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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Draker One

Product type(s) PT 18

(RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin) as included in the Union list of approved active substances]

Case Number in R4BP: [BC-EA059420-67]

Evaluating Competent Authority: Greece

Date: [August 2022]

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# CONCLUSION

**Conclusion for Physico-chemistry**

Draker one is a microencapsulated (CS) insecticide (PT 18) product, containing 10% w/w Cypermethrin (as pure active substance), corresponding to 10.53 % w/w (as technical grade active substance; min. purity: 95%).

Its physicochemical properties are considered acceptable for microencapsulated (CS) product. The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable. From the experimental data obtained according to UN Corrosion to Metals Test, it can be concluded that Draker one is classified as corrosive to metals, H290.

Acceptable data from accelerated and two years shelf life storage stability studies stored in right doses bottles in polyethylene indicate that the product is anticipated to be stable for up to two years at ambient temperature when stored in the proposed commercial packaging. Moreover after 8 weeks of storage at 40°C vials in PET/PE did not present any deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena. The test item formulation sample, at the end of the storage period 7 days at 0 ± 2°C and after 24 hours of thermal equilibrium at 23 ± 2°C and a single inversion, did not show separation of solid or liquid material, nor changes in its physical state.

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

**Conclusion for Human Health**

Regarding human health hazards, the biocidal product Draker One should be classified as STOT-RE Category 2; H373 (nervous system), due to the classification of the active substance cypermethrin and its concentration in the biocidal product.

Regarding risk assessment, the primary exposure of both professional and non-professional users does not entail unacceptable risks for human health, provided that professional users wear protective gloves and impermeable coveralls and the product is used according to the instructions of use.

However, regarding secondary excposure, a risk has been identified for infants and toddlers and therefore a specific risk mitigation measure is proposed to be included in the product label. Hence, no concern arises for these populations groups.

**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 for all Uses, when following the label instructions of DRAKER ONE.

**Conclusion for Efficacy:**

Several efficacy studies (laboratory and field studies) were submitted by the applicant to support the intended uses of Draker One (containing cypermethrin 10% w/w) against the claimed target organisms.

Based on the results of the submitted efficacy studies, the product was effective when applied, as:

* Crack and crevice treatment by professionals and non-professionals, indoors for the control of German cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*) and Black garden ant workers (*Lasius niger*) at 40 to 75 ml of a 2% insecticide solution/m2 (for cockroaches) and 40 to 100 ml of 1% insecticide solution/m2 (for ants). Higher doses are intended for porous surfaces and lower doses for non-porous surfaces.The product has a residual period of 2 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches and ant workers is expected within 30 minutes after exposure of insects to the treated surfaces”.
* Surface outdoor treatment around buildings against tiger (*Aedes albopictus*) and house (*Culex pipiens*) mosquitoes at 40 ml of a 0.5% insecticide solution/m2. The product provides sufficient control of mosquitos when appled at a distance up to 1.1 m from the treated surfaces. The product has no residual action against mosquitoes.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| Draker One | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Vebi Istituto Biochimico S.r.l. |
| **Address** | via Desman, 43. 35010 – Borgoricco, Italy |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Vebi Istituto Biochimico S.r.l. |
| **Address of manufacturer** | via Desman, 43. 35010 – Borgoricco, Italy |
| **Location of manufacturing sites** | via Desman, 43. 35010 – Borgoricco, Italy |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin technical cis:trans 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 Ltd.  Name of substance supplier according art 95: Limaru (acting for Tagros). |
| **Address of manufacturer** | Jhaver Centre, Rajah Annamalai Building,  IV Floor, 72, Marshalls Road,  600 008 Egmore, Chennai, India |
| **Location of manufacturing sites** | 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 is provided in the confidential annex.

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

Yes 🞎

No 🗹

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **Common name** | Cypermethrin Technical 40/60 |
| **Chemical name** | cypermethrin cis:trans 40:60; (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate |
| **C.A. name** | Cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-  dimethylcyclopropane carboxylate |
| **IUPAC name** | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate  (4 isomer pairs: cis-1, cis-2, trans-3, trans-4) |
| **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 prurity of the source (based on the technical equivalence of) used for the preparation of Draker One formulation:95% w/w  Cypermethrin isomer ratio 40% ≤ cis isomers ≤ 60%  Minimum purity according to Commission Implementing Regulation (EU) 2018/1130: 92% w/w |
| **Structural formula** |  |
| **Molecural formula** | C22H19Cl2NO3 |
| **Molecular weight** | 416.3 g/mol |

#### Candidate(s) for substitution

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. 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”1 and in line with “Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR”2 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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **"Minimun pure" AS content (%)** | **Minimum purity in the source of the AS (%)** | **Content of the AS used for the formulation of the BP (%)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Cypermethrin  cis/trans +/- 40/60  (min. purity 95% w/w) | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 10.0 | 95.0 | 10.0 (pure)  10.53 (technical) |
| Non-active substance | Confidential information. Please refer to the confidential information annex | | | | | | Up to 100 |

Complete composition of the product is reported in confidential annex.

#### Information on technical equivalence

The supplier of the active substance (i.e. cypermethrin) used in the formulation of the biocidal product Draker One has been considered equivalent pursuant to Article 54 of Regulation (EU) no. 528/2012 to the reference source evaluated for approval and it is present in the Article 95 list of and meets all the requirements for the technical equivalence

The source of the active substance cypermethrin in Draker One 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.

Data on the active substance are available through Letter of access (IUCLID, section 13). Data on the product are available in theIUCLID dossier

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

The product does not contain substances of concern.

#### Type of formulation

|  |
| --- |
| CS Microincapsulated |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Corrosive to metals 1 H290  STOT RE 2 H373 (nervous system)  Aquatic Acute 1 H400  Aquatic Chronic 1 H410 |
| Hazard statement | H290: May be corrosive to metals  H373: May cause damage to nervous system through prolonged or repeated exposure.  H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
| **Labelling** | |
| Hazard Pictograms | GHS08 GHS09 |
| Signal words | Warning |
| Hazard statements | H290: May be corrosive to metals  H373: May cause damage to nervous system through prolonged or repeated exposure.  H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.  P102 Keep out of reach of children.  P103 Read carefully and follow all instructions.  P234 Keep only in original packaging  P260 Do not breathe spray.  P273 Avoid release to the environment.  P314 Get medical advice/attention if you feel unwell.  P390 Absorb spillage to prevent material damage.  P501 Dispose of contents and container in accordance with applicable regulations. |
| Contains  cypermethrin cis/trans +/-40/60; (RS)-alfa-cyano-3-phenoxybenzyl (1RS,3RS; 1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | |
| Note | - |

### Authorised use(s)

#### Use 1 - Crack and crevice treatment, indoor – professional

Table 1. Use # 1 – Crack and crevice treatment, indoor - professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for crack & crevice applications to control infestations of crawling insects |
| **Target organism (including development stage)** | *Blattella germanica* (German Cockroach)  *Lasius niger* (Black garden ant)  *Periplaneta Americana* (American Cockroach) |
| **Field of use** | Indoor areas where wet cleaning is not feasible. Areas under non removable furniture or heating appliances, rooms with electrical appliances, closed bath tubes, areas below kitchen furniture which are closed, basements, crawling spaces, boiler rooms. |
| **Application method(s)** | Crack and crevice treatment by spraying. |
| **Application rate(s) and frequency** | Commercial product has to be diluted in water before use.  It should be applied using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of Draker One is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before reuse. Draker One should be applied throughout the infested area in cracks, crevices and any place where insects may hide and over which they may crawl or settle.  Cockroaches: 40 to 75 ml of a 2% insecticide solution/m2  (Application rate in terms of active substance is 87-163 mg t.g.a.i./m2)  Ants: 40 to 100 ml of 1% insecticide solution/m2.  (Application rate in terms of active substance is 43-109 mg t.g.a.i./m2)  Higher use rate is intended for treatments on porous surfaces and lower for non-porous surfaces.  Product’s efficacy lasts for 2 weeks.  Frequency of application: 1-2 times a year. |
| **Category(ies) of users** | Trained Professional  Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Apply into cracks and crevices, in non wet cleaned areas where insects are used to hide or rest, i.e. under non removable furniture or heating appliances, rooms with electrical appliances, closed bath tubes, areas below kitchen furniture which are closed, basements, crawling spaces, boiler rooms, cellars, attics.  Applications in the appropriate way maintain product’s efficacy for 2 weeks.  Do not mix with other insecticides. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Do not apply the product in areas that are wet cleaned or might be submerged by water.  For use only in areas that are inaccessible to infants, toddlers and pets.  Professional and trained professional users should wear protective gloves and impermeable coveralls during application of the product and cleaning of the spraying equipment.  Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.  Keep cats away from treated areas due to high sensitivity to pyrethroids.  Remove or cover terrariums, aquariums and animal cages before application.  Turn off aquarium air-filter during use. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

#### Use 2 - Crack and crevice treatment, indoor - non-professional

Table 2. Use # 2 - Crack and crevice treatment, indoor - non-professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for crack & crevice applications to control crawling insects |
| **Target organism (including development stage)** | *Blattella germanica* (German Cockroach)  *Lasius niger* (Black garden ant)  *Periplaneta Americana* (American Cockroach) |
| **Field of use** | Indoor areas where wet cleaning is not feasible. Areas under non removable furniture or heating appliances, rooms with electrical appliances, closed bath tubes, areas below kitchen furniture which are closed, basements, crawling spaces, boiler rooms. |
| **Application method(s)** | Crack and crevice treatment by spraying. |
| **Application rate(s) and frequency** | Application is performed either *via* hand-held or *via* trigger sprayer. The appropriate volume of Draker One is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use. Draker One should be applied throughout the infested area as a coarse spray to cracks & crevices, where insects may crawl and hide.  Cockroaches:  Bottle with dosing device: measure 2 mL of product and pour in 0.100 L of water into an appropriate container with trigger spray.  Vial 2 mL: pour the content in 0.100 L of water into an appropriate container with trigger spray.  In the case of porous surfaces (e.g. concrete, bricks, woods plastic etc.) treat with 75ml/m2.  In the case of non-porous surfaces (e.g. plastic, metal, ceramics etc.) treat with 40 ml/m2.  (Application rate in terms of active substance is 87-163 mg t.g.a.i./m2)  Ants:  Bottle with dosing device: measure 2 mL of product and pour in 0.200 L of water into an appropriate container with trigger spray.  Vial 2 mL: pour the content in 0.200 L of water into an appropriate container with trigger spray.  In the case of porous surfaces (e.g. concrete, bricks, woods plastic etc.) treat with 100 ml/m2.  In the case of non-porous surfaces (e.g. plastic, metal, ceramics etc.) treat with 40 ml/m2.  (Application rate in terms of active substance is 43-109 mg t.g.a.i./m2)  Product efficacy remains for 2 weeks after treatment.  Frequency of application: 1-2 times a year. |
| **Category(ies) of users** | Non-professional users (general public) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Apply into cracks and crevices, in non wet cleaned areas where insects are used to hide or rest, i.e. under non removable furniture or heating appliances, rooms with electrical appliances, closed bath tubes, areas below kitchen furniture which are closed, basements, crawling spaces, boiler rooms, cellars, attics.  Applications in the appropriate way maintain product’s efficacy for 2 weeks.  Knockdown of cockroaches and ant workers is expected within 30 minutes after exposure of insects to the treated surfaces.  Do not mix with other insecticides.  If the infestation persists despite following the label instructions, contact a pest control operator. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Do not apply the product in areas that are wet cleaned or might be submerged by water.  For use only in areas that are inaccessible to infants, toddlers and pets.  Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.  Keep cats away from treated areas due to high sensitivity to pyrethroids.  Remove or cover terrariums, aquariums and animal cages before application.  Turn off aquarium air-filter during use. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

#### Use 3 - Treatment around building – Mosquitoes – professional

Table 3. Use # 3 - Treatment around building - Mosquitoes - professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for around building treatments against mosquitoes. |
| **Target organism (including development stage)** | *Culex pipiens* (house mosquito)  *Aedes albopictus* (tiger mosquito) |
| **Field of use** | Outdoor, around building in rural areas. |
| **Application method(s)** | Surface treatment by spraying. |
| **Application rate(s) and frequency** | The product has to be diluted in water before use.  Application is performed using any conventional manual or power sprayer equipped to produce a coarse spray at low pressure. The appropriate volume of Draker One is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use. Draker One should be applied throughout the infested area as a coarse spray on surface of walls around the building or in places like terraces to prevent the entrance of mosquitoes.  40 ml of a 0.5% insecticide solution/m2.  (Application rate in terms of active substance is 22 mg t.g.a.i./m2)  Mortality is reached in a few minutes.  Frequency of application 1-2 times a year. |
| **Category(ies) of users** | Trained Professional  Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Product acts against mosquitoes by vapour. Surface treatment on walls around the building or in places like terraces to prevent the entrance of mosquitoes. Apply in the vicinity of doors and windows on walls, in humid nooks, under tables or on walls close to ornamental green where insects rest. Mosquitoes fly close to the ground and therefore rest in the lower part of the walls; to obtain the best results treat on a band of wall up to 150-160 cm height. Do not apply directly on ornamental plants. The product provides sufficient control of mosquitoes at a distance up to 1.1 m from the treated surfaces.  The product has rapid knock-down against mosquitoes.  The product has no residual action against mosquitoes. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Treat on a band of wall up to 150-160 cm height.  Apply only in areas where floor is not connected or near sewer.  Do not use where release to drains (sewer) and/or surface water cannot be prevented.  Do not re-enter in the treated area until the insecticide solution is completely dried.  For use only in areas that are inaccessible to infants, toddlers and pets.  Keep cats away from treated areas due to high sensitivity to pyrethroids.  Professional and trained professional users should wear protective gloves and impermeable coveralls during application of the product and cleaning of the spraying equipment. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

#### Use 4 - Treatment around building - Mosquitoes - non-professional

Table 4. Use 4 - Treatment around building – Mosquitoes - non-professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for around building treatments against mosquitoes. |
| **Target organism (including development stage)** | *Culex pipiens* (house mosquito)  *Aedes albopictus* (tiger mosquito) |
| **Field of use** | Outdoor, around building in rural areas. |
| **Application method(s)** | Surface treatment by spraying. |
| **Application rate(s) and frequency** | The product has to be diluted in water before use.  Application is performed either via hand-held or via trigger sprayer. The appropriate volume of Draker One is added to the required volume of clean water and agitated. If a delay occurs between treatments, re-agitation is needed before re-use.Draker one should be applied throughout the infested area as a coarse spray on surface.  Bottle with dosing device: measure 5 mL of product and pour in 1 L of water into an appropriate container with trigger spray.  Vial 5 mL: pour the content in 1 L of water into an appropriate container with trigger spray.  Treat 25 m2 with 1 L of solution (40ml/m2).  (Application rate in terms of active substance is 22 mg t.g.a.i./m2)  Frequency of application 1-2-time a year |
| **Category(ies) of users** | Non-professional users (general public) |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| Product acts against mosquitoes by vapour. Surface treatment on walls, around building, in humid nooks, under tables or close to ornamental green where insects rest. The product provides sufficient control of mosquitoes at a distance up to 1.1 m from the treated surfaces Mosquitoes fly close to the floor and therefore rest in the lower part of the walls; to obtain the best results treat on a band of wall up to 150-160 cm height.  The product has rapid knock-down against mosquitoes.  The product has no residual action against mosquitoes.  Do not apply directly on ornamental plants.  If the infestation persists or the area is particularly subject to mosquitoes’ infestation, contact a pest control operator and inform the municipality for vector control. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Treat on a band of wall up to 150-160 cm height.  Apply only in areas where floor is not connected or near sewer.  Do not use where release to drains (sewer) and/or surface water cannot be prevented.  Do not re-enter in the treated area until the insecticide solution is completely dried.  For use only in areas that are inaccessible to infants, toddlers and pets.  Keep cats away from treated areas due to high sensitivity to pyrethroids. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

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

|  |
| --- |
| Please, see general directions for use in section 2.1.5. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Always read the label before use.  Please, see specific instructions for use detailed in above sections.  Strategies for managing the development of resistance:  - Where possible, application treatments should be recommended to be combined with non-chemical measures.  - Where an extended period of control is required, treatments should be alternated with products containing active substances with different mode of action.  - In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action 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. |

#### Risk mitigation measures

|  |
| --- |
| Do not apply in presence of food/feedstuff.  Remove any tool that may enter in contact with food/feedstuff during treatment.  For use only in areas that are inaccessible to infants, toddlers and pets.  Keep cats away from treated areas due to high sensitivity to pyrethroids.  Professional and trained professional users should wear protective gloves and impermeable coveralls during application of the product and cleaning of the spraying equipment.  Please refer to use specific RMMs, as detailed in above sections. |

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

|  |
| --- |
| 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: 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. |

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

|  |
| --- |
| Dispose of contents/container in accordance with local waste management regulations.  Do not empty into drains. Do not reuse the packaging. |

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

|  |
| --- |
| Keep out of reach of children.  Store away from food, drinks or feeding stuff.  Do not store at temperature lower than 0°C  Do not store above 40°C.  Shelf-life: 2 years, in original container at room temperatures.  Avoid extreme temperatures and exposure to direct sunlight. |

### Other information

|  |
| --- |
| Contains cypermethrin; May cause paresthesia. |

### 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)** |
| Vial | 1 mL  3 mL  5 mL  10 mL  15 mL  20 mL  *carton Box with 1, 2, 3, 4, 5 pieces.* | PET/PE | thermoseale | Non-professional | Yes |
| Bottle | 50 mL | HDPE | cap HDPE | Non-professional | Yes |
| Right doses bottle/Bettix | 100 mL | Bettix HDPE | cap HDPE | Non-professional | Yes |
| Bottle | 100 mL | Bottle Multilayer COEX/EVOH | cap PP | Non-professional | Yes |
| Bottle | 50 mL | HDPE | cap HDPE | professional | Yes |
| Right doses bottle/Bettix | 100 mL | Bettix HDPE | cap PP | professional | Yes |
| Bottle | 100 mL  *with and without carton Box.* | Bottle Multilayer  COEX/EVOH | cap PP | professional | Yes |
| Bottle | 250 mL | Professional | Yes |
| Bottle | 500 mL | Professional | Yes |
| Bottle | 1 L | Professional | Yes |
| Right doses bottle/Bettix | 300 mL | Bettix HDPE | cap PP | Professional | Yes |
| Right doses bottle/Bettix | 1 L | Bettix HDPE | cap HDPE | Professional | Yes |
| Vial | 1 mL  3 mL  5 mL  10 mL  15 mL  20 mL  *carton Box with 1, 2, 3, 4, 5, 10,50, 100 pieces.* | PET/PE | thermosealed | Professional | Yes |
| Tanks | 5 L  10 L  20 L | COEX/PA | cap PP | Professional | Yes |

***Notes:***

***PET/PE also mentioned as APET/BPET/PE:*** *APET stands for Amorphous-PET, while BPET is a commercial name to identify an APET containing recycled PET (from both PIR - post industrial recycled -, and PCR - post consumer recycled-). So, the difference between APET and BPET is just based on the presence or not of recycled PET resin inside. The layer which stays in direct contact with the product inside the vials is always the PE, in particular a LD-PE (Low Density Polyethylene).*

***Carton box*** *must not be considered as a secondary as described in the packaging directive 94/62/EC. It is designed as the selling unit in case of the smaller packs to easily meet and manage labelling requirements, in accordance with article 17, 18 and 29 of Regulation 1272/2008. Especially, for the 100 mL Bottle ( Non- professional) , Box will be used only in those cases where the label’s text length will not fit into the available space on the bottle in order to ensure the readability of the text.* *Without carton box the packaging is not transparent since the vial is not transparent. The proposed storage conditions do not include the cardboard.*

***COEX/EVOH:*** *In TDS it is mentioned that COEX is made of HDPE (type HHM 5502 BN / BC 82) 0,7 mm Adhesive (resins type PX 3236) 0,02 mm EVOH (type DC 3203 RB) 0,02 mm. None of the packaging is transparent. The proposed storage conditions do not include the cardboard. The carton box does not affect product’s storage since all packaging materials in contact with the formulation are non-transparent and waterproof. HDPE is the layer in contact with the formulation.*

***COEX/PA:*** *It is not transparent. In TDS it is mentioned that COEX is made of HDPE (Adhesive (resins type PX 3236) and PA. According with manufacturer information the layer in contact with the product in jerrycane is Polyammide.*

***Bettix*** *is a specific design of bottle in* ***HDPE****. This kind of packaging could be called in different ways, i.e. Bettix, right doses bottle, bottle with twin neck, double neck bottle. Please refer to the picture and the data sheets to visualize the packagings. The only difference between a HDPE bottle and Bettix HDPE is the shape of the container, not the material.*

***Non-professional packaging:*** *In the 100 ml bottle with twin neck (Bettix) the dosing device comes with the packaging itself since one of the neck serves as a volumetric doser; while considering the 50 ml bottle, a common disposable syringe without needle can be used as the dosing device.*

Accelerated storage stability test for 8 weeks at 40°C demonstrated compatibility with the packaging material “right doses bottle in polyethylene”. Draker One is a water based formulation. According to Guidance on the BPR (Volume I Parts A+B+C) all packaging types, apart from metal are supported with no further data. Nonetheless the applicant supported APET/BPET/PE with seepage data.

Therefore, all the above-mentioned proposed packaging is considered acceptable for commercial use.

|  |
| --- |
| **Conclusion on the packaging of the biocidal product** |
| Full accelerated storage stability test for 8 weeks at 40°C and 2 years shelf life at ambient temperature using right doses bottles in polyethylene, demonstrated compatibility with the packaging material “right doses bottle in polyethylene. In addition, in order to have a complete view of the product, applicant provided seepage data on the PET / PE vials.  According to BPR (Volume I Parts A+B+C), for water based formulation, extrapolation to all types of packaging is considered acceptable.As DRAKER SC is a water based all the proposed packaging (see Table above) could be considered for commercial use~~.~~ |

### Documentation

#### Data submitted in relation to product application

* Physical state at 20 °C and 101.3 kPa
* Colour at 20 °C and 101.3 kPa
* Odour at 20 °C and 101.3 kPa
* Acidity / alkalinity
* Relative density / bulk density
* Storage stability test – accelerated storage (bottle)
* Storage stability test – accelerated storage (vial)
* Storage stability test – long term storage at ambient temperature (study plan)
* Storage stability test – long term storage at ambient temperature (study plan 2021)
* Storage stability test – low temperature stability test for liquids
* Suspensibility, spontaneity and dispersion stability
* Wet sieve analysis and dry sieve test
* Emulsifiability, re-emulsifiability and emulsion stability
* Particle size distribution, content of dust/fines, attrition, friability
* Persistent foaming
* Flowability/Pourability/Dustability
* Surface tension
* Viscosity
* Flammable liquids
* Corrosive to metals
* Oxidizing Properties for Liquids
* Methods for detection and identification
* Efficacy studies
* *In vitro* test for skin irritation

#### 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.

## 2.2. Assessment of the biocidal product

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

For a detailed description of intended uses, please see section 2.1.4.

**Use 1 - Crack and crevice spot treatment, indoor - professional**

Table 5. Use # 1 – Crack and crevice spot treatment, indoor - professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for crack & crevice applications to control infestations of crawling insects |
| **Target organism (including development stage)** | *Blattella germanica* (German Cockroach)  *Blatta orientalis* (Oriental Cockroach)  *Lasius niger* (Black garden ant)  *Periplaneta Americana* (American Cockroach) |
| **Field of use** | Indoor. Areas under non removable furniture or heating appliances, in attics, basements, garages, crawling spaces, boiler rooms, etc. |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Commercial product has to be diluted in water before use.  Cockroaches: 40 to 100 ml of a 2% insecticide solution/m2, corresponding to 0.088 to 0.22 g of cypermethrin/m2.  Ants: 40 to 100 ml of 1% insecticide solution/m2 corresponding to 0.044 to 0.11 g of cypermethrin/m2.  Higher use rate is intended for treatments on non-porous surfaces.  Product’s efficacy lasts for 4 weeks.  Frequency of application: 1-2 times a year. |
| **Category(ies) of users** | Professional and trained professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

**Use 2 - Crack and crevice spot treatment, indoor - non-professional**

Table 6. Use # 2 - Crack and crevice spot treatment, indoor - non-professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for crack & crevice applications to control crawling insects |
| **Target organism (including development stage)** | *Blattella germanica* (German Cockroach)  *Blatta orientalis* (Oriental Cockroach)  *Lasius niger* (Black garden ant)  *Periplaneta Americana* (American Cockroach) |
| **Field of use** | Indoor. Areas under non removable furniture or heating appliances, in attics, basements, garages, crawling spaces, boiler rooms, etc. |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Commercial product has to be diluted in water before use.  Cockroaches: 40 to 75 ml of a 2% insecticide solution/m2, corresponding to 0.088 to 0.16 g of cypermethrin/m2.  Ants: 40 to 100 ml of 1% insecticide solution/m2 corresponding to 0.044 to 0.11 g cypermethrin/m2.  Higher use rate is intended for treatments on non-porous surfaces.  Product’s efficacy lasts for 4 weeks.  Frequency of application: 1-2 times a year. |
| **Category(ies) of users** | Non-professional (general public) |
| **Pack sizes and packaging material** | Please see the relevant section. |

**Use 3 - Treatment around building – Mosquitoes - professional**

Table 7. Use # 3 - Treatment around building - Mosquitoes - professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for around building treatments against mosquitoes. |
| **Target organism (including development stage)** | *Culex pipiens* (house mosquito)  *Aedes albopictus* (tiger mosquito) |
| **Field of use** | Outdoor. Around building in gardens, patios, gazebo |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Commercial product has to be diluted in water before use.  40 ml of a 0.5% insecticide solution/m2 corresponding to 0.022 g of cypermethrin/m2. Mortality is reached in a few minutes and efficacy lasts for two weeks. |
| **Category(ies) of users** | Professional and trained professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

