rural areas, and Scenario 4, 8 and 9F (worst case PECs) give a direct release to soil, the direct release to soil concentration is used. This can be considered a worst case with respect to 180 days TWA PECsoil.

4 Default values were obtained from ECHA Guidance on the BPR (October 2017)

Based on the above the Predicted Environmental Concentration in fish-eating and earthworm-eating predators are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition values (ETE) via food chain** | | |
| **Scenario** | ***PECoral, fish-eating predator*** | ***PECoral, earthworm-eating predator*** |
| 3 | 7.46E-04 | 3.08E-04 |
| 4 | Not applicable | 6.87E-03 |
| 8 | Not applicable | 2.91E-02 |
| 9F | 3.32E-04 | 3.51E-03 |

#### Risk characterisation

***Atmosphere***

Conclusion: Direct emission in atmosphere is considered not relevant using the product.

No risk for the atmosphere was foreseen.

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 5.96E-07 |
| Scenario 2 | 8.04E-07 |
| Scenario 3  (urban areas) | 2.05E-06 |
| Scenario 4 | n.a. |
| Scenario 5 | 1.19E-06 |
| Scenario 6 | 1.61E-06 |
| Scenario 7 | 2.98E-07 (Private use)  4.02E-07 (Industrial use) |
| Scenario 8 | n.a. |
| Scenario 9A | No release in STP |
| Scenario 9B | No release in STP |
| Scenario 9C | No release in STP |
| Scenario 9D | No release in STP |
| Scenario 9E | No release in STP |
| Scenario 9F | No release in STP |

Conclusion: According to the obtained PEC/PNEC ratios, the use of DURACID is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between the predicted environmental concentration and the predicted no-effect concentration is below 1 for all scenarios.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater [mg/L]** | **PEC/PNECsed [mg/kgwwt]** |
| Scenario 1 | 1.30E-02 | 1.30E-01 |
| Scenario 2 | 1.76E-02 | 1.76E-01 |
| Scenario 3  (urban areas) | 4.48E-02 | 4.48E-01 |
| Scenario 4 | n.a. | n.a. |
| Scenario 5 | 2.60E-02 | 2.60E-01 |
| Scenario 6 | 3.53E-02 | 3.52E-01 |
| Scenario 7 | 6.53E-03 (Private use)  8.78E-03 (Industrial use) | 6.52E-02 (Private use)  8.78E-02 (Industrial use) |
| Scenario 8 | n.a. | n.a. |
| Scenario 9A |  |  |
| grs-N\* | 1.13E-02 | 1.13E-01 |
| ars-N\* | 3.33E-03 | 3.34E-02 |
| Scenario 9B |  |  |
| grs-N\* | 1.12E-02 | 1.12E-01 |
| ars-N\* | 3.30E-03 | 3.32E-02 |
| Scenario 9C |  |  |
| grs-N\* | 1.26E-02 | 1.26E-01 |
| ars-N\* | 3.73E-03 | 3.72E-02 |
| Scenario 9D |  |  |
| grs-N\* | 1.48E-02 | 1.48E-01 |
| ars-N\* | 4.38E-03 | 4.38E-02 |
| Scenario 9E |  |  |
| grs-N\* | 9.25E-03 | 9.26E-02 |
| ars-N\* | 2.73E-03 | 2.72E-02 |
| Scenario 9F |  |  |
| grs-N\* | 1.99E-02 | 1.99E-01 |
| ars-N\* | 5.85E-03 | 5.86E-02 |

(\*)

* grs-water-N: ratio based on concentration in grassland surface water/groundwater if nitrogen immission standard is applicable
* ars-water-N: ratio based on concentration in arable land surface water/groundwater if nitrogen immission standard is applicable

Conclusion: According to the OECD 14 (2006) (ENV/JM/MONO(2006)4), «the amount of biocide present in the manure is related to the nitrogen content and the nitrogen load, which is allowed according to the immission standard».

