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)



FREE LAND 10 EC

Product type(s) PT 18

Cypermethrin as included in the Union list

of approved active substances

Case Number in R4BP: BC-PU059150-19

Evaluating Competent Authority: Greece

Date: November 2022

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# CONCLUSION

Free Land 10 EC is an emulsifiable concentrate insecticide (PT 18), containing nominal (pure) active ingredient of 10.0 % w/w Cypermethrin.

**Conclusion for Physico-chemistry**

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

Acceptable data from accelerated storage stability study and long term storage stability study at ambient temperature demonstrate that the product is stable for up to two years at ambient temperature when stored in its initial commercial packaging (from HDPE).

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

**Conclusion for Human Health**

Regarding human health hazards, the biocidal product FREE LAND 10 EC 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 coated coveralls and the product is used according to the instructions of use. Furthermore, the secondary exposure of the general public does not entail unacceptable risks for human health.

**Conclusion for Environment**

According to the environmental risk assessment for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning), Scenario 4 – *Targeted residual treatment around the building against mosquitoes* xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx The risk of the remaining uses is acceptable when FREE LAND 10 EC is used according to indication of use.

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**Conclusion for Efficacy:**

Several efficacy studies (laboratory, simulated and field studies) were submitted by the applicant to support the intended uses of Free Land 10EC (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:

* Spot treatment by professionals and non-professionals, indoors for the control of German (*Blattella germanica*), Oriental (*Blatta orientalis*) cockroaches and Black garden ant (*Lasius niger*) at 40 g /m2 of a 0.5% solution (for non-porous surfaces) and 50 g /m2 of 1% solution (for porous surfaces).The product has a residual period of 4 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches is expected 4 hours after after exposure of insects to the treated surfaces” (Intended Uses # 1 and 2, as applied for by the applicant).
* Crack and crevice treatment by professionals and non-professionals, indoors for the control of German (*Blattella germanica*), Oriental (*Blatta orientalis*) cockroaches and Black garden ant (*Lasius niger*) at 40 g /m2 of a 0.5% solution (for non-porous surfaces) and 50 g /m2 of 1% solution (for porous surfaces).The product has a residual period of 4 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches is expected 4 hours after after exposure of insects to the treated surfaces” (Intended Uses # 3 and 4, as applied for by the applicant).
* Surface outdoor treatment around buildings against tiger mosquito (*Aedes albopictus*) by professionals and non-professionals at 50 g /m2 of a 0.5% solution. The product has 3 days residual action against mosquitoes. The product provides sufficient control of mosquitoes when applied at a distance of 50 cm from the treated surfaces (Intended Uses # 8 and 9, as applied for by the applicant).
* XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
* Direct application around and at the entrance of the ant nest, outdoors, at 25 gr/ nest, by professionals and non-professionals. (Intended Uses # 11 and 12, as applied for by the applicant).

Although the Intended Uses# 5 (Indoor barrier application in crack & crevice, professional use), #6 (Indoor barrier application in crack & crevice, non-professional use) and #7 (Indoor flying wasp control) were included in the original dossier, they were not further supported by the applicant and therefore, were not evaluated by the eCA.

The overall conclusion of the evaluation is that the biocidal product FREE LAND 10 EC meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore **can be authorised** for the uses:

Use # 1 (Indoor spot application against crawling insects-Professional users),

Use # 2 (Indoor spot application against crawling insects-General public),

Use # 3 (Indoor application in crack & crevice against crawling insects-Professional users),

Use # 4 (Indoor application in crack & crevice against crawling insects-General public),

Use # 5 (Surface, targeted residual treatment around the building against tiger mosquito-Professional users) (Outdoor in rural areas),

Use # 6 (Surface targeted residual treatment around the building against tiger mosquito-General public) (Outdoor in rural areas),

Use # 7 (Ant nest eradication-Professional users) and

Use # 8 (Ant nest eradication-General public);

as specified in the Summary of Product Characteristics (SPC).