**Use 4 - Treatment around building - Mosquitoes - non-professional**

Table 8. Use 4 - Treatment around building - Mosquitoes- non-professional

|  |  |
| --- | --- |
| **Product Type** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide intended for around building treatments against mosquitoes. |
| **Target organism (including development stage)** | *Culex pipiens* (house mosquito)  *Aedes albopictus* (tiger mosquito) |
| **Field of use** | Outdoor. Around building in gardens, patios, gazebo |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Commercial product has to be diluted in water before use.  40 ml of a 0.5% insecticide solution/m2 corresponding to 0.022 g of cypermethrin/m2. Mortality is reached in a few minutes and efficacy lasts for two weeks. |
| **Category(ies) of users** | Non-professional (general public) |
| **Pack sizes and packaging material** | Please see the relevant section. |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830.6302 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Liquid at 20°C. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.1 |
| Colour at 20 °C and 101.3 kPa | OPPTS 830.6303 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | White at 20°C. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.1 |
| Odour at 20 °C and 101.3 kPa | OPPTS 830.6304 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Characteristic odour at 20°C. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.1 |
| Acidity / alkalinity | CIPAC method MT 75.3 and OECD Test No 122 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | pH value of the neat test item without dilution was 3.7 (rounded mean value of two measurements)  pH value of a 1 % w/v aqueous dispersion (water, HPLC grade, obtained by the Lab Water Purification System) of the test item sample was 5.0 (rounded mean value of two measurements) at a temperature of 20°C.  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.  Clarifications provided by the applicant regarding pH difference between the neat and 1% dilute sample and can be found in the Confidential PAR since it contains confidential information on manufacturing method. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.2 |
| **eCA remark**:  Since the pH was >4, the acidity/alkalinity property has not been performed and should not to be considered for the 1% aqueous dilution. | | | | |
| Relative density / bulk density  Liquid form | Guideline A.3 in Council Regulation (EC) No 440/2008 part A, CIPAC method MT 3.2 and OECD Test No 109  Pycnometer method | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Test item density is 1.0309 g/mL at 20°C, the relative density (𝐷2020) is 1.0327 and the relative density (𝐷420) is 1.0309. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.3 |
| Storage stability test – **accelerated storage** | Test performed according to MT 46 “Accelerated storage procedure”.  Other guidelines and methods used during the test:  - GIFAP Monograph No. 17, 2nd edition, June 2009: Guidelines for Specifying the Shelf Life  of Plant Protection Products  - EPA Guidelines OPPTS 830.6302 (1996); OPPTS 830.6303 (1996); OPPTS 830.6304  (1996)  - CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical  Methods for Technical and Formulated Pesticides:  MT 46 “Accelerated storage procedure”  MT 18 “Standard waters”  MT 75.3 “Determination of pH values”  MT 47.3 “Persistent foam”  MT 185 “Wet sieve test”  MT 148 “Pourability of suspension concentrates”  MT 160 “Spontaneity of dispersion of suspension concentrates”  MT 184 “Suspensibility of formulations forming suspensions on dilution with water”  MT 187 “Particle size analysis by laser diffraction”  MT 36.3 “Emulsion characteristics and re-emulsification properties”  Note. Since the pH value ranged from 4 to 10, the acidity or alkalinity test (CIPAC MT 31 or 191) was not performed.  - OECD Guidelines for Testing Chemicals:  Test Guideline No. 122, Paris, 2013 “Determination of pH, Acidity and Alkalinity”  Test Guideline No. 110, Paris, 1981 “Particle size distribution/Fibre length and diameter  distributions”.  - Cypermethrin active ingredient content with the Internal Analytical Method No. 0546/2019  adjusted and validated in GLP Study CH – 0546/2019.  - Compatibility (resistance) of the packaging material (corrosion characteristics)  - Weights prior to and after the storage period of 8 weeks at 40°C.  The ECHA (European Chemicals Agency) Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment, Part A+B+C, Version 2.0, May 2018. | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | *Packaging*  Initial characterisation: Right doses bottle in polyethylene.  After 8 weeks at 40°C: Right doses bottle in polyethylene “A1”, “A2” and “B”.  *Weight variation (%)*  Initial characterisation: -  After 8 weeks at 40°C: “A1”: -0.08%; “A2”: -0.08% “B”: -0.07%.  *Appearance (Colour, odour and physical state)*  Initial characterisation: White liquid with characteristic odour.  After 8 weeks at 40°C: White liquid with characteristic odour.  *Cypermethrin active ingredient content*  Initial characterisation (T0): 9.80 ± 0.07 % w/w; Cis: 3.94 ± 0.03 % w/w; Trans: 5.86 ± 0.04 % w/w.  After 8 weeks at 40°C: 9.51 ± 0.01 % w/w (-2.96% respect T0); Cis: 3.80 ± 0.01 % w/w (-3.55% respect T0); Trans: 5.71 ± 0.01 % w/w (-2.56% respect T0).  *Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)*  Initial characterisation: -  After 8 weeks at 40°C: The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.  *pH value (neat test item)*  Initial characterisation: 3.7  After 8 weeks at 40°C: 3.5  *pH value (1% aqueous dilution)*  Initial characterisation: 5.0  After 8 weeks at 40°C: 4.8  *Persistent foam*  Initial characterisation: Foam after 1 minute: 0.5 % v/v = 0 mL; 2.0 % v/v = 0 mL  After 8 weeks at 40°C: Foam after 1 minute: 0.5 % v/v = 0 mL; 2.0 % v/v = 0 mL  *Pourability of Suspension Concentrates*  Initial characterisation: 2.03 % as residue 0.11 % as rinsed residue.  After 8 weeks at 40°C: 2.02 % as residue 0.15 % as rinsed residue.  *Emulsion Characteristics*  Initial characterisation: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.5% v/v and 2.0% v/v)  After 8 weeks at 40°C: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.5% v/v and 2.0% v/v).  *Wet Sieve Test*  Initial characterisation: No residue on the 0.075 mm (75 μm) sieve  After 8 weeks at 40°C: No residue on the 0.075 mm (75 μm) sieve.  *Particle Size Analysis by Laser Diffraction*  Initial characterisation: Dv 10: 1.10 μm; Dv 50: 6.02 μm; Dv 90: 18.3 μm; Volume < 45 μm: 96.66 % Volume > 75 μm: 0.26 %  After 8 weeks at 40°C: Dv 10: 1.10 μm; Dv 50: 5.96 μm; Dv 90: 18.1 μm; Volume < 45 μm: 98.11 % Volume > 75 μm: 0.02 %.  *Suspensibility*  Initial characterisation: 0.5 % v/v: 95.2 %; 2.0 % v/v: 94.6 %  After 8 weeks at 40°C: 0.5 % v/v: 96.1 %; 2.0 % v/v: 96.7 %  *Spontaneity of Dispersion*  Initial characterisation: 5.00 % v/v: 90.5 %  After 8 weeks at 40°C: 5.00 % v/v: 87.4 %.  From the obtained results it can be concluded that no significant change was found in the active ingredient content for the test item stored right doses bottles in polyethylene for 8 weeks of storage at 40°C, compared with the results obtained in the validation study (GLP Study No. CH – 0546/2019), and the analyses after 8 weeks comply with the tolerance and therefore are in accordance with the declared value.  No change in the appearance, colour, odour and weight variation was found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.  Moreover, no significant changes in physical properties (pH value, persistent foam, pourability, emulsion characteristics, wet sieve test, particle size distribution by laser diffraction, suspensibility and spontaneity of dispersion) were found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, comparing the initial characterisation.  Conclusion:  From the above reported data, it can be concluded that the DRAKER ONE formulation sample is stable in its commercial packaging under the tested accelerated storage conditions (8 weeks at 40°C).  *According to bibliography added in the document “2021-02 - Manufacturing method Draker One” (attached in section 13 of IUCLID), high temperatures can destabilize microcapsules, therefore, we preferred to test the product at 40 °C.* | DRAKER ONE: Determination of the Accelerated Storage Stability and Corrosion Characteristics. GLP Study No. CH - 0547/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.4.1 |
| Storage stability test – **accelerated storage** | - GIFAP Monograph No. 17, 2nd edition, June 2009: Guidelines for Specifying the Shelf Life of Plant Protection Products  - CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical  Methods for Technical and Formulated Pesticides:  MT 46.4 “Accelerated storage procedure”  - Compatibility (resistance) of the packaging material (corrosion characteristics)  - Weights prior to and after the storage period of 8 weeks at 40°C. | Test item: DRAKER ONE  Packaging: 10 mL vial APET/BPET/PE  Active ingredient content Cypermethrin: Nominal active ingredient Cypermethrin: 10.0 % w/w  Active ingredient content Cypermethrin: 9.95 % w/w  Batch number: 3601710 | The product was stable under accelerated storage conditions tested.  Assessment has been performed by internal and external visual examination of five containers. After 8 weeks of storage at 40°C, the results of the observations carried out on the 10 mL vials APET/BPET/PE labelled as “A1”, “A2”, “A3”, “A4” and “A5”, were as follows.  The vials did not present any deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena.  Weight variation (%)  After 8 weeks of storage at 40°C, the data of weight variation for the test item sample stored in the 10 mL vials APET/BPET/PE labelled from “A1” to “A20” are described in the following table.   |  |  |  |  | | --- | --- | --- | --- | |  | Weight at the beginning (g) | Weight  at the end (g) | Variation  (%) | | 10 mL vial APET/BPET/PE “A1” | 12.36 | 11.85 | -4.13 | | 10 mL vial APET/BPET/PE “A2” | 12.38 | 11.94 | -3.55 | | 10 mL vial APET/BPET/PE “A3” | 12.38 | 11.89 | -3.96 | | 10 mL vial APET/BPET/PE “A4” | 12.36 | 11.92 | -3.56 | | 10 mL vial APET/BPET/PE “A5” | 12.31 | 11.80 | -4.14 | | 10 mL vial APET/BPET/PE “A6” | 12.36 | 11.79 | -4.61 | | 10 mL vial APET/BPET/PE “A7” | 12.25 | 11.78 | -3.84 | | 10 mL vial APET/BPET/PE “A8” | 12.33 | 11.76 | -4.62 | | 10 mL vial APET/BPET/PE “A9” | 12.36 | 11.90 | -3.72 | | 10 mL vial APET/BPET/PE “A10” | 12.32 | 11.83 | -3.98 | | 10 mL vial APET/BPET/PE “A11” | 12.33 | 11.79 | -4.38 | | 10 mL vial APET/BPET/PE “A12” | 12.32 | 11.80 | -4.22 | | 10 mL vial APET/BPET/PE “A13” | 12.27 | 11.77 | -4.07 | | 10 mL vial APET/BPET/PE “A14” | 12.40 | 11.91 | -3.95 | | 10 mL vial APET/BPET/PE “A15” | 12.02 | 11.54 | -3.99 | | 10 mL vial APET/BPET/PE “A16” | 12.36 | 11.92 | -3.56 | | 10 mL vial APET/BPET/PE “A17” | 12.33 | 11.87 | -3.73 | | 10 mL vial APET/BPET/PE “A18” | 12.47 | 12.05 | -3.37 | | 10 mL vial APET/BPET/PE “A19” | 12.40 | 11.83 | -4.60 | | 10 mL vial APET/BPET/PE “A20” | 12.40 | 11.97 | -3.47 | | DRAKER ONE: Determination of the Accelerated Storage Stability and Corrosion Characteristics. GLP Study No. CH – 0781/2021. December 14, 2021.  GLP compliance: yes  IUCLID section 3.4.1 |
| **eCA remark:** Full accelarated storage stability data are available using HDPE packaging that could be considered the worst condition compared to the COEX packaging. In addition, in order to have a complete view of the product, applicant provided an additional GLP report using PET / PE vials for storage. Besides the visual examination of both external and internal packaging, the study analysed the compatibility (resistance) of the packaging material and the weight variation (%) by technical balance. According to BPR (Volume I Parts A+B+C), for water based formulation, extrapolation to all types of packaging is considered acceptable. As DRAKER SC is a water based all the proposed packaging could be considered for commercial use.  Should be added on the label the phrase: *“Do not store above 40 °C.”*  In addition, regarding acidity/alkalinity, see above. | | | | |
| 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.  - ECHA (European Chemicals Agency) Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment, Part A+B+C, Version 2.0, May 2018. | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019  Packaging: 300 mL or 1 L right doses bottle  in high density polyethylene (HDPE) | The 3 years study is in progress. As applicant stated full report will be submitted at the end of the study.   |  |  |  | | --- | --- | --- | | Test | T0 | After 24 months | | Appearance | White liquid with  characteristic odour | White liquid  with characteristic odour | | Cypermethrin active ingredient content | 9.80 ± 0.07 % w/w  Cis: 3.94 ± 0.03 % w/w  Trans: 5.86 ± 0.04 % w/w | 9.47 ± 0.05 % w/w  Cis: 3.77 ± 0.02 % w/w  Trans: 5.70 ± 0.04 % w/w  (- 3.33% from t0) | | Compatibility |  | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena | | pH value (neat test item) | 3.7 | 3.2 | | pH value (1% aqueous dilution) | 5.0 | 4.5 | | Persistent foam Foam after 1 minute: | Foam after 1 minute:  0.5 % v/v = 0 mL  2.0 % v/v = 0 mL | Foam after 1 minute:  0.5 % v/v = 0 mL  2.0 % v/v = 0 mL | | Pourability of Suspension Concentrates | 2.03 % as residue  0.11 % as rinsed residue | 1.83 % as residue  0.19 % as rinsed residue | | Emulsion  Characteristics | Complete initial  emulsification (0h);  complete re-emulsification  (24h)  for both application rates  (0.5% v/v and 2.0% v/v) | Complete initial  emulsification (0h);  complete re-emulsification (24h) for both  application rates (0.5% v/v and 2.0% v/v) | | Wet Sieve Test | No residue on the  0.075 mm  (75 μm) sieve | Residue onto  0.075 mm (75 μm) sieve:  2.25 % w/w | | Particle Size Analysis  by  Laser Diffraction | Dv 10: 1.10 μm;  Dv 50: 6.02 μm;  Dv 90: 18.3 μm;  % < 45 μm: 96.66 %  % > 75 μm: 0.26 % | Dv 10: 1.26 μm;  Dv 50: 9.40 μm;  Dv 90: 28.2 μm;  % < 45 μm: 95.72 %  % > 75 μm: 1.08 % | | Suspensibility | 0.5 % v/v: 95.2 %  2.0 % v/v: 94.6 % | 0.5 % v/v: 90.9 %  2.0 % v/v: 90.8 % | | Spontaneity of  Dispersion | 5.00 % v/v: 90.5 % | 5.00 % v/v: 91.4 % | | DRAKER ONE: Three Years Storage Stability and Corrosion Characteristics. Study Plan CH – 0548/2019.  GLP compliance: yes  IUCLID section 3.4.1 |
| **eCA remark:** Please confirm if right doses bottle in polyethylene material has been used for 2 years storage at ambient temperature or declare the packaging used **(pending data**).  **Applicant’s response on August 2022:** Applicant confirmed that “*right doses bottle in polyethylene material”* has been used for 2 years storage.  ~~In addition, regarding acidity/alkalinity, see above.~~ | | | | |
| 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  - Compatibility (resistance) of the packaging material (corrosion characteristics)  - Weights prior to and after sampling at each time point for material stored at  ambient warehouse temperature. | Test item: DRAKER ONE  Nominal active ingredient Cypermethrin: 10.0 % w/w  Active ingredient content Cypermethrin: 9.95 % w/w  Batch number:  3601710  Packaging: 10 mL vial APET/BPET/PE | The 3 years study is in progress.  The completion of experimental phase and Draft Report is expected for September 2024. Final Report 1 month after receipt of comments to the draft report. | DRAKER ONE: Three Years Storage Stability and Corrosion Characteristics. Study Plan CH – 0585/2021. August 04, 2021. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | The experimental phase started on October 16, 2019 and was completed on October 24, 2019.  Initially, the test item is a homogeneous blank liquid.  After 24 hours at 0 ± 2°C : no visual separation of solid or liquid material was noted.  After 7 days at 0 ± 2°C : no visual separation of solid or liquid material was noted.  The values of temperature recorded during the storage period at 0 ± 2°C (Evisense SensorLabguard, Internal code No. 559-T), are reported below.  From 16/10/2019 to 23/10/2019  Minimum Temperature (°C) = -1.82  Maximum Temperature (°C) = 0.28  Mean Temperature (°C) = -0.83  Standard Deviation = 0.63  After 24 hours of thermal equilibrium at room temperature (23 ± 2°C) and after a single inversion, no visual separation of solid or liquid material was noted.  The values of temperature recorded during the thermal equilibrium at room temperature 23 ± 2°C (Data logger, Internal code No. 973-H), are reported below.  From 23/10/2019 to 24/10/2019  Minimum Temperature (°C) = 22.4  Maximum Temperature (°C) = 24.8  Mean Temperature (°C) = 23.1  Standard Deviation = 0.5  The test item formulation sample, at the end of the storage period 7 days at 0 ± 2°C and after 24 hours of thermal equilibrium at 23 ± 2°C and a single inversion, did not show separation of solid or liquid material, nor changes in its physical state. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.4.1 |
| **eCA remark:** The phrase “Do not store at temperature lower than 0°C” will be added in the label. | | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Data waiving, since the packaging characteristics (packaging materials are not transparent) protect the product from light; therefore, the effect of light does not need to be addressed. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | MT 46 “Accelerated storage procedure” | Test item: DRAKER ONE  Packaging: Right doses bottle in polyethylene  Active ingredient content Cypermethrin: 10.00 % w/w (pure)  Batch number: LAB21052019. | No significant change was found in the active ingredient content for the test item stored right doses bottles in polyethylene for 8 weeks of storage at 40°C, compared with the results obtained in the validation study (GLP Study No. CH – 0546/2019), and the analyses after 8 weeks comply with the tolerance and therefore are in accordance with the declared value.  No change in the appearance, colour, odour and weight variation was found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.  Moreover, no significant changes in physical properties (pH value, persistent foam, pourability, emulsion characteristics, wet sieve test, particle size distribution by laser diffraction, suspensibility and spontaneity of dispersion) were found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, comparing the initial characterisation.  From the above reported data, it can be concluded that the DRAKER ONE formulation sample is stable in its commercial packaging under the tested accelerated storage conditions (8 weeks at 40°C). | DRAKER ONE: Determination of the Accelerated Storage Stability and Corrosion Characteristics. GLP Study No. CH - 0547/2019. January 27, 2020.  GLP compliance: yes |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | MT 46 “Accelerated storage procedure” | Test item: DRAKER ONE  Packaging: Right doses bottle in polyethylene  Active ingredient content Cypermethrin: 10.00 % w/w (pure)  Batch number: LAB21052019 | No change in the appearance, colour, odour and weight variation was found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. | DRAKER ONE: Determination of the Accelerated Storage Stability and Corrosion Characteristics. GLP Study No. CH - 0547/2019. January 27, 2020.  GLP compliance: yes |
| Wettability | - | - | Data waiving since the data are required only for solid preparations which are to be dispersed in water. | - |
| Suspensibility, spontaneity and dispersion stability | *Suspensibility*  CIPAC method MT 184 and MT 18  *Spontaneity of dispersion* CIPAC method MT 160 and MT 18 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019  Tested 0.5 % v/v and 2.0 % v/v suspensions. | *Suspensibility*  The suspensibility of the formulation sample after 30 minutes in Standard Water D at about 30°C, is as follows:  Cypermethrin  Suspension at 0.5 % v/v = Suspensibility 95.2 %  Suspension at 2.0 % v/v = Suspensibility 94.6 %  *Spontaneity of dispersion*  The spontaneity of dispersion of the formulation sample after a single inversion and 5 minutes stand-by in Standard Water D at room temperature, is as follows:  Cypermethrin  Suspension at 5 % v/v Spontaneity of dispersion 90.5 % | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| Wet sieve analysis and dry sieve test | MT 185 “Wet sieve test” | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | For the test item formulation sample no residue was found on the 0.075 mm (75 μm) sieve in each of two wet sieving test. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| Emulsifiability, re-emulsifiability and emulsion stability | MT 36.3 “Emulsion characteristics and re-emulsification properties” | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019  Tested 0.5 % v/v and 2.0 % v/v suspensions. | From the experimental data obtained according to CIPAC method MT 36.3 in Standard Water D, it can be concluded that for test item formulation sample, a complete initial emulsification was noted after a single inversion and waiting for 30 seconds either for 0.5 % v/v and 2.0 % v/v suspensions.  Moreover, a complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds either for 0.5 % v/v and 2.0 % v/v suspensions.  Table. Emulsion stability and re-emulsification for the 0.5 % v/v emulsion.   |  |  |  |  | | --- | --- | --- | --- | | Time after dilution | Free Oil  (mL) | Cream  (mL) | Emulsifiability | | 0 h (\*) | - | - | complete initial emulsification | | 0.5 h | 0 | 0 | - | | 2.0 h | 0 | 0 | - | | 24.0 h | 0 | 0 | - | | 24 h and 10 inversions (\*\*) | - | - | complete re-emulsification | | 24.5 h | 0 | 0 | - |   Table. Emulsion stability and re-emulsification for the 2.0 % v/v emulsion.   |  |  |  |  | | --- | --- | --- | --- | | Time after dilution | Free Oil  (mL) | Cream  (mL) | Emulsifiability | | 0 h (\*) | - | - | complete initial emulsification | | 0.5 h | 0 | 0 | - | | 2.0 h | 0 | 0 | - | | 24.0 h | 0 | 2.0  (at the bottom) | - | | 24 h and 10 inversions (\*\*) | - | - | complete re-emulsification | | 24.5 h | 0 | 0 | - | | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| **eCA remark:** In general, emulsifiability and re-emulsifiability test should be conducted using CIPAC Standard Waters A and D. However, as this test, it is not a requirement for CS formulations, no further data is required. Emulsifiability and re-emulsifiability test it is considered as supportive information. | | | | |
| Disintegration time | - | - | Data waiving since disintegration time is applicable only to products that are tablets (depend on disintegration of the tablet in a solvent). | - |
| Particle size distribution, content of dust/fines, attrition, friability | CIPAC method MT 187 and OECD guideline No. 110 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | The test item formulation sample presents the following particle size distribution:  Dv 10 (μm) = 1.10  Dv 50 (μm) = 6.02  Dv 90 (μm) = 18.3  Volume < 45 μm (%) = 96.66  Volume > 75 μm (%) = 0.26 | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| Persistent foaming | MT 47.3 “Persistent foam” | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019  Tested 0.5 % v/v and 2.0 % v/v suspensions. | From the experimental data obtained according to CIPAC method MT 47.3 in Standard Water D, it can be concluded that, after 1 minute, the persistent foam of test item formulation sample is 0 mL for 0.5 % v/v and 2.0 % v/v suspensions, as mean of two determinations. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| Flowability/Pourability/Dustability | MT 148 “Pourability of suspension concentrates” | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Pourability (rinsibility) at 20°C of the test item formulation sample is 2.03 % as residue and 0.11 % as rinsed residue (mean value of two measurements). | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 3.5 |
| Burning rate — smoke generators | - | - | Not applicable. The product is not a smoke generator. | - |
| Burning completeness — smoke generators | - | - | Not applicable. The product is not a smoke generator. | - |
| Composition of smoke — smoke generators | - | - | Not applicable. The product is not a smoke generator. | - |
| Spraying pattern — aerosols |  |  | Non applicabile. The product is not an aerosol. |  |
| Physical compatibility | - | - | Not applicable. The product is not intended to be used with other products (including other biocidal products). | - |
| Chemical compatibility | - | - | Not applicable. The product is not intended to be used with other products (including other biocidal products). Moreover, no possible incompatibility with any products is known. | - |
| Degree of dissolution and dilution stability | - | - | Degree of dissolution:  data waiving since the information is required for products used in a water soluble bag and for all tablets.  The dissolution rate should be demonstrated regarding tablets and products used in  water soluble bags in water  Dilution stability:  data waiving since the DRAKER ONE product is already an aqueous solution in the starting product which is further diluted in water. | - |
| Surface tension | Guideline A.5 in Council Regulation (EC) No 440/2008 part A and OECD Guideline No. 115 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Surface tension at 20°C of the undiluted test item is 38.3 mN/m and the surface tension at 20°C of 0.5 % v/v and 2.0 % v/v test item aqueous solutions is 40.1 mN/m and 36.4 mN/m, respectively.  According to the interpretation of the results suggested in the A.5 method, the test item should be regarded as a surface-active material. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes |
| Viscosity | CIPAC method MT 192 and OECD Guideline No. 114  Rotational viscometer | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | The product does not contain >10% hydrocarbons.  The test item is a non-Newtonian liquid and its dynamic viscosity changes with the shear rate.  The dynamic viscosity ranges of the test item formulation sample, determined at 20°C and 40°C, using a cylindrical spindle (rotational viscometer), are as follows:  at 20°C  - dynamic viscosity from 1110.00 cP to 422.00 cP  - shear-rate range (sec-1) from 1.02 to 20.40 (from 3 to 60 rpm, spindle SC4-31)  at 40°C  - dynamic viscosity from 703.33 cP to 185.40 cP  - shear-rate range (sec-1) from 1.02 to 34.00 (from 3 to 100 rpm, spindle SC4-31).  Kinematic viscosity = Dynamic viscosity / Density  Kinematic viscosity = 1110.00 mPa\*s/1.0309 g/cm3= 1076.73 mm2/s at 20°C  Kinematic viscosity = 422.00 mPa\*s/1.0309 g/cm3= 409.35 mm2/s at 20°C  Kinematic viscosity = 703.33 mPa\*s/1.0309 g/cm3= 682.25 mm2/s at 40°C  Kinematic viscosity = 185.40 mPa\*s/1.0309 g/cm3= 179.84 mm2/s at 40°C | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Draker One is a white liquid with characteristic odour at 20°C. pH value of the neat test item without dilution was 3.7 and the pH value of a 1 % w/v aqueous dispersion of Draker one was 5.0 at a temperature of 20°C. Density of Draker One is 1.0309 g/mL at 20°C; the relative density (𝐷2020) is 1.0327 and the relative density (𝐷420) is 1.0309.  No significant change was found in the active ingredient content for the test item stored right doses bottles in polyethylene for 8 weeks of storage at 40°C, compared with the results obtained in the validation study (GLP Study No. CH – 0546/2019), and the analyses after 8 weeks comply with the tolerance and therefore are in accordance with the declared value. No change in the appearance, colour, odour and weight variation was found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. Moreover after 8 weeks of storage at 40°C vials in PET/PE did not present any deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena.  No significant changes in physical properties (pH value, persistent foam, pourability, emulsion characteristics, wet sieve test, particle size distribution by laser diffraction, suspensibility and spontaneity of dispersion) were found for the test item stored in right doses bottles in polyethylene for 8 weeks of storage at 40°C, comparing the initial characterisation.  From the above reported data, it can be concluded that the DRAKER ONE formulation sample is stable in its commercial packaging under the tested accelerated storage conditions (8 weeks at 40°C).  The test item formulation sample, at the end of the storage period 7 days at 0 ± 2°C and after 24 hours of thermal equilibrium at 23 ± 2°C and a single inversion, did not show separation of solid or liquid material, nor changes in its physical state.  The suspensibility of the formulation sample after 30 minutes in Standard Water D at about 30°C, was 95.2 % (suspension at 0.5 % v/v) and 94.6% (suspension at 2.0 % v/v). The spontaneity of dispersion of the formulation sample after a single inversion and 5 minutes stand-by in Standard Water D at room temperature, was 90.5 % (suspension at 5 % v/v). For Draker one formulation sample no residue was found on the 0.075 mm (75 μm) sieve in each of two wet sieving test. From the experimental data obtained according to CIPAC method MT 36.3 in Standard Water D, it can be concluded that for Draker one formulation sample, a complete initial emulsification was noted after a single inversion and waiting for 30 seconds either for 0.5 % v/v and 2.0 % v/v suspensions. Moreover, a complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds either for 0.5 % v/v and 2.0 % v/v suspensions.  Draker one presents the following particle size distribution:  Dv 10 (μm) = 1.10  Dv 50 (μm) = 6.02  Dv 90 (μm) = 18.3  Volume < 45 μm (%) = 96.66  Volume > 75 μm (%) = 0.26.  After 1 minute, the persistent foam of test item formulation sample is 0 mL for 0.5 % v/v and 2.0 % v/v suspensions. Pourability (rinsibility) at 20°C of the test item formulation sample is 2.03 % as residue and 0.11 % as rinsed residue. Surface tension at 20°C of the undiluted test item is 38.3 mN/m and the surface tension at 20°C of 0.5 % v/v and 2.0 % v/v test item aqueous solutions is 40.1 mN/m and 36.4 mN/m, respectively. According to the interpretation of the results suggested in the A.5 method, the test item should be regarded as a surface-active material. The test item is a non-Newtonian liquid and its dynamic viscosity changes with the shear rate.  The dynamic viscosity ranges of the test item formulation sample, determined at 20°C and 40°C, using a cylindrical spindle, are as follows:  at 20°C  - dynamic viscosity from 1110.00 cP to 422.00 cP  - shear-rate range (sec-1) from 1.02 to 20.40 (from 3 to 60 rpm, spindle SC4-31)  at 40°C  - dynamic viscosity from 703.33 cP to 185.40 cP  - shear-rate range (sec-1) from 1.02 to 34.00 (from 3 to 100 rpm, spindle SC4-31).  **Proposed to be added in the label:**   * The phrase *“**Do not store at temperature lower than 0°C”* * The phrase *“Do not store above 40 °C.”* * Shelf life at 24 months * Classified as corrosive to metals, H290. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | - United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests  and Criteria ST/SG/AC.10/11/Rev. 5 (2009),  Appendix 6 “Screening Procedures”, Section 3 “Screening procedures for substance which  may have explosive properties”. | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Explosive properties of the product have been assessed according to CLP Regulation, Annex I, section 2.1.4.2. Screening procedure.  According to CLP Regulation, section 2.1.4.3., point (c), the acceptance procedure for the hazard class ‘explosives’ need not be applied for an organic substance, or a homogenous mixture of organic substances, containing a chemical group (or groups) associated with explosive properties, if the exothermic decomposition energy is less than 500 J/g.  Draker one is a homogenous mixture of organic substances containing chemical groups associated with explosive properties, and exothermic decomposition energy is less than 500 J/g.  Even though Differential Scanning Calorimetry (DSC) analysis performed for DRAKER ONE was not a GLP study, it is deemed valid for the abovementioned screening procedure (i.e. for screening GLP is not mandatory). As a results of Differential Scanning Calorimetry (DSC) analysis, Draker one presents a small exothermic event until 500°C with a Area (J.g-1) of 16.51 J.g-1. The total heat of decomposition of the test item DRAKER ONE is < 500 J.-g 1 and therefore the test item is not a candidate for classification as a UN Class 1 explosive substance. | DRAKER ONE: Determination of the Explosive properties by preliminary Differential Scanning Calorimetry (DSC) analysis. Non GLP Study CH – 0306/2020.  June 11, 2020.  GLP compliance: no  IUCLID section 4.1 |
| Flammable gases | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Flammable aerosols | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Oxidising gases | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Gases under pressure | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Flammable liquids | A.9 method (Flash point) in Council Regulation (EC) No 440/2008 of 30 May 2008 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | The measurements were carried out at 1010 mbar atmospheric pressure.  Two tests were performed and the same behaviour was observed in all determinations.  The test item didn’t show the typical flammability phenomena until 135°C, as mean of three measurements.  From the experimental data obtained according to the A.9 method in Council Regulation (EC) No 440/2008 of 30 May 2008, it can be concluded that the test item formulation sample is not flammable. | DRAKER ONE: Determination of the Physico-chemical Properties. GLP Study No. CH – 0545/2019. January 27, 2020.  GLP compliance: yes  IUCLID section 4.6 |
| Flammable solids | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Self-reactive substances and mixtures | Justification for the non-submission of data | - | Data waiving since the a.s. is not classified as ‘explosive’ or ‘self-reactive substance’ and there are no chemical groups associated with explosive or self-reactive  properties in any of the co-formulants, either. | - |
| Pyrophoric liquids | Justification for the non-submission of data | - | Data waiving since the experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperatures, i.e. the product is known to be stable at room temperature for prolonged periods of time (days). | - |
| Pyrophoric solids | As above | - | Not applicable since the product is a liquid. | - |
| Self-heating substances and mixtures | As above | - | Data waiving. In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids | - |
| Substances and mixtures which in contact with water emit flammable gases | Justification for the non-submission of data | - | Data waiving since the product is known not react with water (water-based product, with an high water content). | - |
| Oxidising liquids | - Council Regulation (EC) No 440/2008 of 30 May 2008, Part A: Methods for the Determination  of Physico-Chemical Properties: A.21 “Oxidizing Properties (Liquids)”.  - United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests  and Criteria ST/SG/AC.10/11/Rev. 5 (2009): Part III, Section 34.4.2, Test O2: “Test for  oxidizing liquids (UN)”. | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | The test item and reference substances were mixed with the cellulose in ratio 1:1 by mass. The test item is considered or classified as “Not Division 5.1”, since a pressure rise to 2070 kPa was not attained in the repeated tests conducted on the five test item mixtures | DRAKER ONE: Determination of the Oxidizing Properties for Liquids - GLP Study No. CH – 0305/2020, July 01, 2020  GLP compliance: yes  IUCLID section 4.4 |
| **eCA Remark*.*** *Draker* formulation is not considered as an oxidizing liquid according to A21 test nor expected to present oxidizing properties based on the components and their contents in the formulated product. However, for completeness purpoces according to the CLP, the UN Test O.2 test is expected to be conducted for the renewal of the product. | | | | |
| Oxidising solids | Justification for the non-submission of data | - | Not applicable since the product is a liquid. | - |
| Organic peroxides | Justification for the non-submission of data | - | Not applicable. Draker One does not contain organic peroxides. | - |
| Corrosive to metals | UN Corrosion to Metals Test Criteria, Test C.1  CTL SOP No. 437 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin):  Purity (active ingredient) 10% (pure). | The percentage mass losses on steel and aluminium were found to be < 13.5 % over  7 days, however, the maximum pit depth on both aluminium and steel coupons was > 120 μm. The sample is therefore a candidate for classification as a corrosive substance  of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods  Recommendations). | UN Corrosion to Metals Testing on a Sample of Draker One.  Report Number GLP3016007339R1/2020, May 20, 2020  GLP compliance: yes  IUCLID section 4.16 |
| **eCA remark:** Draker one is classified as corrosive to metals, H290. | | | | |
| Auto-ignition temperatures of products (liquids and gases) | EC Regulation No. 440/2008 A.15 | Test item: DRAKER ONE  Active ingredient content (Cypermethrin): 10.00 % w/w (pure)  Batch number: LAB21052019 | Auto-ignition temperature of the test item formulation sample is 495°C (ignition delay time: 9.18 seconds; quantity of test item: 200 μL). | DRAKER ONE: Determination of the Auto-ignition Temperature for liquids and the Viscosity. ChemService S.r.l. Controlli e Ricerche. Final Report CH – 0089/2021. March 29, 2021. |
| Relative self-ignition temperature for solids | Justification for the non-submission of data | - | Not applicable since the product is a liquid solution. | - |
| Dust explosion hazard | Justification for the non-submission of data | - | Data waiving sinceDraker One is not a powder and does not contain (nor is able to produce) dust. | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| From the experimental data obtained according to the A.9 method in Council Regulation (EC) No 440/2008 of 30 May 2008, it can be concluded that Draker one is not flammable.From the experimental data obtained according to UN Corrosion to Metals Test CTL SOP No. 437, it can be concluded that Draker one is corrosive to metals.From the experimental data the product Draker one is not a oxidising liquid. |

### Methods for detection and identification

*Scope*

This method is applicable to the quantitative determination of Cypermethrin active ingredient in DRAKER ONE 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) *versus* the sum of the four peaks areas in DRAKER ONE test item solutions.