According to the obtained PEC/PNEC ratios, the use of DURACID is safe for the aquatic and sediment drewlling organisms since the ratio between the predicted environmental concentration and the predicted no-effect concentration is below 1 for all scenarios.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 | 3.15E-04 |
| Scenario 2 | 4.25E-04 |
| Scenario 3  (urban areas) | 1.08E-03 |
| Scenario 3  (rural areas) | 1.00E-02 |
| Scenario 4 | 2.26E-01 |
| Scenario 5 | 6.30E-04 |
| Scenario 6 | 8.50E-04 |
| Scenario 7 | 1.57E-04 (Private use)  2.12E-04 (Industrial use) |
| Scenario 8 | 9.46E-01 |
| Scenario 9A |  |
| ars-N\* | 1.92E-02 |
| grs-N\* | 6.50E-02 |
| Scenario 9B |  |
| ars-N\* | 1.91E-02 |
| grs-N\* | 6.45E-02 |
| Scenario 9C |  |
| ars-N\* | 2.13E-02 |
| grs-N\* | 7.26E-02 |
| Scenario 9D |  |
| ars-N\* | 2.51E-02 |
| grs-N\* | 8.52E-02 |
| Scenario 9E |  |
| ars-N\* | 1.57E-02 |
| grs-N\* | 5.31E-02 |
| Scenario 9F |  |
| ars-N\* | 3.36E-02 |
| grs-N\* | 1.14E-01 |

Conclusion: According to the OECD 14 (2006) (ENV/JM/MONO(2006)4), «the amount of biocide present in the manure is related to the nitrogen content and the nitrogen load, which is allowed according to the immission standard».

From the data presented above, the use of DURACID poses an unacceptable risk to the terrestrial environment since the PEC/PNEC ratios are below 1.

***Groundwater***

|  |  |
| --- | --- |
| **Summary table on calculated PEC values** | |
|  | **PECgw**  **(mg/L)** |
| Scenario 1 | 5.22E-10 |
| Scenario 2 | 7.04E-10 |
| Scenario 3  (urban areas) | 1.79E-09 |
| Scenario 3  (rural areas) | 6.98E-08 |
| Scenario 4 | 1.55E-06 |
| Scenario 5 | 1.04E-09 |
| Scenario 6 | 1.41E-09 |
| Scenario 7 | 2.61E-10  (Private use)  3.52E-10 (Industrial use) |
| Scenario 8 | 6.59E-06 |
| Scenario 9A |  |
| grs-N\* | 4.52E-07 |
| ars-N\* | 1.33E-07 |
| grs-P2O5\* | 4.85E-07 |
| ars-P2O5\* | 1.10E-07 |
| Scenario 9B |  |
| grs-N\* | 4.49E-07 |
| ars-N\* | 1.32E-07 |
| grs-P2O5\* | 4.74E-07 |
| ars-P2O5\* | 1.08E-07 |
| Scenario 9C |  |
| grs-N\* | 5.05E-07 |
| ars-N\* | 1.49E-07 |
| grs-P2O5\* | 5.33E-07 |
| ars-P2O5\* | 1.21E-07 |
| Scenario 9D |  |
| grs-N\* | 5.93E-07 |
| ars-N\* | 1.75E-07 |
| grs-P2O5\* | 5.91E-07 |
| ars-P2O5\* | 1.35E-07 |
| Scenario 9E |  |
| grs-N\* | 3.70E-07 |
| ars-N\* | 1.09E-07 |
| grs-P2O5\* | 3.79E-07 |
| ars-P2O5\* | 8.63E-08 |
| Scenario 9F |  |
| grs-N\* | 7.95E-07 |
| ars-N\* | 2.34E-07 |
| grs-P2O5\* | 9.15E-07 |
| ars-P2O5\* | 2.08E-07 |

Conclusion: based on the comparison between exposure and the generic limit value of 1,0E-04 mg/L for groundwater, no risk for groundwater compartment is expected.