*Preparation of the stock reference material solution*

Using an analytical balance, a volumetric flask and a volumetric pipette, a stock reference material solution in eluent has been prepared as reported in table below.

|  |  |  |  |
| --- | --- | --- | --- |
| 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, three working standard solutions have been prepared for linear calibration in eluent with 10 % v/v of 2-propanol, as detailed in table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 | 0 | 0 |
| WSS 1 | 1 | 10 | 100 | 5.00 – 15.00 |
| WSS 3 | 2 | 10 | 200 |
| WSS 5 | 3 | 10 | 300 |

(1) Calculated with respect to the nominal test item weight in repeatability (1000 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 1000 mg of the test item into 50.00 mL volumetric flask, make to volume with 2-Propanol, mix vigorously for 2 minutes and then, place in an ultrasonic bath for 5 minutes.

That time elapsed, place the stock test item solution in an upright position free from vibration and let to cool at room temperature for about 10 minutes.

Filter using 0.45 μm PTFE syringe filter an aliquot of the supernatant and then, dilute 1:10 the stock filtered test item solution with eluent.

Transfer an aliquot of the diluted solution into a vial for the HPLC analysis.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Stock test item solution (STIS) | | Diluted test item solution (DTIS) | |
| Nominal weight  (mg) | Volume  (mL) | Taken volume  (mL) (1) | Total volume  (mL) (2) |
| Test item | 1000 | 50.00 | 1.00 | 10.00 |

(1) Volume taken from stock test item solution

(2) Total volume of diluted test item solution.

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 A | iso octane/ethyl acetate at 99.5/0.5 % v/v |
| Eluent (isocratic) | A 100 % |
| 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 13 minutes |
| Cypermethrin Trans I ret. Time | about 17 minutes |
| Cypermethrin Trans II ret. time | about 19 minutes |
| Total analysis time | 35 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 Draker One) | HPLC/UV  (HPLC mod. 1200 equipped with UV detector, autosampler, managed by Chemstation software).  detector wavelength 278 nm | Spike A:  Cypermethrin added 98.83 g/kg  Spike B:  Cypermethrin added 99.56 g/kg | 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  Injected range: 104.45 - 313.34 μg/mL  Linearity Range: 5.22 - 15.67 % w/w  Cypermethrin Cis isomer  Injected range: 45.15 - 135.46 μg/mL  Linearity Range: -  Cypermethrin Trans isomer  Injected range: 59.29 - 177.87 μg/mL  Linearity Range: -  Cypermethrin  y = 15403x - 42990  r = 0.99979 | Specific  Cyper Cis I RT = 11.435 min  Cyper Cis II RT = 13.066 min  Cyper Trans I RT = 16.415 min  Cyper Trans II RT = 18.745 min | Spike A:  Cypermethrin added 98.83 g/kg  Cypermethrin found 96.60 g/kg  Cypermethrin recovery 97.75%  Spike B:  Cypermethrin added 99.56 g/kg  Cypermethrin found 96.31 g/kg  Cypermethrin recovery 96.73% | Total mean recovery 97.2% | - | Not required | DRAKER ONE: Validation of the Analytical Method for the Determination of Cypermethrin Active Ingredient Content. GLP Study No. CH – 0546/2019. January 27, 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 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 | 104.45 – 313.34 | 5.22 – 15.67 |
| Cypermethrin Cis isomer | 5 | 45.15 – 135.46 | - |
| Cypermethrin Trans isomer | 5 | 59.29 – 177.87 | - |

(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 | 9.80 | 0.07 | 0.69 | 1.90 | 0.36 |
| Cypermethrin Cis isomer | 5 | 3.94 | 0.03 | 0.70 | 2.18 | 0.32 |
| Cypermethrin Trans isomer | 5 | 5.86 | 0.04 | 0.71 | 2.05 | 0.35 |

(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

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**

According to the SANCO/3030/99 rev. 5 in the recovery test, two independent recovery determination (two different weights) were performed and the additions corresponding to the 100% of the nominal concentration of the active ingredient in the test item were prepared and analyzed.

Each spike and the mean of the two recoveries were in the range 90 to 110 % as expected for active ingredient content between 1.0 % w/w and 10 % 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. | 97.75 | |
| Spike B | 1 det. | | 96.73 |

Summary:

In order to define the elution order of the four isomers of Cypermethrin, the method was developed starting from CIPAC method 332/TC/M/- (volume 1C, pages 2047-2056) and preliminary non GLP tests on the test item were performed to find the best conditions to avoid any interference and analysis procedure.

CIPAC method 332/TC/M/- stated that using a RX-SIL column and 0.5 % v/v ethyl acetate in iso-octane as eluent the order of elution is isomer αR, 1R-cis + αS, 1S-cis (Cypermethrin Cis I isomer), isomer αS, 1R-cis + αR, 1S-cis (Cypermethrin Cis II isomer), isomer αR, 1R-trans + αS, 1S-trans (Cypermethrin Trans I isomer) and isomer αS, 1R-trans + αR, 1S-trans (Cypermethrin Trans II isomer).

Moreover the detector wavelength to use for Cypermethrin is 278 nm since the four isomers of Cypermethrin have the same molar absorption and consequently the same response.

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).

The precision test was performed by five determinations of the test item. 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.

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

in the range 90 to 110 % for active ingredient content between 1.0 % w/w and 10 % 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.

The method is capable to distinguish cypermethrin’s isomers. These values were calculated considering the results obtained in the repeatability test. In the available validation study, the cis and trans isomers were determined and all details of the analysis are reported.

The cis:trans ratio in the test item was the follow:

Cis: 40.2 %

Trans: 59.8 %

Appicant’s Comment on SOCs:

*“No analytical methods for residues are necessary for any other co-formulants in the product since neither of them is a substance of concern. None is classified as Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). As for co-formulants classified hazardous for the environment, none is present at concentrations which lead to the classification of the product. In conclusion, no co-formulant need to be monitored.”*

|  |
| --- |
| **Conclusion on the methods for detection and identificationof the product** |
| An analytical method by HPLC/UV for the determination of cypermethrin isomers was found to be valid in terms of linearity, precision, accuracy, for the determination of Cypermethrin in Draker One.  No substances of concern have been identified. |

**Analytical methods for monitoring of active substances and residues in food and feeding stuff**

Acceptable analytical methods for cypermethrin residues in soil, air and water (as summarized below) are available in the CAR of cypermethrin.

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) (Annex IIA, point 4.2) | GC with MS detection, LOQ = 0.05 mg/kg (LOQ = 0.5 μg/kg for sediment) |
| Air (principle of method and LOQ) (Annex IIA, point 4.2) | GC with MS detection, LOQ = 0.375 μg/m3 |
| Water (principle of method and LOQ) (Annex IIA, point 4.2) | GC with electron capture detection, LOQ = 0.01 μg/L |
| Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2) | Not evaluated |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1) | 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) (Annex IIIA, point IV.1) | 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).  No further information is required for the current submission.. |

### 2.2.5 Efficacy against target organisms

#### 2.2.5.1 Function and field of use

Main group 3: Pest control.

EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods.

Fields of use

Draker One is a microencapsulated (CS) insecticide (PT 18) product, containing 10% w/w cypermethrin (as pure active substance), corresponding to 10.53 % w/w (as technical grade active substance; min. purity: 95%). The product is intended for use, indoor or / and outdoor, by both professional and non-professional users to control German cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*), Black garden ants (*Lasius niger*) and mosquitoes (the tiger mosquito *Aedes albopictus* and the house mosquito *Culex pipiens*).

The overall use pattern is described in chapter 2.1.4.

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

The product is an insecticide intended to be used for the control of German Cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*), Black garden ants (*Lasius niger*) and mosquitoes (the tiger mosquito *Aedes albopictus* and the house mosquito *Culex pipiens*).

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

Efficacy of Draker One has been assessed in terms of KD, mortality and population reduction, as detailed in section 2.2.5.5.

Draker One is intended to be used by both professionals and non-professionals, indoors or/ and outdoors. Draker One acts on harmful organisms by contact resulting in death.

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

Cypermethrin cis:trans/40:60 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.

#### Efficacy data

The individual trials for Uses # 1 and # 2 are presented in the following table:

| **Use # 1 and Use # 2 - Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number: LAB20042021 | *Periplaneta americana*  American cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile - vitrified side) tiles.  Adults were placed for 60 min. on treated tiles, under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40mL/m2 of a 2% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and then at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non – porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 8.00±3.74%  - 7 min: 36.00±6.00%  - 10 min: 78.00±3.74%  - 15 min: 94.00±4.00%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2-7min: 0.00±0.00%  - 10 min: 14.00±5.10%  - 15 min: 60.00±3.16%  - 20 min: 84.00±2.45%  - 25 min: 94.00±2.45%  ≥ 30 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 -5 min: 0.00±0.00%  - 7 min: 26.00±7.48%  - 10 min: 58.00±3.74%  - 15 min: 82.00±3.74%  - 20 min: 96.00±2.45%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Martini S. (2017),  Report No: Q098- 21- 01. |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number: LAB21052019 | *Blattella germanica*  German cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on porous surface) | Laboratory conditions.  Direct contact to treated porous (granite) tiles.  Adults were placed for 60 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 75mL/m2 of a 2% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Porous surface  T0  Knockdown:  - 2 min: 0%  - 5 min: %  - 7 min: 96.00±2.45  ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2 min: 0%  - 5 min 18.00±3.74%  - 7 min 42.00±3.74%  - 10 min 92.00±3.74  ≥ 15 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 min: 0%  - 5 min: 18.00±3.74%  - 7 min: 56.00±5.10%  - 10 min: 84.00±4.00%  ≥ 15 min: 100.00±0.00%  Mortality:  - 24h: 98.00±2.00 %  In the untreated controls, knockdown and mortality was 0%. | Drago A. (2020),  Report No:  Q05 9-20-03 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number: LAB21052019 | *Periplaneta americana*  American cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on porous surface) | Laboratory conditions.  Direct contact to treated porous (granite) tiles.  Adults were placed for 60 min. on treated tiles, under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 75mL/m2 of a 2% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 4.00±2.45%  - 7 min: 56.00±6.78%  - 10 min: 92.00±3.74%  - 15 min: 96.00±2.45%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 4.00±2.45%  - 7 min: 10.00±4.47%  - 10 min: 42.00±5.83%  - 15 min: 90.00±6.32%≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 -7 min: 0.00±0.00%  - 10 min: 20.00±7.07%  - 15 min: 84.00±5.10%  - 20 min: 96.00±2.45%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 98.00±2.00 %  In the untreated controls, knockdown and mortality was 0%. | Drago A. (2020),  Report No:  Q05 9-20- 02 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number: LAB13022018A9 | *Blattella germanica*  German cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles -side up) and porous (marble) tiles.  Adults were placed for 30 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface).  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment only for non porous). | Non - porous surface  T0  Knockdown:  - 2 min: 6.00±4.00%  - 5 min: 64.00±4.00%  - 7 min: 88.00±3.74%  ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 64.00±8.12%  - 48h: 96.00±2.45%  - 72h: 100.00±0.00%  T1  Knockdown:  - 2min: 0.00±0.00%  - 5 min: 22.00±3.74%  - 7 min: 72.00±3.74%  - 10 min: 90.00±3.16%  ≥ 15 min: 100.00±0.00%  Mortality:  - 24h: 2.00±2.00%  - 48h: 44.00±7.48%  - 72h: 86.00±6.00%  - 96h: 100.00±0.00%  T2  Knockdown:  - 2 min: 4.00±4.00%  - 5 min: 54.00±5.10%  - 7 min: 86.00±2.45%  ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 6.00±4.00%  - 48h: 44.00±7.48%  - 72h: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 14.00±2.45%  - 7 min: 44.00±4.00%  - 10 min: 72.00±3.74%  - 15 min: 96.00±2.45%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 74.00±5.10%  - 48h: 94.00±2.45%  - 72h: 100.00±0.00%  T1  Knockdown:  - 2 - 5min: 0.00±0.00%  - 7 min: 20.00±3.16%  - 10 min: 70.00±3.16%  - 15 min: 90.00±3.16%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 12.00±5.83%  - 48h: 82.00±4.90%  - 72h: 98.00±2.00%  - 96h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Drago A. and Martini S. (2018)  Report No:  V E B D R O 0 6 0 3 1 8 ‐ 0 3 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number: LAB13022018A | *Periplaneta*  *americana*  American cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles -side up) and porous (marble) tiles.  Adults were placed for 30 min. on treated tiles, under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface).  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non - porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 14.00±6.78%  - 7 min: 46.00±9.27%  - 10 min: 66.00±9.27%  - 15 min: 90.00±5.48%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 86.00±5.10%  - 48h: 90.00±5.48%  - 72h: 100.00±0.00%  T1  Knockdown:  - 2-7 min: 0.00±0.00%  - 10 min: 8.00±3.74%  - 15 min: 78.00±3.74%  - 20 min: 88.00±2.00%  - 25 min: 96.00±2.45%  - 30 min: 100.00±0.00%  Mortality:  - 24h: 54.00±9.27%  - 48h: 64.00±11.22%  - 72h: 68.00±7.35%  - 96h: 76.00±6.78%  - 120h: 82.00±8.60%  - 144h: 82.00±6.63%  - 168h: 100.00±0.00%  T2  Knockdown:  - 2 -5 min: 0.00±0.00%  - 7 min: 52.00±4.90%  - 10 min: 74.00±5.10%  - 15 min: 88.00±4.90%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 48.00±11.58%  - 48h: 64.00±13.64%  - 72h: 90.00±4.47%  -96h: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  - 2 – 5 min: 0.00±0.00%  - 7 min: 4.00±2.45%  - 10 min: 30.00±3.16%  - 15 min: 62.00±5.83%  - 20 min: 84.00±5.10%  - 25 min: 96.00±2.45%  - 30 min: 100.00±0.00%  Mortality:  - 24h: 58.00±16.85%  - 48h: 66.00±13.27%  - 72h: 94.00±4.00%  - 96h: 100.00±0.00%  T1  Knockdown:  - 2 - 15min: 0.00±0.00%  - 20 min: 6.00±4.00%  - 25 min: 38.00±8.60%  - 30 min: 54.00±8.12%  Mortality:  - 24h: 2.00±2.00%  - 48h: 12.00±5.83%  - 72h: 30.00±3.16%  - 96h: 54.00±5.10%  - 120h: 74.00±4.00%  - 144h: 84.00±6.78%  - 168h: 90.00±5.48%  T2  Knockdown:  - 2 -10 min: 0.00±0.00%  - 15 min: 38.00±8.60%  - 20 min: 66.00±6.78%  - 25 min: 78.00±5.83%  -30 min: 92.00±3.74%  Mortality:  - 24h: 2.00±2.00%  - 48h: 42.00±8.60%  - 72h: 76.00±5.10%  - 96h: 94.00±2.45%  - 120h: 98.00±2.00%  In the untreated controls, knockdown and mortality was 0%. | Drago A. and Martini S. (2018)  Report No:  V E B D R O 0 6 0 3 1 8 ‐ 0 1 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number:  LAB13022018A | *Blatta orientalis*  Oriental cockroach (adults,  5 females and 5 males) | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles -side up) and porous (marble) tiles.  Adults were placed for 30 min. on treated tiles, under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (10 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface).  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). T1 and T2 assessments were only carried out on non -porous tiles. | Non - porous surface  T0  Knockdown:  - 2 – 7 min: 0.00±0.00%  - 10 min: 6.00±4.00%  - 15 min: 36.00±6.78%  - 20 min: 72.00±4.90%  - 25 min: 88.00±4.90%  -30 min: 94.00±4.00%  Mortality:  - 24h: 12.00±3.74%  - 48h: 48.00±8.60%  - 72h: 64.00±8.12%  - 96h: 78.00±5.83%  - 120h: 90.00±4.47%  - 144h: 94.00±4.00%  - 168h: 100.00±0.00%  T1  Knockdown:  - 2-5 min: 0.00±0.00%  - 7 min: 4.00±4.00%  - 10 min: 52.00±10.68%  - 15 min: 88.00±5.83%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 52.00±6.63%  - 48h: 70.00±5.48%  - 72h: 90.00±4.47%  - 96h: 100.00±0.00%  T2  Knockdown:  - 2 -7 min: 0.00±0.00%  - 10 min: 4.00±2.45%  - 15 min: 44.00±7.48%  - 20 min: 72.00±3.74%  - 25 min: 92.00±3.74  -30 min: 100.00±0.00%  Mortality:  - 24h: 26.00±9.27%  - 48h: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  - 2 - 10 min: 0.00±0.00%  - 15 min: 12.00±5.83%  - 20 min: 70.00±9.49%  - 25 min: 84.00±6.78%  - 30 min: 90.00±5.48%  Mortality:  - 24h: 2.00±2.00%  - 48h: 24.00±4.00%  - 72h: 42.00±3.74%  - 96h: 68.00±2.00%  -120h: 88.00±3.74%  - 144h: 96.00±2.45%  - 168h: 98.00±2.00%  In the untreated controls, knockdown and mortality was 0%. | Drago A. and Martini S. (2018)  Report No:  V E B D R O 0 6 0 3 1 8 ‐ 0 4 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number:  LAB20042021 | *Lasius niger*  Black garden ant  (adults) | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles - vitrified side) and porous (granite) tiles.  Adults were placed for 60 min. on treated tiles, under transparent plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (20 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 1% solution (on non-porous surface) and 100 mL/m2 of a 1% solution (on porous surface).  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non - porous surface  T0  Knockdown:  - 2 - 5 min: 0.00±0.00%  - 7 min: 1±01%  - 10 min: 17±04%  - 15 min: 44±05%  - 20 min: 86±06%  - 25 min: 97±02%  ≥ 30 min: 94.00±4.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2-5 min: 0.00±0.00%  - 7 min: 4.00±1.87%  - 10 min: 17.00±2.55%  - 15 min: 78.00±4.90%  - 20 min: 96.00±1.87%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 1.00±1.00%  - 7 min: 7.00±3.00%  - 10 min: 24.00±5.10%  -15 min: 78.00±4.36%  - 20 min: 98.00±1.22%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  Porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 8.00±2.55%  - 7 min: 36.00±6.20%  - 10 min: 71.00±9.41%  - 15 min: 92.00±4.64%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2- 5 min: 0.00±0.00%  - 7 min: 8.00±1.22%  - 10 min: 39.00±4.85 %  - 15 min: 84.00±5.10%  - 20 min: 98.00±2.00%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2- 5 min: 0.00±0.00%  - 7 min: 1.00±1.00%  - 10 min: 8.00±2.55%  - 15 min: 38.00±6.63%  - 20 min: 82.00±5.39%  -25 min: 99.00±1.00%  ≥ 30 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Martini S. (2021),  Report No. Q08 9A-20-04 |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) – Batch number:  LAB13022018A | *Lasius niger*  Black garden ant  adults | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles - side up) and porous (marble) tiles.  Adults were placed for 30 min. on treated tiles, under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 replicates / treatment (20 adults – workers / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 1% solution (on non-porous surface) and 100 mL/m2 of a 1% solution (on porous surface).  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non - porous surface  T0  Knockdown:  - 2 - 5 min: 0.00±0.00%  - 7 min: 1±001%  - 10 min: 6.00±2.92%  - 15 min: 38.00±5.83%  - 20 min: 84.00±7.65%  - 25 min: 97.00±2.00%  - 30 min: 100.00±0.00%  Mortality:  - 24h: 79.00±4.85%  - 48h: 98.00±1.22%  T1  Knockdown:  - 2-7 min: 0.00±0.00%  - 10 min: 13.00±5.39%  - 15 min: 85.00±4.47%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 2.00±1.22%  - 7 min: 2.00±1.22%  - 10 min: 3.00±1.22%  -15 min: 81.00±1.87%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 3.00±2.00%  - 7 min: 15.00±6.52%  - 10 min: 39.00±15.20%  - 15 min: 83.00±9.43%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 91.00±2.92%  - 48h: 100.00±0.00%  T1  Knockdown:  - 2- 7 min: 0.00±0.00%  - 10 min: 13.00±3.74%  - 15 min: 93.00±3.00%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2- 15 min: 0.00±0.00%  - 20 min: 82.00±5.39%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Drago A. and Martini S. (2018),  Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 5. |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Periplaneta americana,* American cockroach(adults) | Field test  Indοor application in cracks and crevices. | Field conditions.  Test performed in 3 rooms (40 m2) of car mechanical workshop. There was distance between the rooms to prevent insects entry from one to another.  In order to estimate the population density, sticky traps (2/room) baited with specific attractant tablets were set out where cockroaches were expected to be observed and were checked after 24h.  Three (3) replicates for each treatment. No untreated sites were used as controls.  The product was applied, in crack and crevices at a dose of 40ml/m2 of a 2% solution (on non porous) and 75 ml/ m2 of a 2% solution (on porous). The number of cockraches present was counted post- treatment (after 48 hours, 1, 2 and 8 weeks). | Population reduction  Room 1:  - 48h: 100%  - 1 week: 90%  - 2 weeks: 97.6%  - 8 weeks: 100%  Room 2:  - 48h: 100%  - 1 week: 93.5%  - 2 weeks: 98.1%  - 8 weeks: 72.7%  Room 3:  - 48h: 94.7%  - 1 week: 90.3%  - 2 weeks: 96.3%  - 8 weeks: 75.1%  Mean Reduction:  - 48h: 94.7%  - 1 week: 90.3%  - 2 weeks: 96.3%  - 8 weeks: 75.1% | Drago A. (2020), Report No: P011-20-03. |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Blattella germanica,* German cockroach(adults) | Field test  Indoor application in cracks and crevices. | Field conditions (public housing for the elderly).  Test performed in 3 rooms (54 m2) of a retirement home. There was distance between the rooms to avoid interference from one to another.  In order to estimate the population density, sticky traps (2/room) baited with specific attractant tablets were set out where cockroaches were expected to be observed and were checked after 24h.  Three (3) replicates for each treatment. No untreated sites were used as controls.  The product was applied, in crack and crevices at a dose of 40ml/m2 of a 2% solution (on non porous) and 75 ml/ m2 of a 2% solution (on porous). The number of cockraches present was counted post- treatment (after 48 hours, 1, 2 and 8 weeks). | Population reduction  Room 1:  - 48h: 100%  - 1 week: 92.2%  - 2 weeks: 100%  - 8 weeks: 100%  Room 2:  - 48h: 70%  - 1 week: 92%  - 2 weeks: 97.1%  - 8 weeks: 80%  Room 3:  - 48h: 65.4%  - 1 week: 100%  - 2 weeks: 95.1%  - 8 weeks: 65.4%  Mean Reduction:  - 48h: 78.5%  - 1 week: 94.7%  - 2 weeks: 97.4%  - 8 weeks: 81.8% | Drago A. (2020), Report No: P011-20-01. |
| Insecticide (PT18)  Indoor application against crawling insects | Crack and crevice spot applications  (indoor), Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Lasius niger,* Black garden ant (workers) | Field test  Indoor and outdoor application in cracks and crevices. | Field conditions (public housing for the elderly).  Test performed in 6 hallways (each hallway being a replication). Three (3) hallways were chosen as treated replications (Rep 1; Rep 2 and Rep 3). In each hallway, the test product was applied in 3 sites where ants were present. The sites were selected at the opposite sides of the hallway (ca. 2.5 m wide) but were part of the same ant colony.  Three (3) untreated hallways were used as controls).  In order to estimate the population density, sticky traps (2/room) baited with specific attractant tablets were set out where ants were expected to be observed and were checked after 24h.  The product was applied, in crack and crevices at a dose of 40ml/m2 (on non porous) and 100 ml/ m2 (on porous) of a 1% solution. The number of ants present was counted post- treatment (after 48 hours, 1 and 2 weeks). | Population reduction  Replication 1:  - 48h: 84.8%  - 1 week: 100%  - 2 weeks: 100%  Replication 2:  - 48h: 100%  - 1 week: 85.3%  - 2 weeks: 81.8%  Replication 3:  - 48h: 86.8%  - 1 week: 85.5%  - 2 weeks: 88.8%  Mean Reduction:  - 48h: 90.5%  - 1 week: 90.3%  - 2 weeks: 90.2% | Drago A. (2020), Report No: P011-20-02. |

The individual trials for Uses # 3 and # 4 are presented in the following table:

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Aedes albopictus*  (tiger mosquito)  (females) | Laboratory test (forced contact test on non-porous and porous surface) | Laboratory conditions.  Direct contact to treated non -porous (ceramic tiles - side up) and porous (marble) tiles.  Adults were placed for 60 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 treated replications (10 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 0.5% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and then at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non - porous surface  T0  Knockdown:  - 2 - 5 min: 0.00±0.00%  - 7 min: 64.00±6.78%  - ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 6.00±2.45%  - 7 min: 22.00±5.83%  -10 min: 66.00±5.10%  ≥ 15 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 4.00±2.45%  - 7 min: 28.00±8.60%  - 10 min: 76.00±10.30%  -15 min: 94.00±4.00%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  - 2 -7 min: 0.00±0.00%  - 10 min: 8.00±3.74%  - 15 min: 22.00±3.74%  - 20 min: 56.00±12.08%  - 25 min: 94.00±4.00%  ≥ 30 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2- 10 min: 0.00±0.00%  - 15 min: 22.00±3.74%  - 20 min: 82.00±5.83%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2- 7 min: 0.00±0.00%  -10 min: 2.00±2.00%  -15 min: 64.00±8.72%  - 20 min: 96.00±2.45%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Drago A. (2020), Report No: Q05 9-20-01 |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Culex pipiens* (house mosquito)  (females) | Laboratory test (forced contact test on porous surface) | Laboratory conditions.  Direct contact to treated porous (granite) tiles.  Adults were placed for 60 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 treated replications (10 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 0.5% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and then at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Porous surface  T0  Knockdown:  - 2 -5 min: 0.00±0.00%  - 7 min: 2.00±2.00 %  - 10 min: 4.00±2.45%  - 15 min: 14.00±4.00%  - 20 min: 34.00±5.10%  - 25 min: 62.00±11.58%  - 30 min: 80.00±7.07%  - 35 min: 96.00±2.45%  ≥ 40 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2- 10 min: 0.00±0.00%  - 15 min: 2.00±2.00%  - 20 min: 28.00±3.74%  - 25 min: 96.00±2.45%  ≥ 30 min: 100.00±0.00%  Mortality:  - 24h: 94.00±2.45%  T2  Knockdown:  - 2- 7 min: 0.00±0.00%  -10 min: 6.00±2.45%  -15 min: 48.00±3.74%  - 20 min: 68.00±5.83%  - 25 min: 96.00±2.45%  ≥ 30 min: 100.00±0.00%  Mortality:  - 24h: 90.00±7.75%  In the untreated controls, knockdown and mortality was 0%. | Drago A. (2020), Report No: Q05 9-20-04 |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB20042021 | *Culex pipiens* (house mosquito)  (females) | Laboratory test (forced contact test on non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (vitrified side of ceramic tiles) surface.  Adults were placed for 60 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 treated replications (10 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 of a 0.5% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 - 40 min and then at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 2 weeks. Three assessments were carried out: T0 (after treatment), T1 (1 week after treatment) and T2 (2 weeks after treatment). | Non-porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 10.00±3.16%  - 7 min: 38.00±5.83%  - 10 min: 66.00±2.45%  - 15 min: 82.00±2.00%  - 20 min: 96.00±2.45%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2 min: 2.00±2.00%  - 5 min: 12.00±3.74%  - 7 min: 32.00±4.90%  - 10 min: 72.00±3.74%  - 15 min: 88.00±2.00%  - 20 min: 96.00±2.45%  ≥ 25min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 4.00±2.45%  - 7 min: 18.00±2.00%  - 10 min: 64.00±6.78%  - 15 min: 82.00±3.74%  - 20 min: 94.00±2.45%  ≥ 25min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%. | Martini S. (2021), Report No: Q089A-21-03 |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB13022018A | *Culex pipiens* (house mosquito)  (females) | Laboratory test (forced contact test on porous and non-porous surface) | Laboratory conditions.  Direct contact to treated porous (marble) and non-porous (side up of ceramic tiles) surface.  Adults were placed for 30 min. on treated tiles, under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  5 treated replications (20 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 mL/m2 (on non-porous surface) and 100 mL/m2 (on porous surface) of a 0.5% solution.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Knockdown was recorded at 2, 5 and 7 min, then every 5 minutes from 10 to 30 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 4 weeks. Five assessments were carried out: T0 (after treatment), T1 (1 week after treatment), T2 (2 weeks after treatment), T3 (3 weeks after treatment) and T4 (4 weeks after treatment, only on non-porous surface). | Non-porous surface  T0  Knockdown:  - 2 min: 3.00±1.22%  - 5 min: 12.00±2.55%  - 7 min: 35.00±5.70%  - 10 min: 66.00±3.32%  - 15 min: 83.00±2.55%  - 20 min: 97.00±2.00%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 85.00±5.00%  - 48h: 100.00±0.00%  T1  Knockdown:  - 2 min: 3.00±2.00%  - 5 min: 11.00±3.32%  - 7 min: 21.00±2.45%  - 10 min: 74.00±1.87%  - 15 min: 87.00±2.00%  - 20 min: 98.00±1.22%  ≥ 25min: 100.00±0.00%  Mortality:  - 24h: 87.00±2.55%  - 48h: 100.00±0.00%  T2  Knockdown:  - 2 min: 1.00±1.00%  - 5 min: 6.00±1.87%  - 7 min: 20.00±1.58%  - 10 min: 65.00±7.58%  - 15 min: 88.00±2.55%  - 20 min: 96.00±1.00%  - 25 min: 98.00±1.22%  - 30 min: 99.00±1.00%  Mortality:  - 24h: 72.00±2.55%  - 48h: 100.00±0.00%  T3  Knockdown:  - 2 -5 min: 0.00±0.00%  - 7 min: 7.00±3.74%  - 10 min: 21.00±4.00%  - 15 min: 83.00±2.55%  - 20 min: 93.00±1.22%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 80.00±4.47%  - 48h: 100.00±0.00%  T4  Knockdown:  - 2 -5 min: 0.00±0.00%  - 7 min 3.00±1.22%  - 10 min: 11.00±1.87%  - 15 min: 48.00±8.75%  - 20 min: 79.00±4.00%  - 25 min: 90.00±3.54%  - 30 min: 94.00±1.87%  Mortality:  - 24h: 77.00±2.55%  - 48h: 99.00±1.00%  Porous surface  T0  Knockdown:  - 2 min: 0.00±0.00%  - 5 min: 11.00±1.87%  - 7 min: 24.00±1.87%  - 10 min: 45.00±3.54%  - 15 min: 61.00±2.92%  - 20 min: 78.00±2.55%  - 25 min: 90.00±1.58%  - 30 min: 95.00±1.58  Mortality:  - 24h: 72.00±2.55%  - 48h: 97.00±1.22%  T1  Knockdown:  - 2-7 min: 0.00±0.00%  - 10 min: 10.00±1.58%  - 15 min: 20.00±2.74%  - 20 min: 70.00±5.24%  - 25 min: 92.00±2.55%  - 30 min: 97.00±1.22%  Mortality:  - 24h: 78.00±2.55%  - 48h: 100.00±0.00%  T2  Knockdown:  - 2 -7 min: 0.00±0.00%  - 10 min: 2.00±1.22%  - 15 min: 14.00±1.87%  - 20 min: 46.00±8.43%  - 25 min: 53.00±8.15%  - 30 min: 74.00±6.20%  Mortality:  - 24h: 70.00±7.07%  - 48h: 100.00±0.00%  T3  Knockdown:  - 2 -7 min: 0.00±0.00%  - 10 min: 3.00±1.22%  - 15 min: 11.00±3.32%  - 20 min: 19.00±4.00%  - 25 min: 27.00±5.61%  - 30 min: 42.00±7.52%  Mortality:  - 24h: 61.00±10.30%  - 48h: 91.00±5.34%  In the untreated controls, knockdown and mortality was 0%. | Drago A. and Martini S. (2018), Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 8 |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Aedes albopictus, Culex pipiens* (tiger and house mosquito)  (females, 5 - 10 days old) | Field test. Outdoor application | Field conditions (outdoor areas).  Test performed in 3 rectangular outdoor areas infested by *Aedes albopictus*. Each area was protected by a roof and the floor was tiled or concrete made. In one side of the area there was a wall whereas in the other 3 sides there were plants in pots to form a hedge.  In each area, 4 cylindrical cages containing 15 females of *Aedes albopictus* and *Culex pipiens* were hung at different heights. Each cage (5.5 cm in diameter and 5.5 cm in height) was made of 1 mm-mesh metallic net. The cages were placed in humid nooks and close to the ornamental green where mosquitoes are used to rest. Specifically, the cages where hung into the parcel to simulate the distribution of the mosquitoes. Such cages were hung by metallic hooks to the branch of the plants in pots, not in contact with any surface. The position of the cage was between 0.3 and 1.10 metres, equally distributed along the vegetation.  The ability of the product to provide protection from mosquitoes was evaluated by assessing the wild tiger mosquito population with the Human Landing Technique. Three different volunteers exposed arms and legs’ skin in each replication for 3 minutes and the number of landings was counted.  Percentage of protection against *Aedes albopictus* was calculated according to Mulla’s formula (1971), which takes into account the variation of mosquitoes’ density in both of the areas (treated and control) during the test and also respect to the pre-treatment.  Three (3) untreated areas were used as controls).  The product was sprayed as a surface treatment onto the selected area (walls, up to 1,60 m, humid nooks and close to the ornamental green where insects rest. The product was applied uniformly over the selected area from a distance of 50 cm. The application was performed using a hand pump sprayer (Gloria 505 T).  The product was applied at a dose of 40ml/m2 of a 0.5% solution.  Evaluation of efficacy was performed by HL, counting the number of probings on the same volunteers for 3 minutes at 30 minutes, 1 and 2 hours after treatment.  Knockdown was recorded at 2, 5 and 10 min. Mortality was recorded after 24 hours. | *Aedes albopictus*  Knockdown  - 2 min: 94.44 ± 0.43%  - 5 min: 100.00±0.00%  - 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  *Culex pipiens*  Knockdown  - 2 min: 94.44 ± 1.14%  - 5 min: 94.44 ± 0.43%  - 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%%  In the untreated controls, knockdown was 0% and mortality 1.11±0.43% (for *Aedes albopictus*) and 0.56±0.43% (for *Culex pipiens*).  The reduction percentage of landings of *Aedes albopictus* was 93.4% after 30 minutes, 90% after 1 hour and 98.2% after 2 hours. | Drago A. (2020)  Report No: P011-20-04 |
| Insecticide (PT18)  Treatment around building - Mosquitoes | Outdoor, around building in rural areas.  Professional/  Non-professionals | Draker One (cypermethrin 10.0% w/w as pure active substance) - Batch number:  LAB21052019 | *Aedes albopictus, Culex pipiens* (tiger and house mosquito)  (females, 5 - 10 days old) | Field test. Outdoor application | Field conditions (residential areas).  Test performed in 5 houses (detached and semi-detached) with gardens, infested by *Aedes albopictus* and *Culex pipiens*.  The purpose of the test was to demonstrate whether an insecticide treatment applied to an external wall of the building was able to guarantee protection in the indoor areas.  On each site, 4-5 ovitraps were set out in the vegetated areas located north of the buildings, in humid and shady areas, generally close to vegetation. Monitoring the larvae had the purpose of detecting the size of the population present and which portion of the garden / building was the most suitable to perform the test.  Based on the data obtained from the ovitraps, the most suitable room of the building was identified (on the ground floor and with at least one window facing north).  Adult mosquito monitoring pre- and post- treatment was carried out with BG-sentinel traps to capture adult mosquitoes.  A pre-treatment record of the adult mosquitoes present outside (in the garden) and inside the room was carried out.  The traps were positioned inside the room centrally.  The traps were kept working for 8 hours from 4pm to 10pm. During monitoring, only the identified north window was kept open, while all the other doors and windows in the room were kept closed.  Once the Pre-treatment count of adult mosquitoes was carried out, the window was closed and the trap was restarted and kept working for 16 hours in the same position in order to catch any other insect left inside the room.  The product was applied as a surface treatment on the outside wall of the buildings, up to 160 cm in height, at a dose of 40ml/m2 of a 0.5% solution.  Subsequently, the window was opened and both Traps (A-indoors and B-outdoors) were switched on and kept in the same way as for Pre-treatment counts of adults. During the Post-Treatment counts only the specific window remained open, while all other windows were kept closed.  Efficacy (population reduction) was recorded 24h after treatment. | Pre and Post-treatment results (population reduction) for adults indoor  Site 1 (19 m2)  Pre-–treatment:  *Aedes albopictus*: 9 adults  *Culex pipiens*: 8 adults  Post –treatment  *Aedes albopictus*: 1 adults  *Culex pipiens*: 0 adults  24h: :94%  Site 2 (7 m2):  Pre-–treatment:  *Aedes albopictus*: 3 adults  *Culex pipiens*: 8 adults  Post –treatment  *Aedes albopictus*: 0 adults  *Culex pipiens*: 1 adults  24h: :91%  Site 3 (20 m2)  Pre-–treatment:  *Aedes albopictus*: 11 adults  *Culex pipiens*: 8 adults  Post –treatment  *Aedes albopictus*: 0 adults  *Culex pipiens*: 0 adults  24h: 100%  Site 4 (14 m2)  Pre-–treatment:  *Aedes albopictus*: 7 adults  *Culex pipiens*: 15 adults  Post –treatment  *Aedes albopictus*: 1 adults  *Culex pipiens*: 1 adults  24h: 91%  Site 5 (15.75 m2)  Pre-–treatment:  *Aedes albopictus*: 9 adults  *Culex pipiens*: 9 adults  Post –treatment  *Aedes albopictus*: 0 adults  *Culex pipiens*: 0 adults  24h: 100% | Castellini S. (2021) Efficacy insecticide evaluation of DRAKER ONE (Cypermethrin 10% a.i. Microencapsulated Insecticide) for the control of Mosquitoes (*Culex pipiens* and *Aedes albopictus*) in Italy |

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| **Conclusion on the efficacy of the product** |
| Several efficacy studies (laboratory and field studies) were submitted by the applicant to support the intended uses of Draker One (containing cypermethrin 10% w/w) against the claimed target organisms.  Based on the results of the submitted efficacy studies, the product was effective when applied, as:   * Crack and crevice treatment by professionals and non-professionals, indoors for the control of German cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*) and Black garden ant workers (*Lasius niger*) at 40 to 75 ml of a 2% insecticide solution/m2 (for cockroaches) and 40 to 100 ml of 1% insecticide solution/m2 (for ants). Higher doses are intended for porous surfaces and lower doses for non-porous surfaces.The product has a residual period of 2 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches and ant workers is expected within 30 minutes after exposure of insects to the treated surfaces”. * Surface outdoor treatment around buildings against tiger (*Aedes albopictus*) and house (*Culex pipiens*) mosquitoes at 40 ml of a 0.5% insecticide solution/m2. The product provides sufficient control of mosquitos when appled at a distance up to 1.1 m from the treated surfaces. The product has no residual action against mosquitoes", since residual efficacy was not evaluated in the field studies against mosquitoes by exposing new batches of insects to aged treated surfaces and counting wild mosquito population reduction with human bait method over time (days) post treatment. |

#### 2.2.5.6 Occurrence of resistance and resistance management

Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocidal uses of cypermethrin cis:trans/40:60.

The principles of strategies for managing the development of resistance are similar for cypermethrin as they are for other synthetic pyrethroids:

* 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 active substances with the same mode of action 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.

#### 2.2.5.7 Known limitations

According to the efficacy trials on Draker One and to cypermethrin properties, no limitations of Draker One are known.

#### 2.2.5.8 Evaluation of the label claims

Intended Uses # 1 & 2 for professionals and non-professionals:

The product is intended to be used for the control of crawling insects *Blattella germanica* (German cockroach), *Lasius niger* (Black garden ant), *Periplaneta americana* (American Cockroach) and ants (*Lasius niger*) indoors as crack and crevice spot treatment at 40 ml/m2 (non porous) to 75 ml /m2 (porous) of a 2% insecticide solution (cockroaches) and 40 ml/m2 (non porous) to 100 ml /m2 (porous) of 1% insecticide solution. The product has a residual period of 2 weeks.

Intended Uses # 3 & 4 for professionals and non-professionals:

The product is intended to be used for around building treatments against mosquitoes *Culex pipiens* (house mosquito) and *Aedes albopictus* (tiger mosquito) at 40 ml/m2 of a 0.5% insecticide solution. Mortality is reached in a few minutes. Apply only around the building or in places like terraces to prevent the entrance of mosquitoes. Apply in spots in the vicinity of doors and windows on walls, in humid nooks, under tables or on walls close to ornamental green where insects rest. Mosquitoes fly close to the ground and therefore rest in the lower part of the walls; to obtain the best results treat on a band of wall up to 150-160 cm height. Do not apply directly on ornamental plants.

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

Lab study - Martini S. (2017), Report No: Q098- 21- 01.

In the lab study by Martini 2017, the product was applied as surface treatment in a forced contact test on non-porous surfaces (ceramic tile - vitrified side) against adults of the American cockroach (*Periplaneta americana*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at 40 mL/m2 of a 2% solution. To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated tiles. According to the results,the product resulted in 100% knockdown in 20-30 minutes and 100% mortality in 24h after exposure of the insects to the treated non-porous surfaces.

Lab study - Drago A. (2020), Report No: Q05 9- 20- 03

In the lab study by Drago A. (2020), the product was applied as surface treatment in a forced contact test on porous (granite) surfaces against adults of the German cockroach (*Blattella germanica*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at 75 mL/m2 of a 2% solution. To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated tiles. According to the results,the product resulted in 100% knockdown in 10-15 minutes and 98-100% mortality in 24h after exposure of the insects to the treated porous surfaces.

Lab study - Drago A. (2020), Report No: Q059-20- 02

In the lab study by Dago 2020, the product was applied as surface treatment in a forced contact test on porous (granite) surfaces against adults of the American cockroach (*Periplaneta americana*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at 75 mL/m2 of a 2% solution. To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated tiles. According to the results,the product resulted in 100% knockdown in 20-25 minutes and 98-100% mortality in 24h after exposure of the insects to the treated non-porous surfaces.

Lab study - Drago A. and Martini S. (2018) Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 3

In the lab study by Drago and Martini 2018, the product was applied as surface treatment in a forced contact test on porous (marble) and non porous (ceramic tiles -side up) surfaces against adults of the German cockroach (*Blattella germanica*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic brush) at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface). To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated non porous tiles and to 1week aged treated porous tiles. According to the results,the exposure of cockroaches to non porous surfaces up to 2-weeks resulted in 100% knockdown in 10-15 minutes and 2-64% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of cockroaches to porous surfaces up to 1 week resulted in 100% knockdown in 20 minutes and 12-74% mortality in 24h after exposure of the insects to the treated surfaces.

Lab study - Drago A. and Martini S. (2018) Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 1

In the lab study by Drago and Martini 2018, the product was applied as surface treatment in a forced contact test on porous (marble) and non porous (ceramic tiles -side up) surfaces against adults of the Aemrican cockroach (*Periplaneta americana*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic brush) at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface). To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated tiles. According to the results, the exposure of cockroaches to non porous surfaces up to 2-weeks resulted in 100% knockdown in 20-30 minutes and 48-86% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of cockroaches to porous surfaces up to 1 week resulted in 92-100% knockdown in 30 minutes and 2-58% mortality in 24h after exposure of the insects to the treated surfaces.

Lab study - Drago A. and Martini S. (2018) Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 4

In the lab study by Drago and Martini 2018, the product was applied as surface treatment in a forced contact test on porous (marble) and non porous (ceramic tiles -side up) surfaces against adults of the Oriental cockroach (*Blatta orientalis*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic brush) at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 2% solution (on porous surface). To evaluate the residual activity, the cockroaches were exposed to 2 weeks aged treated non porous tiles and to 1 week aged treated porous tiles. According to the results,the exposure of cockroaches to non porous surfaces up to 2-weeks resulted in 94-100% knockdown in 20-30 minutes and 12-52% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of cockroaches to porous surfaces up to 1-week resulted in 90% knockdown in 30 minutes and 2% mortality in 24 h (98% in 168h) after exposure of the insects to the treated surfaces.

Lab study - Martini S. (2021), Report No. Q08 9A-20-04

In the lab study by Martini 2021, the product was applied as surface treatment in a forced contact test on non-porous and porous (granite) surfaces against ant adults (*Lasius niger*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 1% solution (on porous surface). To evaluate the residual activity, the ants were exposed to 2 weeks aged treated tiles. According to the results,the exposure of antsto non-porous surfaces up to 2-weeks resulted in 94-100% knockdown in 25-30 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of antsto porous surfaces up to 2-weeks resulted in 94-100% knockdown in 20-30 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.*

Lab study - Drago A. and Martini S. (2018), Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 5.

In the lab study by Drago and Martini 2018, the product was applied as surface treatment in a forced contact test on non-porous (ceramic tiles - side up) and porous (marble) surfaces against ant adults (*Lasius niger*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at a dose of 40 mL/m2 of a 2% solution (on non-porous surface) and 100 mL/m2 of a 1% solution (on porous surface). To evaluate the residual activity, the ants were exposed to 2 weeks aged treated tiles. According to the results,the exposure of antsto non-porous surfaces up to 2-weeks resulted in 100% knockdown in 20-30 minutes and 79-100% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of antsto porous surfaces up to 2-weeks resulted in 100% knockdown in 20-25 minutes and 91-100% mortality in 24h after exposure of the insects to the treated surfaces*.*

Field study - Drago A. (2020), Report No: P011-20-03

In the field study by Drago (2020) the effectiveness of the product was evaluated in naturally infested areas by *Periplaneta americana*. The product was applied indoors, in crack and crevices, at 40ml/m2 (on non porous) and 75 ml/ m2 (on porous) of a 2% solution. When the product was applied as a crack and crevice treatment indoors, provided 96.3% mean population reduction of the American cockroach, 2 weeks after treatment.

Drago A. (2020), Report No: P011-20-01.

In the field study by Drago (2020) the effectiveness of the product was evaluated in naturally infested areas (public housing for the elderly) by *Blattella germanica*. The product was applied indoors, in crack and crevices, at 40ml/m2 (on non porous) and 75 ml/ m2 of a 2% solution (on porous). When the product was applied as a crack and crevice treatment indoors, provided 97.4% mean population reduction of the German cockroach, 2 weeks after treatment.

Drago A. (2020), Report No: P011-20-02.

In the field study by Drago (2020) the effectiveness of the product was evaluated in naturally infested areas (public housing for the elderly) by *Lasius niger*. The product was applied indoors, in crack and crevices, at 40ml/m2 (on non porous) and 100 ml/ m2 of a 1% solution (on porous). When the product was applied as crack and crevice treatment indoors, provided 90.2% mean population reduction of the Black garden ants (workers), 2 weeks after treatment.

Drago A. (2020), Report No: Q05 9-20-01

In the lab study by Drago 2020, the product was applied as surface treatment in a forced contact test on non-porous (ceramic tiles - side up) and porous (marble) surfaces against female adults of *Aedes albopictus*. The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at a dose of 40 mL/m2 of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 2 weeks aged treated tiles. According to the results,the exposure of mosquitoesto non-porous surfaces up to 2 weeks resulted in 100% knockdown in 10-20 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of mosquitoesto porous surfaces up to 2 weeks resulted in 100% knockdown in 25-30 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.*

Drago A. (2020), Report No: Q05 9-20-04

In the lab study by Drago 2020, the product was applied as surface treatment in a forced contact test on porous (granite) surfaces against female adults of *Culex pipiens*. The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at a dose of 40 mL/m2 of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 2 weeks aged treated tiles. According to the results,the exposure of mosquitoesto porous surfaces up to 2 weeks resulted in 100% knockdown in 30-40 minutes and 90-100% mortality in 24h after exposure of the insects to the treated surfaces*.*

Martini S. (2021), Report No: Q089A-21-03

In the lab study by Martini 2021, the product was applied as surface treatment in a forced contact test on non-porous (vitrified side of ceramic tiles) surfaces against female adults of *Culex pipiens*. The product was applied at a dose of 40 mL/m2 of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 2 weeks aged treated tiles. According to the results,the exposure of mosquitoesto non- porous surfaces up to 2 weeks resulted in 100% knockdown in 25 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.*

Drago A. and Martini S. (2018), Report No: V E B D R O 0 6 0 3 1 8 ‐ 0 8

In the lab study by Drago and Martini 2018, the product was applied as surface treatment in a forced contact test on non-porous (vitrified side of ceramic tiles) and porous (marble) surfaces against female adults of *Culex pipiens*. The product was applied at a dose of 40 mL/m2 (on non-porous tiles) and 100 mL/m2 (on porous tiles) of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 4 weeks aged treated tiles. According to the results,the exposure of mosquitoesto non- porous surfaces up to 4 weeks resulted in 94-100% knockdown in 25-30 minutes and 72-87% mortality in 24h after exposure of the insects to the treated surfaces*.* The exposure of mosquitoesto porous surfaces up to 3 weeks resulted in 42-97% knockdown in 30 minutes and 61-78% mortality in 24h after exposure of the insects to the treated surfaces*.*

Drago A. (2020) Report No: P011-20-04

In the field study by Drago 2020 the effectiveness of the product was evaluated in 3 rectangular outdoor areas naturally infested by *Aedes albopictus* and *Culex pipiens*. The product was applied outdoors onto the selected area (walls up to 1,60 m, humid nooks and close to the ornamental green where insects rest) from a distance of 50 cm as a surface treatment (on a band up to 1.6 m height). The application was performed using a hand pump sprayer. The product was applied at a dose of 40ml/m2 of a 0.5% solution. Protection from mosquitoes was evaluated by assessing the wild tiger mosquito population with the Human Landing Technique. Three different volunteers exposed arms and legs’ skin in each replication for 3 minutes and the number of landings was counted. The reduction percentage of landings of *Aedes albopictus* was 93.4% after 30 minutes, 90% after 1 hour and 98.2% after 2 hours.

Castellini S. (2021) Efficacy insecticide evaluation of DRAKER ONE (Cypermethrin 10% a.i. Microencapsulated Insecticide) for the control of Mosquitoes (Culex pipiens and Aedes albopictus) in Italy

In the field study by Castellini S. (2021) the effectiveness of the product was evaluated in 5 houses naturally infested by *Aedes albopictus* and *Culex pipiens*. The purpose of the test was to verify whether an insecticide treatment applied to an external wall of the building was able to guarantee the protection of the indoor areas. The presence of adult mosquitoes inside rooms was assessed before and after the treatment with traps being positioned inside the room centrally. The product was applied on the outside wall of the buildings, up to 1.6 m height, at a dose of 40ml/m2 of a 0.5% solution. Mean efficacy (population reduction) was 95.2%.

Based on the results of the submitted efficacy studies, the intended uses as applied for by the applicant (section 2.2.1) are acceptable from an efficacy point of view, noting however the following:

* For the intended Use # 2 (non-professional users) against crawling insects (cockroaches and ants), the requirements of the guidance for surface treatment for non-professionals should normally be fulfilled, i.e. in lab tests >90% knockdown within a few minutes after contact with the product (or according to the claim) for cockroaches and >90% knockdown in 5-10 minutes (or according to the claim) for ants, directly after spray and at the end of residual period. Mortality according to the label claim, should preferably be ≥90% in 24 hour. According to the submitted lab studies the exposure of crawling insects to porous and non-porous treated surfaces for up to 2-weeks resulted in 100% knockdown in 10-30 minutes after exposure of cockroaches to the treated surfaces and in 100% knockdown in 20-30 minutes after exposure of ant workers to the treated surfaces.

Hence, the intended Use # 2 of the product, from an efficacy point of view, is acceptable as applied for by the applicant, noting that the following limitation is proposed to be included in the PAR & SPC (specific instructions for use): “Knockdown of cockroaches and ant workers is expected within 30 minutes after exposure of insects to the treated surfaces”.

* The intended Uses # 3 and 4 against mosquitoes, are accepted from an efficacy point of view, with the following limitations to be added in the PAR and SPC:

"The product has no residual action against mosquitoes", since residual efficacy was not evaluated in the field studies against mosquitoes by exposing new batches of insects to aged treated surfaces and counting wild mosquito population reduction with human bait method over time (days) post treatment.

“The product provides sufficient control of mosquitos when appled at a distance up to 1.1 m from the treated surfaces”, considering that in the field study by Drago 2020 the caged mosquitoes were exposed up to 1.1 meters distance from the treated surfaces.

According to the applicant, for the intended uses 3&4 the “product acts against mosquitoes by contact and vapour”. However, the action against mosquitoes by contact is supported only by lab studies (forced contact, non-choice tests). No simulated use or field tests under outdoor conditions are submitted exposing mosquitoes to aged treated surfaces by contact. In the field test by Drago 2020 the caged mosquitoes were not in contact with the treated surfaces, supporting the action of the product only by vapour. Hence, the aforementioned statement is proposed to be changed as follows “product acts against mosquitoes by vapour”.

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

Draker One is not intended to be authorised for use in mixture with other biocidal products.

### Risk assessment for human health

**General information**

Human health risk assessment has been performed according to indication provided in ECHA Guidance on the Biocidal Products Regulation, Volume III, Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017. Exposure assessment has been performed according to the ECHA Biocides Human Health Exposure Methodology (2015), the TNsG on Human Exposure (2002) and, where applicable, the User Guidance (2002) as well as the TNsG on Human Exposure (2007).

The assessment of effects on human health for Draker One 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 “Draker One” contains:

* several substances that are not classified (i.e. not hazardous)
* some substances classified for one or more endpoints, that are present in the biocidal product in concentrations below the cut-off values determined according to art. 11 of CLP Regulation.

Only one *in vitro* Skin Irritation Test with the EpiDermTM Model has been performed for Draker One; results of this test are detailed in the relevant section below. The toxicological hazard assessment of the biocidal product Draker One relied on the toxicological information available for the active substance (i.e. cypermethrin) and all the co-formulants (please refer to the Confidential Annex).

Regarding the active substance cypermethrin, the classification adopted in the RAC Opinion in December 2019 was taken into account for the toxicological risk assessment. According to the RAC opinion, cypermethrin is classified H302; H332; H335; H373.