***Primary and secondary poisoning***

Primary poisoning

According to the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional use, it is not believed that insecticide powders are in a form that could be sufficiently appetent to birds or mammals so they would be at risk. Indeed this dustable products is not in granular form and it is not applied together with food attractant.

The product is instead formulated with a bittering agent and, in addition, label states that it should not be applied in areas where pets or other animals can access.

Therefore there is no concern for primary poisoning.

Secondary poisoning

Secondary poisoning occurs when non-target vertebrates eat ants which were poisoned by the product. According to the risk management measures to be undertaken stated in the label (i.e. “Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock “ and “Remove (clean) product and dead insects, when the presence of live insects is stopped”), secondary poisoning is not expected to occur.

However, the following risk characterization of secondary poisoning was performed as a worst case.

Since the PECwater and the PECporewater are not negligible, secondary poisoning should be performed.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning via the aquatic food chain** | | | | | | |
| **Scenario** | ***PECoral, fish-eating predator*** | **PNECbirds1** | **PNECmammals 2** | **PEC/ PNECbirds** | **PEC/ PNECmammals** |  |
| 3 | 7.46E-04 | 33.3 mg/kg/d | 3.3 mg/kg/d | 2.24E-05 | 2.26E-04 |  |
| 4 | Not applicable | 33.3 mg/kg/d | 3.3 mg/kg/d | Not applicable | Not applicable |  |
| 8 | Not applicable | 33.3 mg/kg/d | 3.3 mg/kg/d | Not applicable | Not applicable |  |
| 9F | 3.32E-04 | 33.3 mg/kg/d | 3.3 mg/kg/d | 9.96E-06 | 1.00E-04 |  |
| **Summary table on secondary poisoning via the terrestrial food chain** | | | | | | |
| **Scenario** | ***PECoral, earthworm-eating predator*** | **PNECbirds1** | **PNECmammals 2** | **PEC/ PNECbirds** | **PEC/ PNECmammals** |  |
| 3 | 3.08E-04 | 33.3 mg/kg/d | 3.3 mg/kg/d | 9.25E-06 | 9.33E-05 |  |
| 4 | 6.87E-03 | 33.3 mg/kg/d | 3.3 mg/kg/d | 2.06E-04 | 2.08E-03 |  |
| 8 | 2.91E-02 | 33.3 mg/kg/d | 3.3 mg/kg/d | 8.74E-04 | 8.82E-03 |  |
| 9F | 3.51E-03 | 33.3 mg/kg/d | 3.3 mg/kg/d | 1.05E-04 | 1.06E-03 |  |

1 PNECbird is 33.3 mg/kg food based on 21d NOEC dietary toxicity study on birds, as reported on the AR of cypermethrin.

2 PNECmammal is 3.3 mg/kg food based 2-year oral toxicity study on rats, as reported on the AR of cypermethrin.

Conclusion: The PEC/PNEC ratio is lower than 1 for all uses/scenarios combination, indicating acceptable risk of secondary poisoning trough the aquatic and the terrestrial food-chain.

***Mixture toxicity***

Please, refer to the Exposure assessment and Risk characterisation sections. The product is classified for environmental hazards according to the rules laid down by Regulation 1272/2008 as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410.

The substance leading to the classification of the mixture is the active substance, which is classified as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410 (Macute = 100; Mchronic = 1000). Just one of the co-formulants is classified for environmental hazards: it is classified as Aquatic Chronic 3, H412 and its concentration is well below the concentration limits set out in annex I or Regulation (EC) n. 1272/2008 (CLP) to classify the mixture Please refer to composition in the confidential annex.