The biocidal product Draker One does not contain substances of concern for human health.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

Available data on Draker One to assess skin irritation are reported in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of *in vitro* study on skin irritation** | | | | | |
| **Method,**  **Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In vitro* skin irritation  OECD 439  GLP: yes  RL 1 | Draker One  Batch No: LAB21052019 | Evaluations:  The cell viability based  on cellular mitochondrial dehydrogenase activity, measured by MTT  reduction and conversion into a blue formazan salt that is quantitatively measured after extraction from tissues.  The reduction of cell viability in treated tissues was compared to negative control and expressed as a %. The % reduction in viability is used to predict the irritation potential.  Test duration:  Exposure: 60 min  Post incubation: 42h  Validity of controls:  - Positive control: 5%  SDS solution; mean viability should be < 20% of the negative control tissues.  - Negative control:  DPBS solution; the mean OD value of the three negative control tissues should be ≥ 1.0 e ≤ 2.8.  - For all treated groups the standard deviation value of the % viability should be < 18%. | - DRAKER ONE is non skin irritant: The mean viability of tissues exposed to the test item was 88.9% of the mean negative control value.  - The study is considered to be valid as all validity criteria were within acceptable limits:   * The mean OD value of the three negative control tissues was 2.314. * The positive control result showed 2.6 % viability. * Each standard deviation value of the % viability was below 18. | No remarks | DRAKER ONE:  *In vitro* Skin Irritation Test with the EpiDermTM Model  Study No:  CH-403/  2019. |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not skin irritant. |
| Justification for the value/conclusion | Draker One has been tested in an *in vitro* skin irritation test with the EpiDermTM Model, a three-dimensional human epidermis model in which normal human-derived epidermal keratinocytes have been cultured to form a multilayered highly differentiated epidermis model.  The use of this model for skin corrosion/irritation testing involves topical application of test substances to the surface of the epidermis. The irritancy potential of test substances is predicted by mean tissue viability of tissues exposed to the test substance. The test substance is considered to be at least irritant to skin, if the mean relative viability after 60 minutes exposure and 42 hours post incubation is less or equal (≤) to 50% of the negative control.  In the present study, positive and negative controls showed the expected cell viability values within acceptable limits, hence the study was considered to be valid.  Test item reduced cell viability in comparison to the negative control. The mean viability of tissues exposed to the test item was 88.9% of the mean negative control value, therefore Draker One is not irritant to the skin. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | - |

***Eye irritation***

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| --- | --- |
| **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 Draker one.  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 Draker One contains one co-formulant classified for Eye Damage Cat. 1 (H318) and one co-formulant classified for Eye Irritation Cat. 2 (H319). However, as their concentration in the product is well below the cut-off values determined according to art. 11 of CLP Regulation, no classification for eye damage/irritation is triggered for the biocidal product Draker One. |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Eye irritation.  According to the information requirement of BPR, testing on the product does not need to be conducted if there are valid data available on each of the components of the product, sufficient to allow classification of the mixture based on the rules of CLP 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***

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the value/conclusion | There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation and there is no testing requirement for this endpoint under the BPR.  No animal studies or human data are available to assess respiratory tract irritation for the biocidal product Draker One.  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 and one co-formulant of Draker One are classified as STOT SE Cat. 3, H335. However, as their concentration in the product 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 Draker One, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation.  There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation and there is no testing requirement for this endpoint under the BPR.  Testing on the product does not need to be conducted if there are valid data available on each of the components of the product, sufficient to allow classification of the mixture based on the rules of CLP 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. |

***Skin sensitization***

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| --- | --- |
| **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 Draker One.  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 Draker One 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). |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization.  According to the information requirement of BPR, testing on the product does not need to be conducted if there are valid data available on each of the components of the product, sufficient to allow classification of the mixture based on the rules of CLP 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)***

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| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| 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 Draker One.  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 Draker One 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). |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization.  There are currently no standard tests and no OECD test guidelines available for respiratory tract sensitisation and there is no testing requirement for this endpoint under the BPR.  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*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value/conclusion | Non-toxic *via* the oral route. |
| Justification for the value/conclusion | Acute oral toxicity data are not available for the biocidal product Draker One.  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 Draker One are classified for Acute Oral Toxicity Cat. 4 (H302). However, the concentration of the co-formulant in the product is below the cut-off values reported in Table 1.1 of CLP Regulation, hence it is not considered to be relevant for this endpoint.  According to RAC opinion, cypermethrin has an oral ATE of 500 mg/kg bw. Therefore ATEmix of the product is calculated as follows: 100/ATEmix = 10.53/500; ATEmix = 4778 mg/kg bw.  Since ATEmix of the product is above 2000 mg/kg bw, which is the generic concentration limit triggering classification of a product for acute oral toxicity, no classification is triggered for the biocidal product Draker One. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity.  According to the information requirement of BPR, testing on the product does not need to be conducted since there are valid data available on each of the components sufficient to allow classification of the mixture. |
| 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*

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| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value/conclusion | Non-toxic *via* the inhalation route. |
| Justification for the value/conclusion | Acute inhalation toxicity data are not available for the biocidal product Draker One.  For this endpoint the classification has been estimated by the application of the criteria of CLP Regulation, Annex I (Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin is the only ingredient of the product classified as Acute Tox. Cat. 4, H332 with inhalation ATE = 3.3 mg/L. Therefore ATEmix of the product is calculated as follows:  100/ATEmix = 10.53/3.3; ATEmix = 31.34 mg/L.  Since ATEmix of the product is above 5 mg/L, which is the generic concentration limit triggering classification of a product for acute inhalation toxicity, no classification is triggered for the biocidal product Draker One. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity.  According to the information requirement of BPR, testing on the product does not need to be conducted since there are valid data available on each of the components sufficient to allow classification of the mixture. |
| 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*

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| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value/conclusion | Non-toxic *via* the dermal route. |
| Justification for the value/conclusion | Acute dermal toxicity data are not available for the biocidal product Draker One.  For this endpoint the classification has been estimated by the application of the criteria of CLP Regulation, Annex I (Classification of mixtures based on ingredients of the mixture (Additivity formula).  One co-formulant of Draker One is classified for Acute Tox. Cat. 4, H312. However, as its concentration in the product is below the cut-off values reported in Table 1.1 of CLP Regulation, no classification for acute dermal toxicity is triggered for the biocidal product Draker One. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute dermal toxicity.  According to the information requirement of BPR, testing on the product does not need to be conducted since there are valid data available on each of the components sufficient to allow classification of the mixture. |
| 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. |

***Other effects***

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| --- | --- |
| **Conclusion used in Risk Assessment – Other effects** | |
| Value/conclusion | STOT RE Cat. 2 |
| Justification for the value/conclusion | According to the RAC opinion (December 2019), cypermethrin is classified as STOT RE Cat. 2, H373.  Its concentration in the biocidal product Draker One (10.53%) is above 10%, which is the generic concentration limit triggering classification of a product for STOT RE Cat. 2.  Therefore, **Draker One should be classified as STOT RE Cat. 2,** according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | STOT RE Cat. 2, H373: May cause damage to the nervous system through prolonged or repeated exposure. |

***Information on dermal absorption***

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| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Cypermethrin |
| Value(s) | 13% |
| Justification for the selected value(s) | Dermal absorption value of 13%, proposed in the CAR of cypermethrin, has been used for the exposure assessment of the biocidal product Draker One.  This value has been resulted from an *in vivo* rat dermal absorption study performed with an EC formulation containing 0.0025% cypermethrin (25 mg/L). For more details see below the information from the CAR of cypermethrin.  Since the rat skin is more permeable than human skin, the dermal absorption value of 13% obtained from the *in vivo* rat dermal absorption study is considered as a worst-case value for the human skin.  Moreover, the concentration of cypermethrin in the EC formulation, used in the *in vivo* rat dermal absorption study, is 0.0025%, which is much lower than the concentration of cypermethrin in the biocidal product Draker One (i.e. 10.53%). Therefore, the value of 13% represents a worst-case dermal absorption value for Draker One and has been used for exposure assessment.  *Information from the CAR of cypermethrin*  Dermal absorption was studied in the rat, using human tissue, and in human volunteers. Studies *in vivo* and *in vitro* were performed using typical formulations (Cypermethrin 100 g/l EC, Cypermethrin 500 g/l EC), concentrated or as spray dilution, and an 8 hour exposure.  Based on the results of the *in vitro* dermal absorption in human skin study performed with an EC formulation, the dermal absorption values for cypermethrin including total absorbed, residual skin absorption and 5 tape strips (all tape strips) at 24 h after dosing are for the concentrate (100 mg a.s./L) 37.5%, and for the spray dilution (25 mg a.s./L) 78.6%.  Based on the results of the *in vivo* rat dermal absorption study performed with an EC formulation, the dermal absorption values for cypermethrin including total absorbed, residual skin absorption and 18 tape strips (first two excluded) at 24 h, 72 h or 216 h after dosing are for the concentrate (500 mg a.s./L): 6.7%, 7.0%, 7.6%; and for the spray dilution (25 mg a.s./L): 12.5%, 13.6%, 12.7%. The total absorption increased over time. This was expected as pyrethroids are stored in the skin following dermal exposure and are slowly released in to the systemic circulation.  The outcome of the rat study is supported by the human volunteer study. The estimated dermal absorption based on the phenoxybenzoic acid metabolites 120 h after dosing is 1.2% (range 0.85 to 1.8%) for a 26g/L formulation (applied dose 31mg/800cm²), and only a recovery of 66.6% (skin wash, T-shirt, urine metabolites).  It is well known that the rat skin is more permeable than human skin and it is also well known that the *in vitro* findings generally overpredict the *in vivo* situation (Nohynek et al., 2010, Toxicol. Appl. Pharmacol. 243, 239-259). Moreover, the *in vitro* system used was a static test system, whereas today the more reliable flow-through systems are generally used. In the human volunteer study a recovery of only 66.6% was calculated. However, the purpose of this study was to provide a basis for interpretation of urinary metabolite data in studies of worker exposure, not a complete accounting of administered dose. No mass balance was reported.  Therefore, the *in vivo* dermal absorption study in rats performed with the Cypermethrin 500 g/L EC formulation provides the most reliable dermal absorption data. The dermal absorption of cypermethrin determined in rats *in vivo* resulted in an absorption of 7.6% and 12.7% of the applied dose for the concentrate (500 g/L) and spray dilution (25 mg/L) respectively. The solvents used in the latter formulation are considered to be more likely to carry the active substance through the skin due to the more lipophilic nature. Therefore, this can be used as a worst case.  For the assessment of the human internal dermal exposure to the biocidal product Cypermethrin 100 g/L EW**, a value of 13% is used**, as humans are exposed to a water-based biocidal formulation containing cypermethrin 100 g/L (10% a.s. concentration) or less when applied as a solution (0.1% a.s. concentration in final applied product). |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption. |
| Justification | No data on dermal absorption for Draker One, data from the CAR of cypermethrin can be used. |

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

The biocidal product Draker One does not contain substances of concern.

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

The biocidal product Draker One does not contain mixtures.

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

Screening of endocrine-disrupting properties for co-formulants in the biocidal product Draker One 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 Draker One, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources. The information provided in the MSDSs by the suppliers of the co-formulants was also used.

At the end of the screening, none of the results suggested that any of the co-formulants could have endocrine-disrupting properties. For this reason, the available evidence supports the conclusion that the biocidal product Draker One does not contain co-formulants with endocrine-disrupting properties for human.

Please, refer to the Confidential Annex for further details.

#### Exposure assessment

**Introduction**

The biocidal product Draker One is a water-based microincapsulated (CS) formulation containing cypermethrin (CAS No. 52315-07-8) as active substance.

The nominal (pure) concentration of cypermethrin in the biocidal product is 10% 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 10.53% w/w (i.e. 10% × 100/95), which is used for the risk assessment calculations.

The biocidal product is for use on both indoors and outdoors by professional and non-professional users for the control of crawling insects and mosquitoes. The product should be diluted and mixed before use.

The assessment of human exposure to the active substance cypermethrin resulting from the use of Draker One follows the recommendations of the ECHA Biocides Human Health Exposure Methodology (2015), of the TNsG on Human Exposure (2002) and, where applicable, of the User Guidance (2002) as well as of the TNsG on Human Exposure (2007).

The relevant uses of the biocidal product Draker One are reported in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Professional users** | **Type of applicator** | **Concentration of a.s. in the concentrated product** | **Dilution** | **Concentration of a.s. in the in-use product** | **Application rate** |
| Use 1  Indoor  Crack & crevice treatment  Crawling insects | manual or power sprayer | 10.53% | Cockroaches:  dilute 2 ml of product in a final volume of 100 mL water.  Ants:  dilute 2 ml of product in a final volume of 200 mL water. | Cockroaches:  0.21%  Ants:  0.1053% | Cockroaches:  a.s: 0.16 g/m2  prod: 75ml/m2  Ants:  a.s: 0.105 g/m2  prod: 100ml/m2 |
| Use 3  Outdoor  Surface treatment  around building  Mosquitoes | manual or power sprayer | 10.53% | Dilute 5 ml of product in a final volume of 1000 mL water. | 0.054% | Mosquitoes:  a.s. 0.022 g/m2  prod: 40 ml/m2 |
| **Non-professional users** | **Type of applicator** | **Concentration of a.s. in the concentrated product** | **Dilution** | **Concentration of a.s. in the in-use product** | **Application rate** |
| Use 2  Indoor  Crack & crevice treatment  Crawling insects | hand-held or trigger sprayer | 10.53% | Cockroaches:  dilute 2 ml of product in a final volume of 100 mL water.  Ants:  dilute 2 ml of product in a final volume of 200 mL water. | Cockroaches:  0.21%  Ants:  0.1053% | Cockroaches:  a.s: 0.16 g/m2  prod: 75ml/m2  Ants:  a.s: 0.105 g/m2  prod: 100ml/m2 |
| Use 4  Outdoor  Surface treatment  around building  Mosquitoes | hand-held or trigger sprayer | 10.53% | Dilute 5 ml of product in a final volume of 1000 mL water. | 0.054% | Mosquitoes:  a.s. 0.022 g/m2  prod: 40 ml/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. | Yes | Yes | n.a. |
| Oral | n.a. | No | No | n.a. | Yes | Yes | n.a. |

Human exposure, both primary and secondary, arising from the uses of the biocidal product Draker One (both professional and non-professional users) can be summarised as follows.

*Primary exposure*

* Mixing & loading
* Application
* Cleaning of spray equipment
* Laundering of work clothes

Secondary exposure

* Re-entry of treated spaces (infants, toddlers, children, adults)
* Crawling/playing on treated surfaces (infants, toddlers, children)

In order to estimate the exposure of each relevant population in each task of use (e.g. mixing & loading, application) of the biocidal product, suitable models have been selected in Biocides Human Health Exposure Methodology.

An overview of relevant models selected for each task of use of the product is detailed in the following tables.

|  |  |  |
| --- | --- | --- |
| **Overview of models used for primary human health exposure assessment** | | |
| **Mixing & loading** | | |
| **Use** | **Model used** | **Reference** |
| Use 1  Professional users | Included in application task; Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| Use 2  Non-professional users | ConsExpo 4 - Pest Control Products Fact Sheet - RIVM report 320005002/2006 | RIVM Pest Control Products Fact Sheet, p. 29. |
| Use 3  Professional users | Included in application task; Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| Use 4  Non-professional users | Included in application task; Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| **Application** | | |
| **Use** | **Model used** | **Reference** |
| Use 1  Professional users | Spray Application; Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| Use 2  Non-professional users | ConsExpo 4 - Pest Control Products Fact Sheet - RIVM report 320005002/2006 - Crack and crevice | RIVM Pest Control Products Fact Sheet, p. 38. |
| Use 3  Professional users | Spray Application: Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| Use 4  Non-professional users | Spray Application: Spraying Model 1 | Biocides Human Health Exposure Methodology, p. 204. |
| **Post-application** | | |
| **Use** | **Model used** | **Reference** |
| Use 1 – Use 3  Professional users | Cleaning of spraying equipment in antifouling use (PT21) | Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure “Cleaning of spray equipment in antifouling use (PT21)”. |
| Use 1 – Use 3  Professional users | Laundering of contaminated work clothes at home |  |

|  |  |  |
| --- | --- | --- |
| **Overview of models used for secondary human health exposure assessment** | | |
| **Inhalation route** | **Model** | **Population** |
| Exposure to vapours  (volatilized residues) | Generic Models Algorithms of Biocides Human Health Exposure Methodology | Infants  Toddlers  Children  Adults |
| **Dermal route** | **Model** | **Population** |
| Dermal contact with treated surfaces | ConsExpo - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off | Infants  Toddlers  Children |
| **Oral route** | **Models** | **Population** |
| Oral exposure  (hand-to-mouth contact) | ConsExpo - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Constant rate | Infants  Toddlers |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Mixing and loading | **Primary exposure: direct**  Indoor: crack and crevice treatment | Professional users |
| 2. | Mixing and loading | **Primary exposure: direct**  Outdoor: around the building - Mosquitoes | Professional users |
| 3. | Application | **Primary exposure: direct**  Indoor: crack and crevice treatment | Professional users |
| 4. | Application | **Primary exposure: direct**  Outdoor: around the building - Flying insects | Professional users |
| 5. | Post-application | **Primary exposure: indirect**  Cleaning of spraying equipment | Professional users |
| 6. | Post-application | **Primary exposure: indirect**  Laundering contaminated work clothes at home. | Professional users |
| 7. | Mixing and loading | **Primary exposure: direct**  Indoor: crack and crevice treatment | Non-professional users |
| 8. | Mixing and loading | **Primary exposure: direct**  Outdoor: around the building - Mosquitoes | Non-professional users |
| 9. | Application | **Primary exposure: direct**  Indoor: crack and crevice treatment | Non-professional users |
| 10. | Application | **Primary exposure: direct**  Outdoor: around the building - Flying insects | Non-professional users |
| 11. | Post-application | **Secondary exposure**  Secondary exposure is relevant to the general public entering to treated areas after product application. | 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***

##### Scenario 1. Mixing and loading - Crack and crevice treatment – professional users

Primary exposure of professional users resulting from mixing and loading is included in the application task i.e. in Scenario 3.

##### Scenario 2. Mixing and loading – Outdoor around buildings – Mosquitoes – professional users

Primary exposure of professional users resulting from mixing and loading is included in the application task i.e. in Scenario 4.

##### Scenario 3. Application - Crack and crevice treatment – professional users

Spraying Model 1 (TNsG part 2, p. 143) was used for assessing the scenario concerning indoor crack and crevice application of the biocidal product Draker One by professional users.

Spraying Model 1 is representative of indoor and outdoor, overhead and downward insecticide application by professional users. This model relates to insecticide application to various surfaces and articles in domestic and public areas and is applicable for cracks/crevices treatment. Spraying Model 1 considers mixing and loading to be part of the application process therefore, a separate assessment has not been performed for mixing and loading task.

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

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 3:** **Crack and crevice application of Draker One by professional users** | | |
| Spraying Model 1 (TNsG part 2, p. 143) is considered appropriate to estimate the primary exposure of professional users and includes both mixing/loading task and spraying application.  For professional use, the number of applications *per* day is directly related to the mode of application. According to the TNsG on Human Exposure to Biocides Products (2002), the median duration using “pesticide” is 120 minutes, as much of the operator’s time is spent travelling to the site and surveying. The value of 120 minutes has, therefore, been used in the human risk assessment as the maximum time directly exposed to the insecticide.  By default, professional users should wear suitable protective clothing (impermeable coveralls designed to protect against spray contamination) and protective gloves. Nevertheless, a full assessment including a Tier 1 exposure assessment (no PPE) has been performed for completeness.  The resulting expected total systemic doses, including the total potential exposure (no PPE used) as well as the estimated uptake when protective clothing and gloves are used, are presented in the Annex 3.2 of this document. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professional users | **-** |
| Scenario | Crack and crevice application | **-** |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| Concentration of a.s. in the in-use product (%) | 0.21 | Final concentration of active substance cypermethrin in the in-use diluted product.  The application rate and the dilution of the product for cockroaches was used as worst-case. |
| **Hand Exposure** | |  |
| Indicative value  (mg in-use product/min) | Tier 1: 181 | Indicative value for the deposition on outside of protective gloves (Spraying Model 1). |
| Tier 2: 10.7 | Indicative value for hands exposure inside gloves (Spraying Model 1). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| **Rest of Body Exposure** | |  |
| Indicative value  (mg in-use product/min) | 92 | Indicative exposure value for the rest of the body (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| Clothing penetration (%) | Tier 1  no PPE: 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. |
| Tier 2  impermeable coveralls: 5 | Default protection factor for impermeable coveralls is 95%, according to HEEG opinion 9 “Default protection factors for protective clothing and gloves”. |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| **Inhalation Exposure** | |  |
| Indicative value  (mg in-use product/m3) | 104 | Indicative exposure value for inhalation (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| Inhalation rate (m3/h) | 1.25 | Default short-term inhalation rate for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Inhalation absorption (%) | 100 | Assessment report of cypermethrin. |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |

**Calculations for Scenario 3: Crack and crevice application of the biocidal product Draker One by professional users**

| **Summary table: estimated exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | |
| Scenario 3  Crack and crevice application  Professional users | 1 / no PPE | 0.0091 | 0.149 | **0.1582** |
| 2 / gloves, impermeable coveralls | 0.0091 | 0.0083 | **0.0174** |

**Further information and considerations on Scenario 3**

No further information and considerations available on this scenario.

##### Scenario 4. Application around building – Mosquitoes - professional users

The outdoor use has been considered similar to the indoor use. Spraying Model 1 (TNsG part 2, p. 143) was used for assessing the scenario concerning outdoor application around buildings of the biocidal product Draker One by professional users.

Spraying Model 1 is representative of indoor and outdoor, overhead and downward insecticide application by professional users. This model relates to insecticide application to various surfaces and articles in domestic and public areas. Spraying Model 1 considers mixing and loading to be part of the application process therefore, a separate assessment has not been performed for mixing and loading task.

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

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 4:** **Outdoor** **application around buildings of Draker One by professional users** | | |
| Spraying Model 1 (TNsG part 2, p. 143) is considered appropriate to estimate the primary exposure of professional users and includes both mixing/loading task and spraying application.  For professional use, the number of applications *per* day is directly related to the mode of application. According to the TNsG on Human Exposure to Biocides Products (2002), the median duration using “pesticide” is 120 minutes, as much of the operator’s time is spent travelling to the site and surveying. The value of 120 minutes has, therefore, been used in the human risk assessment as the maximum time directly exposed to the insecticide.  By default, professional users should wear suitable protective clothing (impermable coveralls designed to protect against spray contamination) and protective gloves. Nevertheless, a full assessment including a Tier 1 exposure assessment (no PPE) has been performed for completeness.  The resulting expected total systemic doses, including the total potential exposure (no PPE used) as well as the estimated uptake when protective clothing and gloves are used, are presented in the Annex 3.2 of this document. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professional users | **-** |
| Scenario | Application | **-** |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| Concentration of a.s. in the in-use product (%) | 0.054 | Final concentration of active substance cypermethrin in the in-use diluted product for application around buildings. |
| **Hand Exposure** | |  |
| Indicative value  (mg in-use product/min) | Tier 1: 181 | Indicative value for the deposition on outside of protective gloves (Spraying Model 1). |
| Tier 2: 10.7 | Indicative value for hands exposure inside gloves (Spraying Model 1). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| **Rest of Body Exposure** | |  |
| Indicative value  (mg in-use product/min) | 92 | Indicative exposure value for the rest of the body (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| Clothing penetration (%) | Tier 1  no PPE: 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. |
| Tier 2  impermeable coveralls: 5 | Default protection factor for impermeable coveralls is 95%, according to HEEG opinion 9 “Default protection factors for protective clothing and gloves”. |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| **Inhalation Exposure** | |  |
| Indicative value  (mg in-use product/m3) | 104 | Indicative exposure value for inhalation (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |
| Inhalation rate (m3/h) | 1.25 | Default short-term inhalation rate for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Inhalation absorption (%) | 100 | Assessment report of cypermethrin. |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |

**Calculations for Scenario 4: Application around buildings of the biocidal product Draker One by professional users**

| **Summary table: estimated exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | |
| Scenario 4  Around buildings  Professional users | 1 / no PPE | 0.0023 | 0.038 | **0.041** |
| 2 / gloves, impermeable coveralls | 0.0023 | 0.0022 | **0.0045** |

**Further information and considerations on Scenario 4**

No further information and considerations available on this scenario.

##### Scenario 5. Cleaning of spraying equipment -professional users

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 5: cleaning of spraying equipment by professional users** | | |
| Exposure to the product Draker One can also occur *via* hands and body during cleaning of the spraying equipment. In the absence of a more relevant model, exposure assessment has been performed according to Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure “Cleaning of spray equipment in antifouling use (PT21)”. More specifically the surrogate values from BEAT model database (Delgado et al, 2004) have been used.  It is assumed that professional users wear protective gloves and impermeable coveralls during cleaning of the spraying equipment.  The model and the parameters used for the professional exposure to Draker One are summarised below, while the detailed calculations are presented in the Annex 3.2 of this document. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Professional users | **-** |
| Scenario | Cleaning of spraying equipment | **-** |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| Concentration of a.s. in the in-use product (%) | 0.21 | Final concentration of active substance cypermethrin in the in-use diluted product for crack and crevice application.  The application rate and the dilution of the product for cockroaches was used as worst-case. |
| 0.054 | Final concentration of active substance cypermethrin in the in-use diluted product for application around buildings. |
| Density of product  (mg/μl) | 1.0309 | Product specifications. |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| **Hand Exposure** | |  |
| Indicative value  (μl in-use product/min) | 35.87 | Indicative value for hands exposure. |
| Task duration (min) | 20 | Default value for task duration. |
| Penetration through gloves (%) | 10 | According to the assumptions performed for application task (i.e. Scenario 3, Tier 2), the user wears protective gloves with protection factor 90%, during cleaning of the spraying equipment. |
| **Rest of Body Exposure** | |  |
| Indicative value  (μl in-use product/min) | 19.28 | Indicative exposure value body exposure. |
| Task duration (min) | 20 | Default value for task duration. |
| Clothing penetration (%) | 5 | According to the assumptions performed for application tasks (Tier 2), the professional user wears impermeable coveralls with protection factor 95% during cleaning of the spraying equipment. |

**Calculations for Scenario 5: Cleaning of spraying equipment by professional users**

| **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 5 (i)  Cleaning spraying equipment after crack & crevice application  Professional users | 2 / gloves, impermeable coveralls | - | 4.27 x 10-4 | - | **4.27 x 10-4** |
| Scenario 5 (ii)  Cleaning spraying equipment after  application around buildings  Professional users | 2 / gloves, impermeable coveralls | - | 1.1 x 10-4 | - | **1.1 x 10-4** |

##### Scenario 6. Laundering of contaminated work clothes - professional users

| **Description of Scenario 6:** **Adult professional users laundering contaminated work clothes at home.** | | |
| --- | --- | --- |
| Exposure of adult professional users to the product Draker One 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 Spraying Model 1 (TNsG Part 2, p.143). The indicative dermal exposure value for the body (75th percentile) is 11040 mg spray solution/day. It is also 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 (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| Concentration of a.s. in the in-use product (%) | 0.21 | Final concentration of active substance cypermethrin in the in-use diluted product for crack and crevice application.  The application rate and the dilution of the product for cockroaches was used as worst-case. |
| 0.054 | Final concentration of active substance cypermethrin in the in-use diluted product for application around buildings. |
| Indicative dermal exposure for body (mg product/day | 11040 | Indicative dermal exposure value for the body, according to Spraying Model 1 (TNsG Part 2, p.143). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| Total outer surface area of a medium sized coverall (cm2) | 22700 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Total area of both hands of an adult (cm2) | 820 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Hand contamination (%) | 100 | It is assumed that hand contamination is 100% according to TNsG Part 3, p.43ff, wood preservatives. |
| Transfer coefficient (%) | 30 | The transfer coefficient for contamination (dried fluid) from cotton, knitwear to wet hands is 30% (TNsG Part 2, p.204). |

**Calculations for Scenario 6: Laundering of contaminated work clothes at home by professional users**

| **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 6(i)  Laundering work clothes after crack & crevice application  Professional users | 1 / no PPE | - | 5.44 x 10-4 | - | **5.44 x 10-4** |
| Scenario 6 (ii)  Laundering work clothes after application around buildings  Professional users | 1 / no PPE | - | 1.4 x 10-4 | - | **1.4 x 10-4** |

*Combined scenarios*

Combined scenarios are relevant for professional users exposed to the active substance cypermethrin during application of the product (primary direct exposure – Scenario 3 or Scenario 4), during cleaning of the spraying equipment (primary indirect exposure – Scenario 5) and during laundering of the contaminated work clothes at home (primary indirect exposure – Scenario 6).

The following combinations are made:

* Scenario 3 + Scenario 5 (i) + Scenario 6 (i)
* Scenario 4 + Scenario 5 (ii) + Scenario 6 (ii)

**Combined scenarios**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **mg/kg bw/day** | | | |
| Application,  cleaning, laundering.  Professional users  Scenarios  3 & 5(i) & 6(i) | 2 / gloves, impermeable coveralls | 9.1 x 10-3 | 8.3 x 10-3  +  4.27 x 10-4  +  5.44 x 10-4  =  9.271 x 10-3 | - | **1.84 x 10-2** |
| Application,  cleaning, laundering.  Professional users  Scenarios  4 & 5(ii) & 6(ii) | 2 / gloves, impermeable coveralls | 2.3 x 10-3 | 2.2 x 10-3  +  1.1 x 10-4  +  1.4 x 10-4  =  2.45 x 10-3 | - | **4.75 x 10-3** |

***Non-professional exposure***

##### Scenario 7. Mixing and loading - Crack and crevice treatment – non-professional users

| **Description of Scenario 7: Mixing and loading task for crack and crevice treatment of the biocidal product Draker One by non-professional users.** | | |
| --- | --- | --- |
| Primary exposure of non-professional users during mixing and loading task for crack and crevice application has been estimated using ConsExpo Web, version 1.0.7.  Input parameters used for the exposure assessment are reported in the table below. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non – professional users | - |
| Product fact sheet | Pest control products | - |
| Product category | Mixing and loading | - |
| Product | Mixing and loading | - |
| Scenario | Mixing and loading, liquid | - |
| Frequency | 6 per year | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p.31). |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| **Inhalation exposure** | | |
| Model | Exposure to vapour | - |
| Mode of release | Evaporation from a constant surface | - |
| Exposure duration (min) | 1.33 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Molecular weight matrix (g/mol) | 3000 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Product amount (g) | 500 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Room volume (m3) | 1 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Ventilation rate | 0.6 per hour | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Vapour pressure of cypermethrin (Pa) | 0.0000006 | Assessment Report of cypermethrin. |
| Application temperature (°C) | 25 | Assessment Report of cypermethrin. |
| Molecular weight of cypermethrin (g/mol) | 416.3 | Assessment Report of cypermethrin. |
| Release area (m2) | 0.002 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Emission duration (min) | 1.33 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Inhalation absorption (%) | 100 | Assessment Report of cypermethrin. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Instant application | - |
| Exposed area (cm2) | 820 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Product amount (g) | 0.01 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Retention factor | 1 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |

**Calculations for Scenario 7: Mixing and loading task for crack and crevice treatment of the biocidal product Draker One by non-professional users.**

| **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 7  Mixing&loading for crack & crevice application  Non-professional users | 1 / no PPE | 1.7 x 10-8 | 2.3 × 10⁻³ | - | 2.3 × 10⁻³ |

**Further information and considerations on Scenario 7**

No further information and considerations on this scenario.

##### Scenario 8. Mixing and loading – Outdoor around building – Mosquitoes – non-professional users

Primary exposure of non-professional users resulting from mixing and loading is included in the application task i.e. in Scenario 10.

##### Scenario 9. Application - Crack and crevice treatment – non-professional users

Exposure assessment for application as crack & crevice treatment by non-professional users has been performed using ConsExpo Web version 1.0.7.

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

| **Description of Scenario 9: Crack and crevice application of the biocidal product Draker One by non-professional users.** | | |
| --- | --- | --- |
| Primary exposure of non-professional users for crack and crevice application has been estimated using ConsExpo Web, version 1.0.7.  Input parameters used for the exposure assessment are reported in the table below. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non – professional users | - |
| Product fact sheet | Pest control products | - |
| Product category | Sprays | - |
| Product | Crack & crevice | - |
| Scenario | Application (trigger can) | - |
| Frequency | 9 per year | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (Table 5, p.20). |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Concentration of a.s. in the in-use product (%) | 0.21 | Final concentration of active substance cypermethrin in the in-use diluted product for crack and crevice application.  The application rate and the dilution of the product for cockroaches was used as worst-case. |
| **Inhalation exposure** | | |
| Model | Exposure to spray | - |
| Mode of release | Spraying | - |
| Spray duration (min) | 4 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalatory exposure duration (min) | 240 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Room volume (m3) | 20 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Room height (m) | 2.5 | Standard room height as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Ventilation rate | 0.6 per hour | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalation rate (m3/h) | 1.25 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Mass generation rate (g/s) | 0.4 | Default value, as reported in “New default values for the spray model” RIVM, March 2010. |
| Airborne fraction | 0.008 | Default value, as reported in “New default values for the spray model” RIVM, March 2010. |
| Density non volatile  (g/cm3) | 1.8 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalation cut off diameter (μm) | 15 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Particle distribution - median diameter (μm) | 7.7 | Default value, as reported in “New default values for the spray model” RIVM, March 2010. |
| Particle distribution – arithmetic coefficient of variation | 1.9 | Default value, as reported in “New default values for the spray model” RIVM, March 2010. |
| Maximum diameter (μm) | 50 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalation absorption (%) | 100 | Assessment Report of cypermethrin. |
| Oral non-respirable material exposure | yes | This option includes exposure *via* the oral route of inhaled material that deposits in the higher airways and is ingested. |
| Model | Non-respirable spray model | - |
| Oral absorption (%) | 57 | Assessment Report of cypermethrin. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Constant rate | - |
| Exposed area (cm2) | 820 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Dermal contact rate (mg/min) | 46 | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Release duration (min) | 4 | Spray duration, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |

**Calculations for Scenario 9: Crack and crevice application of the biocidal product Draker One by non-professional users.**

| **Summary table: systemic exposure for general public** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | mg/kg bw/day | | | |
| Scenario 9  Crack and crevice  Non-professional users | 7.1 × 10⁻⁴ | 8.4 × 10⁻⁴ | 6 × 10⁻6 | 1.5 × 10⁻3 |

**Further information and considerations on Scenario 9**

No further information and considerations on this scenario.

##### Scenario 10. Application – Outdoor around buildings – Mosquitoes – non-professional users

Spraying Model 1 (TNsG part 2, p. 143) was used for assessing the scenario concerning outdoor application around buildings of the biocidal product Draker One by non-professional users.

Spraying Model 1 considers mixing and loading to be part of the application process therefore, a separate assessment has not been performed for mixing and loading task.

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

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 10:** **Outdoor** **application around buildings of Draker One by non-professional users** | | |
| Spraying Model 1 (TNsG part 2, p. 143) is considered appropriate to estimate the primary exposure of non-professional users and includes both mixing/loading task and spraying application.  The resulting expected total systemic doses are presented in the Annex 3.2 of this document. | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non-professional users | **-** |
| Scenario | Application | **-** |
| Concentration of a.s. in the concentrated product (%) | 10.53 | Concentration of the active substance cypermethrin in the concentrated product (technical grade). |
| Concentration of a.s. in the in-use product (%) | 0.054 | Final concentration of active substance cypermethrin in the in-use diluted product for application around buildings. |
| **Hand Exposure** | |  |
| Indicative value  (mg in-use product/min) | Tier 1: 181 | Indicative value for the deposition on outside of protective gloves (Spraying Model 1). |
| Task duration (min) | 120 | As a worst-case, task duration for non-professional users is assumed to be 120 min, as for professional users. |
| **Rest of Body Exposure** | |  |
| Indicative value  (mg in-use product/min) | 92 | Indicative exposure value for the rest of the body (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | As a worst-case, task duration for non-professional users is assumed to be 120 min, as for professional users. |
| Clothing penetration (%) | Tier 1  no PPE: 100 | Non-professional users do not wear any protective equipment. |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| **Inhalation Exposure** | |  |
| Indicative value  (mg in-use product/m3) | 104 | Indicative exposure value for inhalation (Spraying Model 1, TNsG part 2, p. 143). |
| Task duration (min) | 120 | As a worst-case, task duration for non-professional users is assumed to be 120 min, as for professional users. |
| Inhalation rate (m3/h) | 1.25 | Default short-term inhalation rate for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Inhalation absorption (%) | 100 | Assessment report of cypermethrin. |
| Body weight (kg) | 60 | Default value for body weight for an adult, according to Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |

**Calculations for Scenario 10: Application around buildings of the biocidal product Draker One by non-professional users**

| **Summary table: estimated exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | |
| Scenario 10  Around buildings  Non-professional users | 1 / no PPE | 0.0023 | 0.038 | **0.041** |

*Combined scenarios*

Combined scenarios are relevant for non-professional users exposed to the active substance cypermethrin during mixing and loading task (primary direct exposure – Scenario 7) and application of the product in crack and crevice (primary direct exposure – Scenario 9).

**Combined scenarios**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| **mg/kg bw/day** | | | |
| Mixing and loading &  Application  Non- professional users  Scenarios  7 & 9 | 1 / no PPE | 1.7 x 10-8  +  7.1 x 10-4  =  7.1 x 10-4 | 2.3 x 10-3  +  8.4 x 10-4  =  3.14 x 10-3 | 6 x 10-6 | 3.8 x 10-3 |

***Exposure of the general public***

##### Scenario 11 - Secondary exposure of the general public

As a worst-case only indoor secondary exposure has been assessed since secondary exposure after outdoor application is deemed less relevant because:

* product concentration in air may be lower due to instant dilution
* usually infants and toddlers don’t crawl on the unpaved floor of rural area; therefore, hand-to-mouth contact is negligible
* usually children don’t play on the floor of rural area or this is less relevant respect the same activity performed indoor.

Secondary exposure - Crack & crevice treatment

Indirect secondary exposure could occur in the residential environment following the application of Draker One. Secondary exposure is considered to be relevant to the general public and is derived *via* inhalation dermal and oral route (hand-to-mouth contact).

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.

Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, a part of residues present on the hands will be dislodged by saliva and eventually ingested.

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.

**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/day,

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 and oral exposure of infants, toddlers and children**

Secondary 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. However, as a worst case, a scenario for the secondary dermal and oral 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.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 11: 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 actual application rate of the product for cracks and crevices application (0.21 g/m2).  Dermal exposure is relevant for infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time.  Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, residues present on the hands will be dislodged by saliva and eventually ingested. Oral exposure has been calculated using the assumption of Bremmer *et al*. (2002) that 10 % of the amount ending up on the skin of the infant is taken up *via* hand-mouth contact. The hands form about 20% of the total uncovered skin and it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that *via* hand-mouth contact 10% of the external dermal exposure is ingested.  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 | Sprays | - |
| Product | Crack and crevice | - |
| Scenario | Post-application (child) | - |
| Application rate  (g/m2) | 75 | The actual application rate of the product for crack and crevice application |
| Concentration of active substance (%) | 0.21 | Final concentration of cypermethrin in the in-use diluted product for crack and crevice application.  The application rate and the dilution of the product for cockroaches was used as worst-case. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Rubbing off | - |
| Exposure frequency | 126 per year | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Exposed area  (palms and backs of both hands) (cm2) | Infant: 196.8  Toddler: 230.4  Child: 427.8 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| Transfer coefficient (m2/hr) | Infant/toddler/child: 0.2 | 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 of product (g/m2) | 19.125 | Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 40), using the actual application rate of Draker One (i.e. taking into account label instruction).  According to RIVM report 320005002 (p.40), “It is assumed that 85% of the total amount sprayed ends up on the floor surface. The 30% of the amount on the floor surface is dislodgeable, i.e., it can be brushed away”.  Therefore, dislodgeable amount for Draker One is calculated as follows:  75 g/m2 x 85% x 30% = 19.125 g/m2 |
| Contact time (min/day) | 60 | Default value for contact time, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Rubbed surface (m2) | 2 | Default value for rubbed surface, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |
| Body weight (kg) | Infant: 8  Toddler: 10  Child: 23.9 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |
| **Oral exposure: hand-to mouth contact** | | |
| Model | Direct product contact | - |
| Loading | Constant rate | - |
| Ingestion rate od product (mg/min) | 6.375 | Calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 28).  “The hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested.  The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact.”  Therefore, the ingestion rate for Draker One is calculated as follows: transfer coefficient x dislodgeable amount x 10% =  (0.2 m2/hr x 19.125 g/m2 x 1000 x 0.1) / 60 = 6.375 mg/min |
| Exposure duration (min) | 60 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Oral absorption (%) | 57 | Assessment report of cypermethrin. |
| Body weight (kg) | Infant: 8  Toddler: 10 | Recommendation no. 14 “Default human factor values for use in exposure assessments for biocidal products. |

**Calculations for Scenario 11: Dermal and oral secondary exposure of infants, toddlers and children**

| **Summary table: systemic exposure for general public** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | mg/kg bw/day | | | |
| Scenario 11  Infants | - | 0.13 | 0.057 | **0.19** |
| Scenario 11  Toddlers | - | 0.1 | 0.046 | **0.15** |
| Scenario 11  Children | - | 0.044 | Not relevant for child | **0.044** |

***Monitoring data***

Monitoring data are not available.

***Dietary exposure***

Food, drinking water or livestock exposure is not foreseen.

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

Livestock exposure is not relevant for Draker One.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake**  (mg/kg bw/day) |
| 3. | Professional users | 1/no PPE | **0.1582** |
| 2 / gloves, impermeable coveralls | **0.0174** |
| 4. | Professional users | 1/no PPE | **0.041** |
| 2 / gloves, impermeable coveralls | **4.5 × 10⁻³** |
| 5(i). | Professional users | 2 / gloves, impermeable coveralls | **4.27 x 10-4** |
| 5(ii). | Professional users | 2 / gloves, impermeable coveralls | **1.1 x 10-4** |
| 6(i). | Professional users | 1/no PPE | **5.44 x 10-4** |
| 6(ii). | Professional users | 1/no PPE | **1.4 x 10-4** |
| 3 & 5(i) & 6(i). | Professional users | 2 / gloves, impermeable coveralls | **0.0184** |
| 4 & 5(ii) & 6(ii). | Professional users | 2 / gloves, impermeable coveralls | **4.75 × 10⁻³** |
| 7. | Non-professional users | 1/no PPE | **2.3 × 10⁻³** |
| 9. | Non-professional users | 1/no PPE | **1.5 × 10⁻3** |
| 10. | Non-professional users | 1/no PPE | **0.041** |
| 7 & 9 | Non-professional users | 1/no PPE | **3.8 × 10⁻3** |
| 11. | Infants | 1/no PPE | **0.19** |
| 11. | Toddlers | 1/no PPE | **0.15** |
| 11. | Children | 1/no PPE | **0.044** |

#### 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 |

At WG-IV-2016, the following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005) as detailed in the following table.

|  |  |  |
| --- | --- | --- |
| **Type of reference value** | **Value** | **Unit** |
| ADI | 0.05 | mg/kg bw/d |
| ARfD | 0.2 | mg/kg bw/d |

***Risk for industrial users***

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

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELlong-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Scenario 3  Application:  crack & crevice  Professional users | 1 / no PPE | 0.022 | **0.1582** | 719% | **no** |
| 2 / gloves, impermeable coveralls | **0.0174** | 79% | **yes** |
| Scenario 4  Application: around building  Professional  users | 1 / no PPE | 0.022 | **0.041** | 186% | **no** |
| 2 / gloves, impermeable coveralls | **0.0045** | 20.5% | **yes** |
| Scenario 5 (i)  Cleaning equipment for crack & crevice application  Professional users | 2 / gloves, impermeable coveralls | 0.022 | **4.27 x 10-4** | 1.94% | **yes** |
| Scenario 5 (ii)  Cleaning spraying equipment for  application around building  Professional users | 2 / gloves, impermeable coveralls | 0.022 | **1.1 x 10-4** | 0.5% | **yes** |
| Scenario 6(i)  Laundering clothes after crack & crevice application  Professional users | 1 / no PPE | 0.022 | **5.44 x 10-4** | 2.5% | **yes** |
| Scenario 6 (ii)  Laundering clothes after application around building  Professional users | 1 / no PPE | 0.022 | **1.4 x 10-4** | 0.6% | **yes** |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AELlong-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Application,  cleaning, laundering.  Professional users  Scenarios  3 & 5(i) & 6(i) | 2 / gloves, impermeable coveralls | 0.022 | **1.74 x 10-2**  **+**  **4.27 x 10-4**  **+**  **5.44 x 10-4**  **=**  **1.84 x 10-2** | 83.5% | **yes** |
| Application,  cleaning, laundering.  Professional users  Scenarios  4 & 5(ii) & 6(ii) | 2 / gloves, impermeable coveralls | 0.022 | **4.5 x 10-3**  **+**  **1.1 x 10-4**  **+**  **1.4 x 10-4**  **=**  **4.75 x 10-3** | 21.6% | **yes** |

**Local effects**

There is no need to consider local effects separately, since the product Draker One is not classified due to its local effects.

**Conclusion**

The primary exposure of professional users is considered acceptable, as the total internal dose is below the long-term AEL, provided that professional users wear protective gloves and impermeable coveralls during application of the product and cleaning of the spraying equipment. Also combined exposure of scenarios [(3, 5(i), 6(i) or 4, 5(ii), 6(ii)] is considered acceptable.

Therefore, there is no concern for the professionals using the biocidal product Draker one, provided that professional users wear protective gloves and impermeable coveralls.

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

| **Scenario number** | **Tier/PPE** | **AELmedium term**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg a.s./kg/d)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| Scenario 7  Mixing&loading; crack & crevice  Non-professional users | 1/no PPE | 0.055 | **2.3 × 10⁻³** | 4.18% | **yes** |
| Scenario 9  Application:  crack & crevice  Non-professional users | 1/no PPE | 0.055 | **1.5 × 10⁻³** | 2.7% | **yes** |
| Scenario 10  Application: around buildings  Professional  users | 1/no PPE | 0.055 | **4.1 x 10-2** | 74.5% | **yes** |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AELlong-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Mixing&loading, Application in crack&crevice  Non-professional users  Scenarios  7 & 9 | 1/no PPE | 0.055 | 2.3 × 10⁻³  +  1.5 × 10⁻³  =  3.8 × 10⁻³ | 6.9% | **yes** |

**Local effects**

There is no need to consider local effects separately, since the product Draker One is not classified due to its local effects.

**Conclusion**

The primary exposure of non-professional users is considered acceptable, as the total internal dose is below the medium-term AEL. Also combined exposure of scenarios (scenarios 7 & 9) is considered acceptable.

Therefore, there is no concern for the non-professional users, when the product is used according to the instructions of use.

***Risk for the general public***

**Systemic effects**

| **Scenario number** | **Tier/PPE** | **AELmedium term**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg a.s./kg/d)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| Scenario 11  Infant | 1/no PPE | 0.055 | **0.19** | 345% | **no** |
| Scenario 11  Toddler | 1/no PPE | 0.055 | **0.15** | 273% | **no** |
| Scenario 11  Child | 1/no PPE | 0.055 | **0.044** | 80% | **yes** |

**Combined scenarios**

Combined scenarios are not relevant for the general public.

**Local effects**

There is no need to consider local effects separately, since the product Draker One is not classified due to its local effects.

**Conclusion**

Regarding secondary exposure of general public, a risk has been identified for infants and toddlers, as the total internal dose is above the medium-term AEL for these populations groups.

Therefore, the following risk mitigation measure is proposed to be included in the product label: “Application of the biocidal product only in areas inaccessible to infants, toddlers and pets”.

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

Risk for consumers via residues in food was not assessed since the product is not proposed for crop use.

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

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product is not necessary since the only active substance in the biocidal product Draker One is cypermethrin and no substances of concern are present in the product.

### Risk assessment for animal health

Risk assessment for animal health is not necessary, since exposure of animals is not expected (i.e. Draker One is not intended to be applied to animals). The product is not used on animals.

### Risk assessment for the environment

**General information**

Environmental risk assessment has been performed according to Biocidal Products Regulation (BPR) EU No 528/2012 and ECHA Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), version 2.0, October 2017.

The biocidal product “Draker One” contains of:

* several substances that are not classified (i.e. not hazardous)
* some substances that are classified for one or more endpoints, that are present in the biocidal product in concentrations below the cut-off values determined according to art. 11 of CLP Regulation.

Moreover, available toxicological information for:

* the active substance (i.e. cypermethrin), and
* all co-formulants

are deemed sufficient for the hazard assessment of Draker One.

For these reasons, in the sections below, environmental 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.

#### Effects assessment on the environment

*PNECs values*

PNECs values used for the risk assessment of the product are the same PNECs values used for the active substance cypermethrin, and are detailed in the table below.

|  |  |
| --- | --- |
| **Cypermethrin** | |
| Surface water | 0.004 μg/l |
| Freshwater sediment | 0.050 mg/Kg wwt (Cypermethrin, CAR, 2019) |
| Microorganisms in STP | 1.63 mg/l |
| Soil | 0.0708 mg/Kg wwt (0.08 mg/Kg soil dw) |

|  |  |
| --- | --- |
| Oral bird | 33.3 mg a.s/kg feed |
| Oral small mammal | 3.3 mg a.s/kg food |

***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***

Ecotoxicity data for the product are not available. Ecotoxicity data are available for each components of the product, and as a result of the application of the classification rules of Annex I of CLP Regulation, the product is classified as Aquatic Acute 1 and Aquatic Chronic 1.

***Further Ecotoxicological studies***

Further ecotoxicological studies are not available.

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

No data available.

***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.

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

Please, refer to section Fate and distribution in exposed environmental compartments.

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

No data available.

***Leaching behaviour (ADS)***

No data available.

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

No data available.

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

No data available.

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

No data available.

***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)***

No data available.

**Acute aquatic toxicity**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Acute aquatic toxicity** | |
| Value/conclusion | Aquatic Acute 1  H400: Very toxic to aquatic life. |
| Justification for the value/conclusion | The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:  The ‘relevant components’ of a mixture are those which are classified ‘Acute 1’or ‘Chronic 1’ and present in a concentration of 0.1 % (w/w) or greater, and those which are classified ‘Chronic 2’, ‘Chronic 3’ or ‘Chronic 4’ and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as ‘Acute 1’ or ‘Chronic 1’ the concentration to be taken into account is (0.1/M) %.  The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:  - classification based on tested mixtures,  - classification based on bridging principles,  - the use of ‘summation of classified components’ and/or an ‘additivity formula’.  The classification of the product has been determined using ecotoxicological data on active substance and co-formulants.  More specifically, cypermethrin and one co-formulant are classified as hazardous for the environment and are relevant substance, due to their concentration, for the classification of the product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute aquatic toxicity |
| Justification | According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected. |

**Chronic aquatic toxicity**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment- Chronic Aquatic toxicity** | |
| Value/conclusion | Aquatic Chronic 1  H410: Very toxic to aquatic life with long lasting effects. |
| Justification for the value/conclusion | The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:  The ‘relevant components’ of a mixture are those which are classified ‘Acute 1’or ‘Chronic 1’ and present in a concentration of 0.1 % (w/w) or greater, and those which are classified ‘Chronic 2’, ‘Chronic 3’ or ‘Chronic 4’ and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as ‘Acute 1’ or ‘Chronic 1’ the concentration to be taken into account is (0,1/M) %. (For explanation M-factor see section 4.1.3.5.5.5.)  The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:  - classification based on tested mixtures,  - classification based on bridging principles,  - the use of ‘summation of classified components’ and/or an ‘additivity formula’.  The classification of the product has been determined using ecotoxicological data on active substance and co-formulants.  More specifically, cypermethrin and one co-formulant are classified as hazardous for the environment and are relevant substance, due to their concentration, for the classification of the product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Chronic aquatic toxicity |
| Justification | According to the specific adaptation rules described in Annex III of BPR, testing on the product was not conducted because there were valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008 and no synergistic effects between the components of the mixture were expected. |

**Measured aquatic bioconcentration**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Aquatic bioconcentration** | |
| Value/conclusion | Cypermethrin does not meet the B or vB screening criteria. |
| Justification for the value/conclusion | Data on bioconcentration are available in the CAR of cypermetrin, as reported below.  *Data on cypermetrin from CAR*  Cypermethrin cis:trans/40:60 is not bioconcentrated according to a flow through OECD 305 E test, with a measured BCF of 373±45 < 2000 L/Kg wwt. The result is further confirmed by BCFwin (EPISUIT) which provide a BCF of 417L/Kgwwt Cypermethrin cis:trans/40:60 is not bioaccumulable (B).  TDCVC and CDCVC metabolite have a Log Pow of 2.672 (calculation based on their smiles code) according to the eq.74 of the TGD, the corresponding BCF is 37.25; therefore, TDCVC and CDCVC metabolites does not fulfil the B criteria. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Aquatic bioconcentration |
| Justification | Data suggest that cypermethrin does not meet the B or vB screening criteria. |

***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)***

No risks for bees or other non-target arthropods are expected when product is used in outdoor applications adhering to label instructions.

***Endocrine-distrupting properties for environment: screening for co-formulants***

Screening of endocrine-distrupting properties of co-formulants has been performed according to CG document “Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products – instructions for applicants”.

Overall, based on available information it is concluded that the product does not contain co-formulants with endocrine distrupting properties for environment.

Please, refer to the Confidential Annex for further details.

#### Exposure assessment

Environmental exposure assessment for each relevant use of the product has been performed following the indication provided in the Emission Scenario Document for PT18. Moreover, recent modifications agreed upon by Member States at the Biocides Technical Meetings and published in the most recent version of the Manual of Technical Agreements were also included to derive the PECs values.

Environmental exposure has been determined for each relevant primary and secondary compartment exposed as a result of indoor and outdoor uses of the product.

Emissions to environmental compartments have been calculated using the European Union System for the Evaluation of Substances (EUSES version 2.2.0).

Environmental toxicity of relevant metabolites of cypermethrin have been discussed in the CAR of cypermethrin and a brief summary is reported below.

*The major degradation pathway of cypermethrin in water, soil, plants, insects, birds and fish consists in the cleavage of cypermethrin into a cyclopropane carbonic acid and dibenzyl (3-phenoxybenzoic acid) moiety (= 3pba). In these degradation studies, DCVC acid accounted for up to 40% of the applied dose in water, 17.4% in soil and 33.4% in plants (as conjugate in this latter case).*

*Maximum percentage of cypermethrin degradation product identified in degradation studies.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | 3-PBA | DCVC | 3 PBAD |
| Photlyse in water\* | 15% | 18% | 3% |
| Photolyse in soil\* | 6% | 3% | / |
| Water | 21% | 38% | / |
| Sediment | 29% | 20% | / |
| Aerobic soil degradation | 10.2% | 17.5%1 | / |
| Anaerobic degradation soil | 35.1% | 31.2% | 0.7 |

\*irradiated samples

1 Trans-DCVC + Cis-DCVC

*The relevant metabolites are 3-PBA and DCVC. Whith such high concentrations of metabolites rapidly found in the various metabolism/ degradation studies, one can consider that its toxicity is covered by the studies on cypermethrin (Evaluation report on the equivalence; Agriphar Confidential 2007).*

Even though in the CAR of cypermethrin an exposure assessment of metabolites has not been performed, for Draker One an environmental risk assessment for metabolites has been performed.

Groundwater concentrations of cypermethrin have been assumed the same of porewater concentration.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | *Indoor*  Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional  Use 2 - Crack and crevice spot treatment, indoor - crawling insects - non-professional  *Outdoor*  Use 3 - Treatment around building - Flying insects (Mosquitoes) - professional  Use 4 - Treatment around the building - Flying insects (Mosquitoes) - non-professional |
| ESD(s) used | Emission Scenario Document for Product Type 18: EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES. 17-Jul-2008. |
| Approach | The approach followed is average consumption based for all scenarios. |
| Distribution in the environment | Calculated based on Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017.  Technical Agreements on Biocides (TAB), v. 2.1 (2019) |
| Groundwater simulation | The concentration in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk. |
| Confidential Annexes | YES: EUSES calculations for all scenarios are reported in confidential Annex. |
| Life cycle steps assessed | Uses of the biocidal product. Production of the biocidal product (that is a formulation) has not been assessed since it out of scope of BPR. Service life is not relevant for this product. |
| Remarks | No remarks. |

***Emission estimation***

**Formulation of the product**

Production of Draker One is an industrial formulation process. Exposure estimation for the formulation of Draker One was not performed since:

* releases into the environment can not take place from formulation process since in the formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed systems). Since a close system is used no emission is expected; in any case eventual (i.e. accidental or due to manteinance) relases of the product are collected and managed as waste
* emissions from product formulation are considered less relevant (since potentially covered by other legislations) compared to emissions from the application - and in service phase of the product, as reported in "Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment, Version 1.0".

##### Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional

Mains input parameters used in EUSES for calculating the local emission arising from use of the biocidal product are reported in the table below.

Table. Indoor crack and crevice spot treatment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment of TIER 1** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | Draker one is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, crack and crevices | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot, crack and crevices treatment for a domestic house is 2 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Total area treated in a large building | 9.3 | m2 | Default value for spot, crack and crevice treatment for large building (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Wet cleaning zone in a standard house (leading to releases to the STP) | 2 | m2 | Default value, ENV TAB 2.1 (2019). |
| Wet cleaning zone in a large building (leading to releases to the STP) | 9.3 | m2 | Default value, ENV TAB 2.1 (2019). |
| Number of standard houses connected to the same STP | 4000 | - | Default value, ENV TAB 2.1 (2019). |
| Number of large buildings connected to the same STP | 300 | - | Default value, ENV TAB 2.1 (2019). |
| Number of emission days | 2 | days | Maximum number of applications per year. |
| **Mixing & loading** |  |  |  |
| Quantity of commercial product used per preparation | 3 | g | 3.0 g of a solution at 10.5% w/w of active substance have to be diluted in a final volume of 150 mL of water.  3.0 g × 10.5/100 = 0.315 g active substance  0.315 g / 0.15 L = 2.1 g/L = 0.21 % |
| Number of preparations per day, standard house | 1 | - | The number of preparations is a function of the size of the buildings. For private, houses, it is assumed that one preparation is sufficient whether performed by general public or professionals.  For larger buildings, which are more likely to be treated by professionals, it is assumed that up to 5 preparations are needed (75 mL/m2\*9.3m2/150mLpreparation = 4.65) |
| Number of preparations per day, large building | 5 | - |
| Container type/volume | 1 litre container with unspecific design | - | - |
| Fraction emitted to air during mixing/loading | 0 | - | OECD ESD PT18, p.44. |
| Fraction emitted to the applicator during mixing/loading | 0.0012 | - | OECD ESD PT18, p.45. |
| Fraction emitted to the floor during mixing/loading | 0.0001 | - | Emission factors to floor expressed as ml of commercial product per operation (conducted by professionals) for containers of 1 L (OECD ESD PT18, p. 46, Table 3.2-3). |
| **Application** | | | |
| Quantity of commercial product applied per m2 | 1.52 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  75 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 75 g x 0.21% = 0.16 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.16 g/m2.  Quantity of commercial product per application is 0.16 x (100/10.5) (i.e. 1.52 g) since the product is at 10.5%. |
| Number of applications per day in a standard house | 1 | d-1 | - |
| Number of applications per day in a large building | 1 | d-1 | - |
| Frequency of application in a standard house | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in standard houses | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Frequency of application in large buildings | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in large buildings | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Fraction emitted to air during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the applicator during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the floor during application | 0.11 | - | Default value (OECD ESD PT18). |
| Fraction emitted to treated surfaces during application | 0.85 | - | Default value for “fraction emitted to treated surfaces” is 0.85. |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | Default cleaning efficiency for spot crack and crevices, as reported in Table 3.3-8, ESD PT18, p. 64. |
| Washable coveralls or disposable coveralls | washable coveralls | - | - |
| Dry or wet cleaning of treated surfaces | Wet cleaning of treated surfaces | - | - |

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment of TIER 2**  **In TIER 2 emission to treated surfaces has been set to 0, since in TIER 1 (i.e. scenario with the default value 0.85) risk was not acceptable for sediment. Therefore, it has been decided to limit the application of the product in areas not subject to wet cleaning. With this RMM emission to surface water will be reduced.** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | Draker one is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, crack and crevices | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot, crack and crevices treatment for a domestic house is 2 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Total area treated in a large building | 9.3 | m2 | Default value for spot, crack and crevice treatment for large building (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Wet cleaning zone in a standard house (leading to releases to the STP) | 2 | m2 | Default value, ENV TAB 2.1 (2019). |
| Wet cleaning zone in a large building (leading to releases to the STP) | 9.3 | m2 | Default value, ENV TAB 2.1 (2019). |
| Number of standard houses connected to the same STP | 4000 | - | Default value, ENV TAB 2.1 (2019). |
| Number of large buildings connected to the same STP | 300 | - | Default value, ENV TAB 2.1 (2019). |
| Number of emission days | 2 | days | Maximum number of applications per year. |
| **Mixing & loading** |  |  |  |
| Quantity of commercial product used per preparation | 3 | g | 3.0 g of a solution at 10.5% w/w of active substance have to be diluted in a final volume of 150 mL of water.  3.0 g × 10.5/100 = 0.315 g active substance  0.315 g / 0.15 L = 2.1 g/L = 0.21 % |
| Number of preparations per day, standard house | 1 | - | The number of preparations is a function of the size of the buildings. For private, houses, it is assumed that one preparation is sufficient whether performed by general public or professionals.  For larger buildings, which are more likely to be treated by professionals, it is assumed that up to 5 preparations are needed (75 mL/m2\*9.3m2/150mLpreparation = 4.65) |
| Number of preparations per day, large building | 5 | - |
| Container type/volume | 1 litre container with unspecific design | - | - |
| Fraction emitted to air during mixing/loading | 0 | - | OECD ESD PT18, p.44. |
| Fraction emitted to the applicator during mixing/loading | 0.0012 | - | OECD ESD PT18, p.45. |
| Fraction emitted to the floor during mixing/loading | 0.0001 | - | Emission factors to floor expressed as ml of commercial product per operation (conducted by professionals) for containers of 1 L (OECD ESD PT18, p. 46, Table 3.2-3). |
| **Application** | | | |
| Quantity of commercial product applied per m2 | 1.52 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  75 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 75 g x 0.21% = 0.16 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.16 g/m2.  Quantity of commercial product per application is 0.16 x (100/10.5) (i.e. 1.52 g) since the product is at 10.5%. |
| Quantity of commercial product applied per m2 | 2.0 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  100 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 100 g x 0.21% = 0.21 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.21 g/m2.  Quantity of commercial product per application is 0.21 x (100/10.5) (i.e. 2.05 g) since the product is at 10.5%. |
| Number of applications per day in a standard house | 1 | d-1 | - |
| Number of applications per day in a large building | 1 | d-1 | - |
| Frequency of application in a standard house | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in standard houses | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Frequency of application in large buildings | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in large buildings | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Fraction emitted to air during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the applicator during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the floor during application | 0.11 | - | Default value (OECD ESD PT18). |
| Fraction emitted to treated surfaces during application | 0.85 | - | Default value (OECD ESD PT18).  Set to zero for application of the product in areas not subject to wet cleaning. |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | Default cleaning efficiency for spot crack and crevices, as reported in Table 3.3-8, ESD PT18, p. 64. |
| Washable coveralls or disposable coveralls | washable coveralls | - | - |
| Dry or wet cleaning of treated surfaces | Wet cleaning of treated surfaces | - | - |