***Aggregated exposure (combined for relevant emission sources)***

The overall exposure to humans and the environment, to the A.S. is not due to different products belonging to the same PT or different PTs. Therefore it was not investigated.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| **Atmosphere**  Emissions in air are considered as negligible. It can be concluded that the use of this product will not pose a significant risk to the atmospheric compartment.  **STP compartment**  There is no concern for microorganisms involved in biodegradation processes in the STP when following the label instructions of DURACID PW.  **Aquatic compartment**  There is no concern for aquatic organisms when following the label instructions of DURACID PW.  **Terrestrial compartment**  The risk characterization for terrestrial compartment is carried out. After the indended use scenario the PEC/PNEC ratio are below 1, indicating a safe use when following the label instructions of DURACID PW.  **Groundwater**  The predicted groundwater concentrations, for all assessed scenarios for both active substances are < 0.1 μg/L (or 1E-04 mg/L), the maximum permissible concentration by directive 2006/18/EC. Therefore the risk to the groundwater environment for the use of Cypermethrin in the product is acceptable.  **Primary and secondary poisoning compartment**  The risk characterization for primary and secordary poisoing compartment is carried out. After the indended use scenario the PEC/PNEC ratio are below 1, indicating a safe use when following the label instructions of DURACID PW.  **Animal housing**  An acceptable risk for DURACID PW to be used in animal housing in arable lands and grasslands, for non-target organisms, is demonstrated provided that label instructions are followed. |

### Measures to protect man, animals and the environment

General directions for use

#### Risk mitigation measures

Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.

The application is allowed only in areas that are not regularly wet-cleaned

Do not apply near bodies of surface water or in the area of water protection zones.

For use only in areas that are inaccessible to infants, children, companion animals and farm animals.

For further details please see Authorized uses

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

If medical advice is needed, have product container or label at hand.

The product contains: cypermethrin. May cause paraesthesia.

IF EXPOSED: Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes.  
  
2.1.9.3 Instructions for safe disposal of the product and its packaging

Dispose of waste and residues in accordance with local authority requirements.

Do not allow runoff to sewer, waterway or ground.

For further details please see Authorized uses

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

Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, food or feed. The product is stable for 2 years at ambient temperature.

### Assessment of a combination of biocidal products

The product is not intended to be authorised for the use with other biocidal products.

### Comparative assessment

Not applicable.