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment of TIER 3**  **In TIER 2 emission to treated surfaces has been set to 0, since in TIER 1 (i.e. scenario with the default value 0.85) risk was not acceptable for sediment. Therefore, it has been decided to limit the application of the product in areas not subject to wet cleaning. With this RMM emission to surface water will be reduced.**  **Moreover, disposable coveralls have been assumed as additional RMM.** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | Draker one is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, crack and crevices | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot, crack and crevices treatment for a domestic house is 2 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Total area treated in a large building | 9.3 | m2 | Default value for spot, crack and crevice treatment for large building (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Wet cleaning zone in a standard house (leading to releases to the STP) | 2 | m2 | Default value, ENV TAB 2.1 (2019). |
| Wet cleaning zone in a large building (leading to releases to the STP) | 9.3 | m2 | Default value, ENV TAB 2.1 (2019). |
| Number of standard houses connected to the same STP | 4000 | - | Default value, ENV TAB 2.1 (2019). |
| Number of large buildings connected to the same STP | 300 | - | Default value, ENV TAB 2.1 (2019). |
| Number of emission days | 2 | days | Maximum number of applications per year. |
| **Mixing & loading** |  |  |  |
| Quantity of commercial product used per preparation | 3 | g | 3.0 g of a solution at 10.5% w/w of active substance have to be diluted in a final volume of 150 mL of water.  3.0 g × 10.5/100 = 0.315 g active substance  0.315 g / 0.15 L = 2.1 g/L = 0.21 % |
| Number of preparations per day, standard house | 1 | - | The number of preparations is a function of the size of the buildings. For private, houses, it is assumed that one preparation is sufficient whether performed by general public or professionals.  For larger buildings, which are more likely to be treated by professionals, it is assumed that up to 5 preparations are needed (75 mL/m2\*9.3m2/150mLpreparation = 4.65) |
| Number of preparations per day, large building | 5 | - |
| Container type/volume | 1 litre container with unspecific design | - | - |
| Fraction emitted to air during mixing/loading | 0 | - | OECD ESD PT18, p.44. |
| Fraction emitted to the applicator during mixing/loading | 0.0012 | - | OECD ESD PT18, p.45. |
| Fraction emitted to the floor during mixing/loading | 0.0001 | - | Emission factors to floor expressed as ml of commercial product per operation (conducted by professionals) for containers of 1 L (OECD ESD PT18, p. 46, Table 3.2-3). |
| **Application** | | | |
| Quantity of commercial product applied per m2 | 1.52 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  75 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 75 g x 0.21% = 0.16 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.16 g/m2.  Quantity of commercial product per application is 0.16 x (100/10.5) (i.e. 1.52 g) since the product is at 10.5%. |
| Quantity of commercial product applied per m2 | 2.0 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  100 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 100 g x 0.21% = 0.21 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.21 g/m2.  Quantity of commercial product per application is 0.21 x (100/10.5) (i.e. 2.05 g) since the product is at 10.5%. |
| Number of applications per day in a standard house | 1 | d-1 | - |
| Number of applications per day in a large building | 1 | d-1 | - |
| Frequency of application in a standard house | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in standard houses | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Frequency of application in large buildings | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in large buildings | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Fraction emitted to air during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the applicator during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the floor during application | 0.11 | - | Default value (OECD ESD PT18). |
| Fraction emitted to treated surfaces during application | 0 | - | Set to zero for application of the product in areas not subject to wet cleaning. |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | Default cleaning efficiency for spot crack and crevices, as reported in Table 3.3-8, ESD PT18, p. 64. |
| Washable coveralls or disposable coveralls | disposable coveralls | - | Disposable coveralls must be used by professionals. |
| Dry or wet cleaning of treated surfaces | Wet cleaning of treated surfaces | - | - |

Calculations for Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional (0.21%)

**TIER 1**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Private use -Houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 6.84 x 10-4 | - |
| Air | 5.21 x 10-5 | . |
| **Industrial use- Large buildings & houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 9.19 x 10-4 | - |
| Air | 7.03 x 10-5 | . |

**TIER 2**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Private use -Houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 1.3 x 10-4 | - |
| Air | 5.21 x 10-5 | . |
| **Industrial use- Large buildings & houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 1.72 x 10-4 | - |
| Air | 7.03 x 10-5 | . |

**TIER 3**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Private use -Houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 7.43 x 10-5 | - |
| Air | 5.21 x 10-5 | . |
| **Industrial use- Large buildings & houses** | | |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 9.71 x 10-5 | - |
| Air | 7.03 x 10-5 | . |

##### Use 2 - Crack and crevice spot treatment, indoor - crawling insects - non-professional

This use is the same of the previous named “Use 1 Crack and crevice spot treatment – crawling insects – professional”, but performed by non-professional users.

The main differences are:

* usually non-professional users don’t use the product in large buildings, but only in house
* the use of disposable coveralls is not applicable for a non-professional user.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | Draker one is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, crack and crevices | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot, crack and crevices treatment for a domestic house is 2 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Wet cleaning zone in a standard house (leading to releases to the STP) | 2 | m2 | Default value, ENV TAB 2.1 (2019). |
| Number of standard houses connected to the same STP | 4000 | - | Default value, ENV TAB 2.1 (2019). |
| Number of emission days | 2 | days | Maximum number of applications per year. |
| **Mixing & loading** |  |  |  |
| Quantity of commercial product used per preparation | 3 g | g | 3.0 g of a solution at 10.5% w/w of active substance have to be diluted in a final volume of 150 mL of water.  3.0 g × 10.5/100 = 0.315 g active substance  0.315 g / 0.15 L = 2.1 g/L = 0.21 % |
| Number of preparations per day, standard house | 1 | - | The number of preparations is a function of the size of the buildings. For private, houses, it is assumed that one preparation is sufficient whether performed by general public or professionals. For larger buildings, which are more likely to be treated by professionals, it is assumed that up to 3 preparations are needed (ESD PT 18, p.47) |
| Container type/volume | 1 litre container with unspecific design | - | - |
| Fraction emitted to air during mixing/loading | 0 | - | OECD ESD PT18, p.44. |
| Fraction emitted to the applicator during mixing/loading | 0.0012 | - | OECD ESD PT18, p.45. |
| Fraction emitted to the floor during mixing/loading | 0.0001 | - | Emission factors to floor expressed as ml of commercial product per operation (conducted by professionals) for containers of 1 L (OECD ESD PT18, p. 46, Table 3.2-3). |
| **Application** | | | |
| Quantity of commercial product applied per m2 | 1.52 | g/m2 | Commercial product at 10.5% is diluted in mixing & loading phase before use. Product used for surface treatment is at 0.21%.  75 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 75 g x 0.21% = 0.16 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.16 g/m2.  Quantity of commercial product per application is 0.16 x (100/10.5) (i.e. 1.52 g) since the product is at 10.5%. |
| Number of applications per day in a standard house | 1 | d-1 | - |
| Frequency of application in a standard house | 1-2 | times a year | - |
| Simultaneity factor for indoor uses of insecticide in standard houses | 2.042 × 10-3 | - | The maximum number of permitted indoor applications of cypermethrin is twice per year per premises. This results in an indoor simultaneity factor for cypermethrin of 0.2%.  Indoor simultaneity factor (37.82 × 0.54)/100 = 0.2%. |
| Fraction emitted to air during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the applicator during application | 0.02 | - | Default value (OECD ESD PT18). |
| Fraction emitted to the floor during application | 0.11 | - | Default value (OECD ESD PT18). |
| Fraction emitted to treated surfaces during application | 0.85 | - | Default value (\*) |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | Default cleaning efficiency for spot crack and crevices, as reported in Table 3.3-8, ESD PT18, p. 64. |
| Washable coveralls or disposable coveralls | washable coveralls | - | - |
| Dry or wet cleaning of treated surfaces | Wet cleaning of treated surfaces | - | - |

(\*) Emission to treated surfaces has been set to 0, since in Scenario 1, TIER 1 (i.e. scenario with the default value 0.85) risk was not acceptable for sediment. Therefore, it has been decided to limit the application of the product in areas not subject to wet cleaning. With this RMM emission to surface water will be reduced.

Calculations for Use 2 - Crack and crevice spot treatment, indoor - crawling insects - non-professional

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 1.30 x 10-4 | - |
| Air | 5.21 x 10-5 | - |

##### Use 3 - Treatment around building - Flying insects (Mosquitoes) - professional

Exposure assessment for treatment with Draker One around building against flying insects (mosquitoes) by professionals has been performed according ESD PT18 and; therefore, taking in consideration:

* when the product is applied in urban areas
* when the product is applied in rural ares.

**Urban areas**

Mains input parameters used in EUSES for calculating the local emission arising from use of the biocidal product are reported in the table below.

Table Treatment around building - Flying insects (Mosquitoes) - Urban area.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of the substance in commercial product | 0.105 | - | i.e. 10.5% w/w |
| Location of the treated surface | Urban area | - | - |
| Cover mixing and loading | yes | - | - |
| Number of standard houses connected to the same STP | 2500 | - | Default value. |
| Number of large buildings connected to the same STP | 300 | - | Default value. |
| Number of emission days | 2 | d.yr-1 | According to label instructions. |
| **Mixing and loading** | | | |
| Quantity of commercial product used per preparation | 5.1 | g | 5.1 g of a solution at 10.5% of active substance have to be diluted in a final volume of 1 L of water.  5.1 g × 10.5/100 = 0.54 g active substance  0.54 g / 1 L = 0.054% |
| Number of preparations per day, standard house | 5 | d-1 | Dose is 22 mg active substance/ m2.  Product is diluted before use to 0.054%.  Quantity of product = 22 x 100/0.054 = 40.7 g/m2  125 m2 x 40.7 g/m2 = 5087 g  About 5 preparation of 1 L. |
| Number of preparations per day, large buildings | 25 | d-1 | Dose is 22 mg active substance/ m2.  Product is diluted before use to 0.054%.  Quantity of product = 22 x 100/0.054 = 40.7 g/m2  625 m2 x 40.7 g/m2 = 25437 g  About 25 preparation of 1 L. |
| Container type/volume | 1 | L | 1 litre container with unspecific design. |
| Fraction emitted to soil during mixing/loading | 0.0001 | - | - |
| **Application** |  |  |  |
| Quantity of commercial product applied per m2 | 0.21 | g/m2 | Dose is 22 mg active ingredient/m2.  Product is at 10.5%.  22\*100/10.5 = 209.5 mg product m2 = 0.2095 g/m2. |
| Area of exterior wall treated per day, standard house | 125 | m2/d | Default value. |
| Area of exterior wall treated per day, large building | 625 | m2/d | Default value. |
| Fraction emitted to soil during application | 0.3 | - | Default value. |
| Fraction emitted to soil due to wash-off by rainfall | 0.5 | - | Default value. |
| Frequency of application in standard houses | 1-2 | times a year | According to label instructions. |
| Simultaneity factor for outdoor use of insecticide in standard houses | 0.002042 | - | - |
| Frequency of application in large building | 1-2 | times a year | According to label instructions. |
| Simultaneity factor for outdoor use of insecticide in large building | 0.002042 | - | - |

Calculations for Scenario 3 - Treatment around the building - Flying insects (mosquitoes) – Urban area

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 0.018 | - |

**Rural area**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TIER 1 assessment: in this first Tier, exposure has been estimated using default areas (both for hause and large buildings) of exterior wall treated per day.** | | | | |
| **Input** | **Value** | **Unit** | | **Remarks** |
| **General** | | | | |
| Fraction of active substance in the commercial product | 0.105 | - | | Draker one is a biocidal product with 10.5% of cypermethrin. |
| Location of the treated surface | Rural area | - | | - |
| Cover mixing and loading | No | - | | It is assumed that usually mixing and loading take place indoor. |
| Bulk density of the soil | 1700 | Kg wwt/m3 | | Default value. |
| Density of solid phase | 2500 | kg/m3 | | Default value. |
| Volume fraction of solids in soil | 0.6 | m3/m3 | | Default value. |
| Soil-water partition coefficient | 1.73E+04 | m3/m3 | | Calculated by EUSES. |
| Conversion factor for soil concentration wet-dry weight soil | 1.133 | kg wwt/ke dwt | | Default value. |
| **Application** | | | | |
| Quantity of commercial product applied per m2 | 0.21 | g/m2 | | As g of product per area.  Calculated as follow.  40 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 40 g x 0.054% = 0.0216 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.022 g/m2.  The commercial product is 10.5%; therefore, the quantity of product is 0.022 x 100/10.5 = 0.21 g/m2 |
| Area of exterior wall treated per day, standard house | 125 | | m2/d | Default value. |
| Area of exterior wall treated per day, large building | 625 | | m2/d | Default value. |
| Soil volume around a standard house | 13 | | m3 | Default value. |
| Soil volume around a large building | 63 | | m3 | Default value. |
| Fraction emitted to soil during application | 0.3 | | - | Default value. |
| Fraction emitted to soil due to wash-off by rainfall | 0.5 | | - | Default value. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TIER 2 assessment: refinement of application areas (both for house and large buildings) of exterior wall treated with some realistic values.**  **For this type of use, the treatment of the entire wall in height (i.e. 2.5 m) is not realistic. It is assumed that a band up to 1.6 m can be treated; therefore, areas of exterior wall treated have been recalculated and, instead, soil volume is the same (i.e. default value).** | | | | |
| **Input** | **Value** | **Unit** | | **Remarks** |
| **General** | | | | |
| Fraction of active substance in the commercial product | 0.105 | - | | Draker One is a biocidal product with 10.5% of cypermethrin. |
| Location of the treated surface | Rural area | - | | - |
| Cover mixing and loading | No | - | | It is assumed that usually mixing and loading take place indoor. |
| Bulk density of the soil | 1700 | Kg wwt/m3 | | Default value. |
| Density of solid phase | 2500 | kg/m3 | | Default value. |
| Volume fraction of solids in soil | 0.6 | m3/m3 | | Default value. |
| Soil-water partition coefficient | 1.73E+04 | m3/m3 | | Calculated by EUSES. |
| Conversion factor for soil concentration wet-dry weight soil | 1.133 | kg wwt/ke dwt | | Default value. |
| **Application** | | | | |
| Quantity of commercial product applied per m2 | 0.21 | g/m2 | | As g of product per area.  Calculated as follow.  40 ml of insecticide solution covers 1 m2. Quantity of active ingredient applied to floor (1 m2) = 40 g x 0.054% = 0.0216 g (density = 1.018).  So, quantity of active ingredient per square metre of floor = 0.022 g/m2.  The commercial product is 10.5%; therefore, the quantity of product is 0.022 x 100/10.5 = 0.21 g/m2 |
| Area of exterior wall treated per day, standard house | 80 | | m2/d | For this type of use, the treatment of the entire wall in height (i.e. 2.5 m) is not realistic. It is assumed that a band up to 1.6 m can be treated; therefore, areas of exterior wall treated have been recalculated and, instead, soil volume is the same (i.e. default value).  Treatment up to 80 m2 has been assumed as a worst-case. This value cover the instructions of use of the product. The value of 80 m2 is in accordance and conservative respect to the surface treated in efficacy studies. |
| Area of exterior wall treated per day, large building | 400 | | m2/d | For this type of use, the treatment of the entire wall in height (i.e. 2.5 m) is not realistic. It is assumed that a band up to 1.6 m can be treated; therefore, areas of exterior wall treated have been recalculated and, instead, soil volume is the same (i.e. default value).  Treatment up to 400 m2 has been assumed as a worst-case. This value cover the instructions of use of the product. |
| Soil volume around a standard house | 13 | | m3 | This parameter remain as a default since it is assumed that not the entire height of the wall is treated, but only a band up to 1.6 m. |
| Soil volume around a large building | 63 | | m3 | This parameter remain as a default since it is assumed that not the entire height of the wall is treated, but only a band up to 1.6 m. |
| Fraction emitted to soil during application | 0.3 | | - | Default value. |
| Fraction emitted to soil due to wash-off by rainfall | 0.5 | | - | Default value. |

Calculations for Use 3 - Treatment around the building - Flying insects – professional – Urban area TIER 1

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Local emission to soil, standard house | 0.0022 | - |
| Local emission to soil, large building | 0.011 | - |

Calculations for Use 3 - Treatment around the building - Flying insects – professional – Rural area TIER 2

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Local emission to soil, standard house | 0.00141 | - |
| Local emission to soil, large building | 0.00706 | - |

##### Use 4 - Treatment around building - Flying insects (mosquitoes) - non-professional

Exposure assessment for this use is covered by “Use 3 - Treatment around building - Flying insects (mosquitoes) – professional – Rural area TIER 2”, but only houses are relevant (i.e. large buildings are not relevant for professionals).

Calculations for Use 4 - Treatment around building - Flying insects (mosquitoes) – non-professional – Rural area TIER 2

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Local emission to soil, standard house | 0.00141 | - |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 416.3 | g/mol | - |
| Melting point | 47 | °C | - |
| Boiling point | Not determined | °C | Boiling did not occur: decomposition was observed |
| Vapour pressure (at 25°C) | 0.0000006 | Pa | - |
| Water solubility (at 20°C) | 0.004 | mg/l | - |
| Log Octanol/water partition coefficient | 5.45 | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | 575000 | l/kg | - |
| Henry’s Law Constant (at 20 °C) | 0.024 | Pa/m3/mol | - |
| Biodegradability | Not biodegradable | - | - |
| Rate constant for STP *[if measured data available]* | Not available | h-1 | Experimental data not available |
| DT50 for biodegradation in surface water | 0.948 | d (at 12ºC) | - |
| DT50 for hydrolysis in surface water | 98.9 | d (at 12ºC /pH 7) | pH 9 = 39.71 hours |
| DT50 for photolysis in surface water | 8.85 (14C phenoxy)  7.10 (14C cyclopropane) | d | cis-isomers are degraded 1.3 to 1.7 times faster than trans-isomers |
| DT50 for degradation in soil | 17.2 | d (at 12ºC) | based on the geom.mean |
| DT50 for degradation in air | 0.749 | d | - |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| Compartment | Percentage [%] | Remarks |
| Air | 5.44 x 10-4 | For all scenarios where STP is relevant. |
| Water | 8.356 |
| Primary settler | 66.15 |
| Surplus sludge | 25.5 |
| Degraded in STP | 0 |

***Metabolites***

As reported in the CAR of cypermethrin (Document II-A, January 2017) the major degradation pathway of cypermethrin in water, soil, plants, insects, birds and fish consists in the cleavage of cypermethrin into a cyclopropane carbonic acid and dibenzyl (3-phenoxybenzoic acid) moiety (i.e. 3pba). In these degradation studies, DCVC acid accounted for up to 40% of the applied dose in water, 17.4% in soil and 33.4% in plants (as conjugate in this latter case).

Maximum percentage of cypermethrin degradation products identified in degradation studies are reported in Table below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **3-PBA** | **DCVC** | **3 PBAD** |
| Photlyse in water \* | 15% | 18% | 3% |
| Photolyse in soil \* | 6% | 3% | / |
| Water | 21% | 38% | / |
| Sediment | 29% | 20% | / |
| Aerobic soil degradation | 10.2% | 17.5% (1) |  |
| Anaerobic degradation soil | 35.1% | 31.2% | 0.7 |

\*irradiated samples

(1) Trans-DCVC + Cis-DCVC

The relevant metabolites are 3-PBA and DCVC.

For 3-PBA, the following PNEC values are available (same values used in CAR of permethrin, April 2014).

|  |  |
| --- | --- |
| **PBA** | |
| Surface water | > 0.010 mg/L |
| Soil (wet weight) | 1.44 mg/kg wwt |
| Sediment | 0.042 mg/kg dwt (0.009 mg/kg wwt) |

For Trans-DCVC and Cis-DCVC PNECs values are not available, in Competent Authority Report of Cypermethrin (Document I, January 2017) it is reported:

“According to the DAR of cypermethrin, TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin.”

In Competent Authority Report of Cypermethrin (Document II-A, January 2017) it is reported:

“With such high concentrations of metabolites rapidly found in the various metabolism/ degradation studies, one can consider that its toxicity is covered by the studies on cypermethrin (Evaluation report on the equivalence; Agriphar Confidential 2007)”.

Since TDCVC and CDCVC metabolites have toxicity values which are 10000x higher than those of cypermethrin but PNECs are not available for these metabolites, as a conservative approach, for DCVC PNECs of cypermehrin have been used.

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kg] | [mg/l] | [mg/m3] |
| Use 1 – TIER 1 - Private use | 2.86 x 10-5 | 1.53 x 10-6 | 0.019 | 6.56 x 10-4 | 1.53 x 10-8 | 7.94 x 10-11 |
| Use 1 – TIER 1 –Industrial use | 3.84 x 10-5 | 2.06 x 10-6 | 0.026 | 8.82 x 10-4 | 2.06 x 10-8 | 1.07 x 10-10 |
| Use 1 – TIER 2 - Private use | 5.41 x 10-6 | 2.91 x 10-7 | 0.00363 | 1.24 x 10-4 | 2.91 x 10-9 | 7.94 x 10-11 |
| Use 1 – TIER 2 –Industrial use | 7.17 x 10-6 | 3.85 x 10-7 | 0.00481 | 1.65 x 10-4 | 3.85 x 10-9 | 1.07 x 10-10 |
| Use 1 – TIER 3 - Private use | 3.10 x 10-6 | 1.67 x 10-7 | 0.00208 | 7.13 x 10-5 | 1.67 x 10-9 | 7.94 x 10-11 |
| Use 1 – TIER 3 –Industrial use | 4.06 x 10-6 | 2.18 x 10-7 | 0.00272 | 9.31 x 10-5 | 2.18 x 10-9 | 1.07 x 10-10 |
| Use 2 | 5.41 x 10-6 | 2.91 x 10-7 | 0.00363 | 1.24 x 10-4 | 2.91 x 10-9 | 7.94 x 10-11 |
| Use 3 – Urban area | 7.53 x 10-4 | 4.04 x 10-5 | 0.505 | 0.017 | 4.04 x 10-7 | 1.49 x 10-13 |
| Use 3 – Rural area  TIER 1 | - | - | - | 0.1 (standard house)  0.103 (large building) | 9.83 x 10-6 (standard house)  1.00 x 10-5 (large building) | - |
| Use 3 – Rural area  TIER 2 | - | - | - | 0.064 (standard house)  0.066  (large building) | 6.29 x 10-6 (standard house)  6.49 x 10-6 (large building) | - |
| Use 4 – Houses – Rural area | - | - | - | 0.064 (standard house) | 6.29 x 10-6 (standard house) | - |

**PECs for metabolites**

Local PECs values for metabolites of a.i. have been calculated for each relevant compartment.

Metabolites concentrations in water, sediment and soil have been calculated using each relevant PEC of the parent modified in order to taking into account the molecular weight difference and the maximum observed levels of the metabolite in the compartment, according to the equation:

PECmetabolite = PECparent x (Max % AR) x (Molar weight fraction)

where:

PECparent = PEC of scenario 2 for water and sediment; PEC of scenario 3 for soil

Max % AR = maximum formation factor for the metabolite in each relevant compartment

Molecular weight fraction = MWmetabolite / MWcypermethrin

For cypermethrin, PECs of its metabolites have been calculated using the highest PECs for their parent multiplied by a formation factor and corrected for the molecular weight. The highest PECs of cypermethrin for water and sediment are those calculated in Use 2 and Use 3 for soil.

**Metabolites of Cypermethrin in the relevant environmental compartments**

|  |  |  |  |
| --- | --- | --- | --- |
| **Surface water** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsw (mg/L) |
| Cypermethrin | - | 416.3 | 2.91 × 10-7 |
| 3-PBA | 21 | 214.2 | 3.14 × 10-8 |
| DCVC | 38 | 209.1 | 5.55 × 10-8 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Sediment of surface water** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsed (mg/kg ww) |
| Cypermethrin | - | 416.3 | 0.00363 |
| 3-PBA | 29 | 214.2 | 5.45 × 10-4 |
| DCVC | 20 | 209.1 | 3.65 × 10-4 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Soil** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsoil (mg/kgww) |
| Cypermethrin | - | 416.3 | 0.066 |
| 3-PBA | 10.2 | 214.2 | 3.46 × 10-3 |
| DCVC | 17.5 | 209.1 | 5.80 × 10-3 |

***Primary and secondary poisoning***

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

- insecticides are applied together with food attractant, or

- insecticides are applied as granular formulation.

Therefore, for Draker One primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

PEC oral,predator/PNEC oral ratios have been determined according to TGD 2003 for fish-eating mammals and birds and for earthworm-eating mammals and birds to demonstrate that there is no unacceptable risk of secondary poisoning following the appropriate use of the product.

PNEC oral, bird

The PNECoral for secondary poisoning of birds is derived by applying an assessment factor of 30 to the chronic NOEC of 1000 mg/Kg feed, resulting in a PNECoral,bird of 33.3 mg/Kg feed.

PNECoral,mammals

The PNECoral for secondary poisoning of mamal is derived by applying an assessment factor of 30 to the chronic rat study (McAusland, Butterworth, Hunt, 1978) NOEC of 5 mg/Kg bw/d, resulting in a PNECoral,mammals of 3.3 mg/Kg food.

According to the TGD (EC, 2003) a calculation for PECoral predator should be conducted if the a.s. shows a potential for bioaccumulation, indicated by a log Kow value >3. Cypermethrin has a slight potential for bioaccumulation, log Kow of 5.45.

The concentration of a contaminant in food (fish) of fish-eating predators (PECoral predator) is derived from the PEC for surface water, the measured BCF for fish and the biomagnification factor (BMF). Since the log Kow of Cypermethrin is 5.45 and a measured BCF for Cypermethrin in the test OECD guideline (1981) part 305E was reported at 373 ± 45 L/kg the default BMF of 10 is used in the calculation (Table 23: Default BMF values for organic substances - Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017).

***Aquatic Compartment (including Risk characterisation for fish eating organisms)***

*Calculating Risk to Fish Eating Predator – Cypermethrin – Use 3-urban area (worst case)*

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Definition** | **Value** |
| Local concentration of Cypermethrin in surface water [mg/L] | Use 3 | 4.04E-05 |
| Bioconcentration factor in fish | BCF | 417 L/kg |
| Biomagnification factor | BMF | 10 |
| Predicted concentration of Cypermethrin in food of the predator [mg/kg] | PECoral, predator = PECwater x BCFfish x BMF | 1.68E-01 |

Calculation for PECoral, predator as an indicator for possible secondary poisoning, resulted in a PEC value of 0.168 mg/kg.

**Terrestrial Compartment (including risk characterisation for earthworm eating organisms)**

*Calculated Risk to Worm Eating Predators*

It is accepted that substances adsorbed to soil particles can be ingested and may bioaccumulate in worms. Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil.

The total concentration in an entire worm can be calculated as the weighted average of the worm’s tissues (through BCF and pore water) and guts contents (through soil concentration). A quantitative risk characterisation for secondary poisoning in the terrestrial compartment (for the food chain soil → earthworm → worm-eating birds or mammals) has been performed below for completeness sake.

PNECoral,bird of 33.3 mg/Kg feed.

PNECoral,mammals of 3.3 mg/Kg food.

**Cypermethrin**

All calculations below were performed only for “Use 3 - Treatment around the building - Flying insects – professional (TIER 1 -large building)”, since it represent the worst case in term of PECS:

PECporewater = 1.00E-05 mg/l

PECsoil = 1.03E-01 mg/kg wwt

PECoral, predator derivation:

The calculation method described in the TGD was used to determine the PECoral, predator for earthworm eating predators as:

Based on the following equation, the concentration of Cypermethrin in an entire worm is:

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

-BCF earthworm

Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism and can be modelled according to the following equation as described by Jager (1998).

*BCFearthworm= (0.84 + 0.012Kow) / RHOearthworm*

*where for RHOearthworm by default a value of 1 (kgwwt.L -1 ) can be assumed.*

Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017 (Equation 104d)

*BCFearthworm=* 3382.9 L/kg

Cporewater = 1.00E-05 mg/L (EUSES 2.2.0)

Csoil = 1.03E-01 mg/kg wwt soil.

Fgut = 0.1 (TGD on Risk Assessment page 132)

-CONVsoil = RHOsoil / (Fsolid x RHOsolid) = 1700 / (0.6 x 2500) = 1.13

Cypermethrin PECoral, predator = 0.0443 mg/kg wet earthworm (Cearthworm)

#### Risk characterisation

***Atmosphere***

Conclusion:The low vapour pressure and Henry’s Law constant of the active substance indicate that loss of cypermethrin in the atmosphere will be negligible.