# ANNEXES[[4]](#footnote-4)

## List of studies for the biocidal product

| **Author(s)** | **Year** | **Title** | **Reference** | **Testing Company** | **Report No.** | **GLP Study (Yes/No)** | **Data Protection Claimed (Yes/No)** | **Data Owner** | **Section No. in IUCLID** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Simona Nichetti | 2020 | **Duracid PW:**  **Determination of the Physico-chemical Properties** | CH – 0181/2020 | ChemService Srl | CH – 0181/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3 and 4 |
| Simona Nichetti | 2020 | **Duracid PW:**  **Validation of the Analytical Method for the**  **Determination of the Active Ingredient Content** | Simona Nichetti, 2020b | ChemService Srl | CH – 0182/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 5 |
| Simona Nichetti | 2020 | **Duracid PW:**  **Determination of the Accelerated Storage Stability**  **and Corrosion Characteristics** | CH – 0183/2020 | ChemService Srl | Study Plan CH –  183/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3 |
| Simona Nichetti | 2020 | **Duracid PW:**  **Three Years Storage Stability and Corrosion Characteristics** | CH – 0184/2020 | ChemService Srl | Study Plan CH –  184/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3 |
| Simona Nichetti | 2021 | **Duracid PW:**  **Determination of the Accelerated Storage Stability**  **(Particle Size Analysis by Laser Diffraction)** | CH – 0190/2021 | ChemService Srl | CH – 0190/2021 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3.4.1 |
| Simona Nichetti | 2020 | **Duracid PW:**  **Determination of the Oxidizing Properties**  **And Explosive Properties** | CH – 0185/2020 | ChemService Srl | CH – 0185/2020 | No | Yes | Vebi Istituto Biochimico S.r.l. | 4 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF**  **“DURACID PW”**  **AGAINST Blattella germanica**  **(FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)** | Andrea Drago, 2020a | Entostudio Srl | VEBDUP04121 9 - 1 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EVALUATION OF**  **“DURACID PW”**  **AGAINST Lasius niger**  **(FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)** | Andrea Drago, 2020b | Entostudio Srl | VE BDUP0412 19 - 3 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF**  **“DURACID PW”**  **AGAINST Blatta orientalis**  **(FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)** | Andrea Drago, 2020c | Entostudio Srl | VEBDUP04121 9 - 1 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Blattella germanica CRACKS AND CREVICES TREATMENT - FIELD TEST** | Andrea Drago, 2020d | Entostudio Srl | VE BDUP0412 19 - 6 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF**  **“DURACID PW”**  **AGAINST Blatta orientalis**  **CRACKS AND CREVICES TREATMENT - FIELD TEST** | Andrea Drago, 2020d | Entostudio Srl | VE BDUP0412 19 - 5 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Ctenocephalides felis CRACKS AND CREVICES TREATMENT - FIELD TEST** | Andrea Drago, 2020f | Entostudio Srl | P010-20- 2 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Cimex lectularius CRACKS AND CREVICES TREATMENT - FIELD TEST** | Andrea Drago, 2020g | Entostudio Srl | P010-20- 1 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Dermanyssus gallinae** | Andrea Drago, 2020h | Entostudio Srl | P010-20- 4 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Vespula germanica NESTS** | Andrea Drago, 2020i | Entostudio Srl | P010-20- 3 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Lasius niger CRACKS AND CREVICES INDOOR TREATMENT - FIELD TEST** | Andrea Drago, 2020l | Entostudio Srl | P068-19-01 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Andrea Drago | 2020 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Cimex lectularius (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)** | Andrea Drago, 2020m | Entostudio Srl | VEBDUP04121 9 - 4 | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Simone Martini | 2021 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Ctenocephalides felis (FORCED CONTACT TEST ON POROUS AND NON-POROUS SURFACE)** | Martini2021a | Entostudio Srl | P052-20-01 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Simone Martini | 2021 | **EFFICACY EVALUATION OF “DURACID PW” AGAINST Dermanyssus gallinae (FORCED CONTACT TEST)** | Martini2021b | Entostudio Srl | P052-20-02 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Ivo Rovetto | 2021 | **Simulated-use study to determine the insecticidal and barrier effect of DURACID PW applied against black ants (Lasius niger) – Italy 2021** | Rovetto2021a | SAGEA Centro di Saggio s.r.l. | 2025.BCD.SAG21 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Ivo Rovetto | 2021 | **Field trial to determine the insecticidal effectiveness of DURACID PW applied**  **against Vespula germanica – Italy 2021**  **(Field trial)** | Rovetto2021b | SAGEA Centro di Saggio s.r.l. | 2032.BCD.SAG21 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Ivo Rovetto | 2021 | **Simulated-use study to determine the efficacy of DURACID PW applied as**  **crack and crevice treatment against black ants (Lasius niger) – Italy 2021** | Rovetto2021c | SAGEA Centro di Saggio s.r.l. | 2033.BCD.SAG21 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |
| Ivo Rovetto | 2022 | **Simulated-use study to determine the efficacy of DURACID PW applied as crack and crevice treatment against oriental cockroaches (Blatta orientalis) – Italy 2021** | Rovetto2022a | SAGEA Centro di Saggio s.r.l. | 2034.BCD.SAG21 | no | yes | Vebi Istituto Biochimico S.r.l. | 6.7, 6.1 |

## Output tables from exposure assessment tools

Calculations of human health exposure assessment for the biocidal product Duracid are included in the embedded word file.



For the environmental exposure assessment, EUSES outputs are attached in the following document:



## New information on the active substance

N.A.

## Residue behaviour

N.A.

## Summaries of the efficacy studies (B.5.10.1-xx)[[5]](#footnote-5)

Refer to the IUCLID dossier.

## Confidential annex

Please refer to separate file.

## Other

N.A.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-3)
4. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-4)
5. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-5)