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECSTP**  **[mg/L]** | **PNECSTP [mg/l]** | **PEC/PNEC** |
| Use 1 – TIER 1 –Private use | 2.86 x 10-5 | 1.63 | 1.75 x 10-5 |
| Use 1 – TIER 1 –Industrial use | 3.84 x 10-5 | 2.36 x 10-5 |
| Use 1 – TIER 2 - Private use | 5.41 x 10-6 | 3.32 x 10-6 |
| Use 1 – TIER 2 –Industrial use | 7.17 x 10-6 | 4.40 x 10-6 |
| Use 1 – TIER 3 - Private use | 3.10 x 10-6 | 1.90 x 10-6 |
| Use 1 – TIER 3 –Industrial use | 4.06 x 10-6 | 2.49 x 10-6 |
| Use 2 | 5.41 x 10-6 | 3.32 x 10-6 |
| Use 3 – Urban area | 7.53 x 10-4 | 4.62 x 10-4 |
| Use 3 – Rural area  TIER 1 | - | - |
| Use 3 – Rural area  TIER 2 | - | - |
| Use 4 – Houses – Rural area | - | - |

Conclusion: As a result of the risk assessment performed there is no risk for STP when the product is used according to the instructions of use.

***Aquatic compartment***

**Freshwater**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECwater**  [mg/l] | **PNECwater [mg/l]** | **PEC/PNEC** |
| Use 1 – TIER 1 –Private use | 1.53 x 10-6 | 0.000004 | 0.38 |
| Use 1 – TIER 1 –Industrial use | 2.06 x 10-6 | 0.52 |
| Use 1 – TIER 2 - Private use | 2.91 x 10-7 | 0.07 |
| Use 1 – TIER 2 –Industrial use | 3.85 x 10-7 | 0.10 |
| Use 1 – TIER 3 - Private use | 1.67 x 10-7 | 0.04 |
| Use 1 – TIER 3 –Industrial use | 2.18 x 10-7 | 0.05 |
| Use 2 | 2.91 x 10-7 | 0.07 |
| Use 3 – Urban area | 4.04 x 10-5 | **10.1** |
| Use 3 – Rural area  TIER 1 | - | - |
| Use 3 – Rural area  TIER 2 | - | - |
| Use 4 – Houses – Rural area | - | - |

**Sediment of freshwater**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECsed**  **[mg/kgwwt]** | **PNECsed [mg/kgwwt]** | **PEC/PNEC x 10 (\*)** |
| Use 1 – TIER 1 –Private use | 0.019 | 0.050 | **3.8** |
| Use 1 – TIER 1 –Industrial use | 0.026 | **5.2** |
| Use 1 – TIER 2 - Private use | 0.00363 | 0.73 |
| Use 1 – TIER 2 –Industrial use | 0.00481 | 0.96 |
| Use 1 – TIER 3 - Private use | 0.00208 | 0.42 |
| Use 1 – TIER 3 –Industrial use | 0.00272 | 0.54 |
| Use 2 | 0.00363 | 0.73 |
| Use 3 – Urban area | 0.505 | **101** |
| Use 3 – Rural area  TIER 1 | - | - |
| Use 3 – Rural area  TIER 2 | - | - |
| Use 4 – Houses – Rural area | - | - |

(\*) According to Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, due to the limitations of the equilibrium partitioning approach, to account for additional exposure via sediment ingestion, for substances with a log Kow ≥ 5 an additional safety factor of 10 is applied to the PNECsediment. The additional factor takes into account the possible additional uptake via sediment ingestion.

Conclusion: As a result of risk assessment performed for aquatic compartment, the risk is unacceptable for the Use 1 Tier 1 (both private and industrial use) for sediment drewlling organisms. The risk is also unacceptable for Use 3 (urban area) for both aquatic organisms and sediment drewlling organisms. Thus, Use 1 Tier 1 and Use 3 (urban area) are **NOT AUTHORIZED.**

***Terrestrial compartment***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECsoil**  **[mg/kg]** | **PNECsoil [mg/kgwwt]** | **PEC/PNEC** |
| Use 1 – TIER 1 –Private use | 6.56 x 10-4 | 0.0708 | 9.27E-03 |
| Use 1 – TIER 1 –Industrial use | 8.82 x 10-4 | 1.25E-02 |
| Use 1 – TIER 2 - Private use | 1.24 x 10-4 | 1.75E-03 |
| Use 1 – TIER 2 –Industrial use | 1.65 x 10-4 | 2.33E-03 |
| Use 1 – TIER 3 - Private use | 7.13 x 10-5 | 1.01E-03 |
| Use 1 – TIER 3 –Industrial use | 9.31 x 10-5 | 1.31E-03 |
| Use 2 | 1.24 x 10-4 | 1.75E-03 |
| Use 3 – Urban area | 0.017 | 2.40E-01 |
| Use 3 – Rural area  TIER 1 | 0.1 (standard house)  0.103 (large building) | **1.41E+00**  **1.45E+00** |
| Use 3 – Rural area  TIER 2 | 0.064 (standard house)  0.066 (large building) | 9.04E-01  9.32E-01 |
| Use 4 – Houses – Rural area | 0.064 (standard house) | 9.04E-01 |

Conclusion: As a result of the risk assessment performed for terrestrial compartment there is risk only in Use 3, Tier 1. Thus, the Use 3, Tier 1 (for both standard house and large buildings) is **NOT AUTHORIZED**.

The risk of the remaining Uses is acceptable when following the label instructions of DRAKER ONE.

***Groundwater***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECGW**  **[mg/l]** | **EU trigger value (mg/L)** | **Acceptable** |
| Use 1 – TIER 1 –Private use | 1.53 x 10-8 | 0.0001 | yes |
| Use 1 – TIER 1 –Industrial use | 2.06 x 10-8 | yes |
| Use 1 – TIER 2 - Private use | 2.91 x 10-9 | yes |
| Use 1 – TIER 2 –Industrial use | 3.85 x 10-9 | yes |
| Use 1 – TIER 3 - Private use | 1.67 x 10-9 | yes |
| Use 1 – TIER 3 –Industrial use | 2.18 x 10-9 | yes |
| Use 2 | 2.91 x 10-9 | yes |
| Use 3 – Urban area | 4.04 x 10-7 | yes |
| Use 3 – Rural area  TIER 1 | 9.83 x 10-6 (standard house)  1.00 x 10-5 (large building) | yes |
| Use 3 – Rural area  TIER 2 | 6.29 x 10-6 (standard house)  6.49 x 10-6 (large building) | yes |
| Use 4 – Houses – Rural area | 6.29 x 10-6 (standard house) | yes |

Risk characterisation Metabolites

*Metabolites of Cypermethrin in surfacewater*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC aquatic (mg/l) | PNEC aquatic (mg/l) | PEC/PNEC |
| 3-PBA | 3.14 × 10-8 | 0.01 | 3.14 x 10-6 |
| DCVC\* | 5.55 × 10-8 | 4.00 x 10-6 | 1.39 x 10-2 |

*Metabolites of Cypermethrin in sediment*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC (mg/kg wwt) | PNECsed (mg/kg wwt) | PEC/PNEC |
| 3-PBA | 5.45 × 10-4 | 0.009 | 6.06 x 10-2 |
| DCVC\* | 3.65 × 10-4 | 5.00 x 10-3 | 7.30 x 10-2 |

*Metabolites of Cypermethrin in soil*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC soil (mg/kg ww soil) | PNECsoil (mg/kg ww soil) | PEC/PNEC |
| 3-PBA | 3.46 × 10-3 | 1.44 | 2.40 x 10-3 |
| DCVC\* | 5.80 × 10-3 | 7.08 x 10-2 | 8.19 x 10-2 |

\*Since PNEC values are not available for the metabolite DCVC in the CAR, as a conservative approach, PNECs of cypermethrin have been used.

***Primary and secondary poisoning***

Primary poisoning

According to OECD Emission Scenario Document for PT18 primary poisoning for birds or mammals, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

- insecticides are applied together with food attractant, or

- insecticides are applied as granular formulation.

Therefore, for Draker One primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

***Aquatic Compartment (including Risk characterisation for fish eating organisms)***

- Risk characterisation for fish-eating birds:

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **PECoral predator (mg/kg)** | **PNECoral (mg /kg)** | **PEC/PNEC** |
| Biota | 0.168 | 33.3 | 5.06E-03 |

- Risk characterisation for fish-eating mammals

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **PECoral predator (mg/kg)** | **PNECoral (mg /kg)** | **PEC/PNEC** |
| Biota | 0.168 | 3.3 | 5.11E-02 |

***Terrestrial Compartment (including risk characterisation for earthworm eating organisms)***

-Risk characterisation for earthworm-eating birds:

The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food (PECoral, predator) and the no-effect-concentration for oral intake (PNECoral) as follows:

PECoral, predator/ PNECoral = 0.0443 /33.3 = 1.33E-03

-Risk characterisation for earthworm-eating mammals:

The risk to the earthworm-eating mammals is calculated as the ratio between the concentration in their food (PECoral, predator) and the no-effect-concentration for oral intake (PNECoral) as follows:

PECoral, predator/ PNECoral = 0.0443 /3.3 = 1.34E-02

Overall risk assessment:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Concentration** | **PECoral predator** | **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** |
| **Scenario: Application, Aquatic**  **compartment** | **PECsurface water**  **(mg/L)** | **(mg/kg wet**  **fish)** |  |  |
| Cypermethrin | 4.04E-05 | 1.68E-01 | 5.06E-03 | 5.11E-02 |
| **Scenario: Application, Terrestrial**  **compartment** | **PECporewater**  **(mg/L)** | **(mg/kg wet**  **earthworm)** |  |  |
| Cypermethrin | 1.00E-05 | 4.43E-02 | 1.33E-03 | 1.34E-02 |

Conclusion

Predicted concentrations of Draker One in the environment from use in PT18 suggests no unacceptable risk of toxicity to birds and mammals from Cypermethrin from secondary poisoning trough the aquatic and terrestrial food-chain via fish and earhworms, respectively.

Comparing the PECoral,predator with the respective PNECs, all PEC/PNEC ratios are below one indicating that there is no unacceptable risk of secondary poisoning following the appropriate use of the product.

***Mixture toxicity***

Mixture toxicity is not relevant for Draker One.

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

Aggregated exposure is not relevant, based on the decision scheme developed by UBA for the following reasons.

1. Cypermethrin is approved in EU as a biocide in 2 PTs: (i) PT 8 and (ii) PT18; however, as a result of the uses of these products, there is no overlap in time and space in Europe, since in PT 8 Cypermethrin is used in industrial preventive wood preservation applied in automated spraying, vacum pressure, double vacum pressure, flow coating or dipping treatment plants.
2. The main constituent of a.s. is not part of other a.s., and a.s. is not a relevant metabolite of other a.s. (and *vice versa*), and there are no other active substances that form the same relevant metabolites
3. In general there is no an overlap in time and space during the use of the product.

Therefore, according the decision scheme developed by UBA, no aggregated exposure estimation is required.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| According to the environmental risk assessment, the **risk** for all relevant environmental compartments (STP, terrestrial, aquatic) **is** **acceptable** for all Uses, when following the label instructions of DRAKER ONE.  [Note: Risks for the environment have been identified for:   * USE 1-TIER 1 (private / industrial use) (risk for sediment drewlling organisms) * USE 3 (Urban area) (risk for both aquatic and sediment drewlling organisms) * USE 3 (Rural area) - TIER 1 (risk for terrestrial environment)]   Regarding the Use 1 - TIER 2 emission, by limiting the application of the product in areas not subject to wet cleaning, the risk of all compartments is considered to be acceptable. The TIER 3 was an additional option and is considered supplementary to the evaluation of the biocide DRAKER ONE.  **Primary and secondary poisoning compartment**  The risk characterization for primary and secordary poisoing compartment is carried out. For all indended uses, the PEC/PNEC ratio are below 1, indicating a **safe use** when following the label instructions of DRAKER ONE. |

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

*Precautions for safe handling*

Avoid contact with skin and eyes, inhaltion of vapours and mists.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers. Advice on general occupational hygiene:

- Contamined clothing should be changed before entering eating areas.

- Do not eat or drink while working.

*Conditions for safe storage, including any incompatibilities*

- Avoid light and sunlight exposure

- Avoid temperatures > 40°C

- Avoid Temperatures < 0°C

Keep away from food, drink and feed.

Incompatible materials: None in particular.

Instructions as regards storage premises: Adequately ventilated premises.

*Transport information*

 

*UN number*

ADR-UN Number: 3082

IATA-UN Number: 3082

IMDG-UN Number: 3082

*UN proper shipping name*

ADR-Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.(cypermethrin cis/trans +/- 40/60; (RS)-alfa-cyano-3-phenoxybenzyl

(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopr opanecarboxylate)

IATA-Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.(cypermethrin cis/trans +/- 40/60; (RS)-alfa-cyano-3-phenoxybenzyl

(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopr opanecarboxylate)

IMDG-Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.(cypermethrin cis/trans +/- 40/60; (RS)-alfa-cyano-3-phenoxybenzyl

(1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopr opanecarboxylate)

*Transport hazard class(es)*

ADR-Class: 9

ADR - Hazard identification number: 90

IATA-Class: 9

IATA-Label: 9

IMDG-Class: 9

*Packing group*

ADR-Packing Group: III

IATA-Packing group: III

IMDG-Packing group: III

*Environmental hazards*

ADR-Enviromental Pollutant: Yes

IMDG-Marine pollutant: Marine Pollutant

Most important toxic component: cypermethrin cis/trans +/-40/60;

(RS)-alfa-cyano-3-phenoxybenzyl (1RS,3RS;

1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarb oxylate

*Special precautions for user*

ADR-Subsidiary hazards: -

ADR-S.P.: 274 335 375 601

ADR-Transport category (Tunnel restriction code): 3 (-) IATA-Passenger Aircraft: 964

IATA-Subsidiary hazards: - IATA-Cargo Aircraft: 964

IATA-S.P.: A97 A158 A197

IATA-ERG: 9L

|  |  |  |  |
| --- | --- | --- | --- |
| IMDG-EmS: | F-A | , | S-F |

IMDG-Subsidiary hazards: -

IMDG-Stowage and handling: Category A IMDG-Segregation: -

*Extinguishing media*

Suitable extinguishing media:

- Water

- Carbon dioxide (CO2)

- CO2 or Dry chemical fire extinguisher.

Extinguishing media which must not be used for safety reasons:

- direct water jets

*Special hazards arising from the substance or mixture*

Do not inhale explosion and combustion gases.

*Advice for firefighters*

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Use suitable breathing apparatus .

*Description of first aid measures*

In case of skin contact: Wash with plenty of water and soap.

In case of eyes contact: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion: Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation: Remove casualty to fresh air and keep warm and at rest.

*Most important symptoms and effects, both acute and delayed*

Symptoms associated with exposure to pyrethroid compounds include skin and eye irritation, irritability to sound or touch, abnormal facial sensation, sensation of prickling, tingling, or creeping on skin, numbness, headache, dizziness, nausea, vomiting, diarrhea, salivation, and fatigue. At very high levels of exposure, muscle twitching and fluid accumulation in the lungs may occur.

*Indication of any immediate medical attention and special treatment needed*

Treatment: Treat symptomatically.

### Assessment of a combination of biocidal products

Draker One is not intended to be authorised for the use in mixture with other biocidal products.

# Annexes[[1]](#footnote-1)

## List of studies for the biocidal product

* Physical state at 20 °C and 101.3 kPa
* Colour at 20 °C and 101.3 kPa
* Odour at 20 °C and 101.3 kPa
* Acidity / alkalinity
* Relative density / bulk density
* Storage stability test – accelerated storage (bottle)
* Storage stability test – accelerated storage (vial)
* Storage stability test – long term storage at ambient temperature (study plan)
* Storage stability test – long term storage at ambient temperature (study plan 2021)
* Storage stability test – low temperature stability test for liquids
* Suspensibility, spontaneity and dispersion stability
* Wet sieve analysis and dry sieve test
* Emulsifiability, re-emulsifiability and emulsion stability
* Particle size distribution, content of dust/fines, attrition, friability
* Persistent foaming
* Flowability/Pourability/Dustability
* Surface tension
* Viscosity
* Flammable liquids
* Corrosive to metals
* Oxidizing Properties for Liquids
* Methods for detection and identification
* Efficacy studies
* *In vitro* test for skin irritation

## Output tables from exposure assessment tools



**EUSES**

**Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional - TIER 1**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2021-DrakerOne-U1-T1 | 2021-DrakerOne-U1-T1 |  | S |
| Study description | 2021-DrakerOne-U1-T1 | 2021-DrakerOne-U1-T1 |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 14ADABA5 | 14ADABA5 |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | U1-Spot C&C profesional T1 | U1-Spot C&C profesional T1 |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.2.1) Indoor, spray application | (18.2.1) Indoor, spray application |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 300 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Number of preparations per day, large building | 3 | 5 | [d-1] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Number of applications per day in a standard house | ?? | 1 | [d-1] | S |
| Number of applications per day in a large building | ?? | 1 | [d-1] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Washable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 365 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Washable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 1,07E-10 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 2,06E-06 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 1,13E-08 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 0,025769 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 2,47E-06 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,35E-08 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 0,030837 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 8,82E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 2,09E-04 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 8,37E-05 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 2,06E-08 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 8,25E-09 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 2,06E-08 | [mg.l-1] | O |
|  |  |  |  |  |
| **LOCAL PECS [PRIVATE USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 7,94E-11 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,53E-06 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 8,40E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 0,019169 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,84E-06 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,01E-08 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 0,022939 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 6,56E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,56E-04 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 6,23E-05 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 1,53E-08 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 6,14E-09 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,53E-08 | [mg.l-1] | O |

**Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional - TIER 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2021-DrakerOne-U1-T2 | 2021-DrakerOne-U1-T2 |  | S |
| Study description | 2021-DrakerOne-U1-T2 | 2021-DrakerOne-U1-T2 |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 6EA8733D | 6EA8733D |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | U1-Spot C&C profesional T2 | U1-Spot C&C profesional T2 |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.2.1) Indoor, spray application | (18.2.1) Indoor, spray application |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 300 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Number of preparations per day, large building | 3 | 5 | [d-1] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Number of applications per day in a standard house | ?? | 1 | [d-1] | S |
| Number of applications per day in a large building | ?? | 1 | [d-1] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Washable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| **CLEANING EMISSIONS FROM APPLICATION** |  |  |  |  |
| **STANDARD HOUSES** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **LARGE BUILDINGS** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 365 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Washable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| **CLEANING EMISSIONS FROM APPLICATION** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 1,07E-10 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 3,85E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 2,11E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 4,81E-03 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 4,61E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 2,52E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 5,76E-03 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 1,65E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 3,91E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 1,56E-05 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 3,85E-09 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 1,54E-09 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 3,85E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **LOCAL PECS [PRIVATE USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 7,94E-11 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 2,91E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 1,59E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 3,63E-03 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 3,48E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,90E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 4,35E-03 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 1,24E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 2,95E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 1,18E-05 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 2,91E-09 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 1,16E-09 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 2,91E-09 | [mg.l-1] | O |

**Use 1 - Crack and crevice spot treatment, indoor - crawling insects - professional - TIER 3**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2021-DrakerOne-U1-T3 | 2021-DrakerOne-U1-T3 |  | S |
| Study description | 2021-DrakerOne-U1-T3 | 2021-DrakerOne-U1-T3 |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 4F313D2F | 4F313D2F |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | U1-Spot C&C profesional T3 | U1-Spot C&C profesional T3 |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.2.1) Indoor, spray application | (18.2.1) Indoor, spray application |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 300 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Number of preparations per day, large building | 3 | 5 | [d-1] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Number of applications per day in a standard house | ?? | 1 | [d-1] | S |
| Number of applications per day in a large building | ?? | 1 | [d-1] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Disposable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| **CLEANING EMISSIONS FROM APPLICATION** |  |  |  |  |
| **STANDARD HOUSES** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **LARGE BUILDINGS** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **PARAMETERS REQUIRED FOR THE DISTRIBUTION MODULE OR FOR CALCULATION OF PECS** |  |  |  |  |
| Number of emission days | 365 | 2 | [d.yr-1] | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Disposable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| **CLEANING EMISSIONS FROM APPLICATION** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 1,07E-10 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 2,18E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 1,19E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 2,72E-03 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 2,61E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,43E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 3,26E-03 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 9,31E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 2,21E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 8,85E-06 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 2,18E-09 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 8,72E-10 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 2,18E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **LOCAL PECS [PRIVATE USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 7,94E-11 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,67E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 9,13E-10 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 2,08E-03 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,99E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,09E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 2,49E-03 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 7,13E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,69E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 6,77E-06 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 1,67E-09 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 6,67E-10 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,67E-09 | [mg.l-1] | O |

**Use 2 - Crack and crevice spot treatment, indoor - crawling insects - non-professional**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2021-DrakerOne-U2 | 2021-DrakerOne-U2 |  | S |
| Study description | 2021-DrakerOne-U2 | 2021-DrakerOne-U2 |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 6847A1CA | 6847A1CA |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | 2021-DrakerOne-U2 | 2021-DrakerOne-U2 |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.2.1) Indoor, spray application | (18.2.1) Indoor, spray application |  | S |
|  |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **PRIVATE USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Select formulation/use | Select | Spray - crack and crevice |  | S |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Cover mixing/loading? | Yes | Yes |  | S |
| Select pest | Select | Cockroaches |  | S |
| Select treatment | Select | Spot, cracks and crevices |  | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 3 | [g] | S |
| Product form | Select | Liquids |  | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 1,52 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **CLEANING** |  |  |  |  |
| Washable coveralls or disposable coveralls? | Select | Washable coveralls |  | S |
| Dry or wet cleaning of treated surfaces? | Select | Wet cleaning of treated surfaces |  | S |
|  |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| **CLEANING EMISSIONS FROM APPLICATION** |  |  |  |  |
| Local emission to wastewater from wet cleaning the treated surfaces | ?? | 0 | [kg.d-1] | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [PRIVATE USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | ?? | 1,45E-08 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | ?? | 2,91E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | ?? | 2,91E-07 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 3,63E-03 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 3,48E-07 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in seawater (dissolved) | ?? | 3,48E-07 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 4,35E-03 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 1,24E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 2,95E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 1,19E-05 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | ?? | 2,91E-09 | [mg.l-1] | O |
| Local PEC in pore water of grassland | ?? | 1,17E-09 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 2,91E-09 | [mg.l-1] | O |

**Use 3 - Treatment around the building - Flying insects – professional – Urban area**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2022-Draker1-U3-T1Ur | 2022-Draker1-U3-T1Ur |  | S |
| Study description | 2022-01 - Draker 1 - Use3 - T1 Urban | 2022-01 - Draker 1 - Use3 - T1 Urban |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 6955E646 | 6955E646 |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | 2022-01 - Draker 1 - Use3 - T1 houses | 2022-01 - Draker 1 - Use3 - T1 houses |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.3.1) Outdoor, flying insects | (18.3.1) Outdoor, flying insects |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Location of the treated surface | Select | Urban area |  | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 5,1 | [g] | S |
| Number of preparations per day, standard house | 1 | 5 | [d-1] | S |
| Number of preparations per day, large building | 3 | 25 | [d-1] | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 0,21 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **RELEASE VIA STP** |  |  |  |  |
| **AIR** |  |  |  |  |
| Annual average local PEC in air (total) | 0 | 2,24E-11 | [mg.m-3] | O |
|  |  |  |  |  |
| **WATER, SEDIMENT** |  |  |  |  |
| Local PEC in surface water during emission episode (dissolved) | 0 | 4,04E-05 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | No |  | O |
| Annual average local PEC in surface water (dissolved) | 0 | 3,32E-05 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | 0 | 0,505138 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 0 | 4,84E-05 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | Yes |  | O |
| Annual average local PEC in seawater (dissolved) | 0 | 3,97E-05 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 0 | 0,604488 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **SOIL, GROUNDWATER** |  |  |  |  |
| Local PEC in agric. soil (total) averaged over 30 days | 0 | 0,017286 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | 0 | 4,10E-03 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | 0 | 1,64E-03 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | 0 | 4,04E-07 | [mg.l-1] | O |
| Local PEC in pore water of grassland | 0 | 1,62E-07 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | 0 | 4,04E-07 | [mg.l-1] | O |

**Use 3 - Treatment around the building - Flying insects – professional – Rural area – Tier 1**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2022-Draker1-U3-T1Ru | 2022-Draker1-U3-T1Ru |  | S |
| Study description | 2022-Draker1-U3-T1Ru | 2022-Draker1-U3-T1Ru |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 4B309B20 | 4B309B20 |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | 2022-Draker1-U3-T1Ru | 2022-Draker1-U3-T1Ru |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.3.1) Outdoor, flying insects | (18.3.1) Outdoor, flying insects |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Location of the treated surface | Select | Rural area |  | S |
| Cover mixing/loading? | No | No |  | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 5,1 | [g] | S |
| Number of preparations per day, standard house | 1 | 5 | [d-1] | S |
| Number of preparations per day, large building | 3 | 25 | [d-1] | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 0,21 | [g.m-2] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **DIRECT RELEASE** |  |  |  |  |
| **SOIL** |  |  |  |  |
| Local PEC at standard house | ?? | 0,099774 | [mg.kgwwt-1] | O |
| Local PEC at large building | ?? | 0,102941 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **GROUNDWATER** |  |  |  |  |
| Local PEC at standard house | ?? | 9,83E-03 | [µg.l-1] | O |
| Local PEC at large building | ?? | 0,010145 | [µg.l-1] | O |

**Use 3 - Treatment around the building - Flying insects – professional – Rural area – Tier 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **STUDY** |  |  |  |  |
| **STUDY IDENTIFICATION** |  |  |  |  |
| Study name | 2022-Draker1-U3-T2Ru | 2022-Draker1-U3-T2Ru |  | S |
| Study description | 2022-Draker1-U3-T2Ru | 2022-Draker1-U3-T2Ru |  | S |
| Author |  |  |  | D |
| Institute |  |  |  | D |
| Address |  |  |  | D |
| Zip code |  |  |  | D |
| City |  |  |  | D |
| Country |  |  |  | D |
| Telephone |  |  |  | D |
| Telefax |  |  |  | D |
| Email |  |  |  | D |
| Calculations checksum | 3F065913 | 3F065913 |  | S |
|  |  |  |  |  |
| **SUBSTANCE** |  |  |  |  |
| **SUBSTANCE IDENTIFICATION** |  |  |  |  |
| General name | cypermethrin | cypermethrin |  | S |
| Description |  |  |  | D |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. |  |  |  | D |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | O |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | S |
| Water solubility at 20 [oC] | 4 | 4 | [µg.l-1] | S |
| Water solubility at 25 [oC] | 4,28E-03 | 4,28E-03 | [mg.l-1] | O |
| Octanol-water partition coefficient | 5,45 | 5,45 | [log10] | S |
|  |  |  |  |  |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** |  |  |  |  |
| **SOLIDS-WATER** |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **AIR-WATER** |  |  |  |  |
| Henry's law constant at test temperature | ?? | 0,024 | [Pa.m3.mol-1] | S |
| Temperature at which Henry's law constant was measured | 20 | 20 | [oC] | S |
| Henry's law constant at 25 [oC] | 0,05825103 | 0,0582 | [Pa.m3.mol-1] | S |
|  |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION RATES** |  |  |  |  |
| **AIR** |  |  |  |  |
| Rate constant for degradation in air | 1,00E+40 | 0,749 | [d] (DT50) | S |
|  |  |  |  |  |
| **SOIL** |  |  |  |  |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
|  |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **BIOCIDE SCENARIO INPUT DATA** |  |  |  |  |
| Usage/production title | 2022-Draker1-U3-T1Ru | 2022-Draker1-U3-T1Ru |  | S |
| Scenario choice for biocides | (18) Insecticides, acaricides and products to control other arthropods | (18) Insecticides, acaricides and products to control other arthropods |  | S |
| Additional scenario information | (18.3.1) Outdoor, flying insects | (18.3.1) Outdoor, flying insects |  | S |
|  |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| Emission scenario |  |  |  | D |
|  |  |  |  |  |
| **INTERMEDIATE RESULTS** |  |  |  |  |
| **RELEASE FRACTIONS AND EMISSION DAYS** |  |  |  |  |
| **INDUSTRIAL USE** |  |  |  |  |
| **GENERAL INPUT** |  |  |  |  |
| Fraction of substance in commercial product | ?? | 0,105 | [-] | S |
| Location of the treated surface | Select | Rural area |  | S |
| Cover mixing/loading? | No | No |  | S |
|  |  |  |  |  |
| **MIXING/LOADING** |  |  |  |  |
| Quantity of commercial product used per preparation | ?? | 5,1 | [g] | S |
| Number of preparations per day, standard house | 1 | 5 | [d-1] | S |
| Number of preparations per day, large building | 3 | 25 | [d-1] | S |
| Container type/volume | Select | 1 litre container with unspecific design |  | S |
|  |  |  |  |  |
| **APPLICATION** |  |  |  |  |
| Quantity of commercial product applied per m2 | ?? | 0,21 | [g.m-2] | S |
| Area of exterior wall treated per day, standard house | 125 | 80 | [m2.d-1] | S |
| Area of exterior wall treated per day, large building | 625 | 400 | [m2.d-1] | S |
| Frequency of application in standard houses | Select | 1-2 times a year |  | S |
| Frequency of application in large buildings | Select | 1-2 times a year |  | S |
|  |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LIFE CYCLE STEPS** |  |  |  |  |
| **LOCAL PECS [INDUSTRIAL USE]** |  |  |  |  |
| **DIRECT RELEASE** |  |  |  |  |
| **SOIL** |  |  |  |  |
| Local PEC at standard house | ?? | 0,063855 | [mg.kgwwt-1] | O |
| Local PEC at large building | ?? | 0,065882 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **GROUNDWATER** |  |  |  |  |
| Local PEC at standard house | ?? | 6,29E-03 | [µg.l-1] | O |
| Local PEC at large building | ?? | 6,49E-03 | [µg.l-1] | O |

## New information on the active substance

New information on the active substance is not available.

## Residue behaviour

No residues of Draker One in food or feed occur.

## Summaries of the efficacy studies (B.5.10.1-xx)[[2]](#footnote-2)

Please, see section 2.2.5.5

## Confidential annex

Please s**ee seperate file.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |

1. 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-1)
2. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-2)