The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| FREE LAND 10 EC | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Activa S.r.l |
| **Address** | Via Feltre, 32, 20123 – Milano, Italy |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Activa S.r.l |
| **Address of manufacturer** | Via Feltre 32 -20132 Milano Italy |
| **Location of manufacturing sites** | (1) c/o ALTHALLER ITALIA s.r.l.  Strada Com.le per Campagna, 5  20078 - San Colombano al Lambro MI-Italy |
| (2) c/o FERBI SRL  Contrada Ripoli  64023 - Mosciano Sant'Angelo (TE)-Italy |
| (3) c/o DIACHEM S.p.A.  Via Mozzanica, 9/11  24043 Caravaggio (BG) - Italy |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin cis:trans 40:60 |
| **Name of substance supplier according to art. 95** | Limaru NV representing Tagros Chemicals India Private Limited for Cypermethrin on the article 95 list |
| **Address of substance supplier according art. 95:** | Paalsesteenweg 170 Bus 7, B-3583 BERINGEN, Belgium |
| **Name of manufacturer** | Tagros Chemicals India Private Ltd. |
| **Address of manufacturer** | Jhaver Centre, Rajah Annamalai Building,  IV Floor, 72, Marshalls Road,  600 008 Egmore, Chennai, India |
| **Location of manufacturing 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

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 |
| **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 purity according to Commission Implementing Regulation (EU) 2018/1130: 92% w/w  Minimum purity from the technical of source used for the preparation of the product Free Land 10 EC: 95 % w/w (Tagros) |
| **Structural formula** | A picture containing clock, watch  Description automatically generated |
| **Molecular weight** | 416.3 g/mol |
| **Molecural formula** | C22H19Cl2NO3 |

#### 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** | **Content** |
| --- | --- | --- | --- | --- | --- |
| cypermethrin | (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 10.0 % w/w  (pure)  10.53 % w/w  (technical)\* |
| Dipropylen glycol monomethyl ether | (2-methoxymethyl-ethoxy) propanol | Solvent | 34590-94-8 | 252-104-2 | 54.47 % w/w |
| Non-active substance | Confidential information. Please refer to the confidential information annex | | | | up to 100 |

\* based on minimum purity of 95% w/w for cypermethrin

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 FREE LAND 10 EC has been considered equivalent pursuant to Article 54 of Regulation (EU) no. 528/2012 to the reference source evaluated for approval by ECHA on

December 2020

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

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

The product contains (2-methoxymethylethoxy) propanol for which an Indicative Occupational Exposure Limit Value (IOELV) is available. Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| EC Emulsifiable concentrate |

### Hazard and precautionary statements

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

| **Classification** | | | |
| --- | --- | --- | --- |
| Hazard category | Specific target organ toxicity - repeated exposure, category 2 H373  Aquatic Acute 1 H400  Aquatic Chronic 1 H410 | | |
| Hazard statement | H373: May cause damage to the 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 | H373: May cause damage to the nervous system through prolonged or repeated exposure.  H410: Very toxic to aquatic life with long lasting effects. | | |
| Precautionary statements | P260 Do not breathe dust / fume / gas / mist / vapours / spray.  P273 Avoid release to the environment.  P314 Get medical advice / attention if you feel unwell.  P391 Collect spillage.  P501 Dispose of contents/container in accordance with local / regional / national / international regulations. | | |
|  | | | |
| Note | **-** | | |

### Authorised uses

#### Use description #1

Table 1. Use # 1 – Indoor spot application against crawling insects-Professional users

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Spot application |
| **Target organism (including development stage)** | Crawling insects  *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Spot application by spraying |
| **Application rate(s) and frequency** | To treat porous surfaces, use 10 g of concentrated product and dilute in 1 L of water (1%); mix thoroughly and apply with an appropriate sprayer at a rate of 50 mL of solution per 1 m²  To treat non-porous surfaces, use 5 g of concentrated product and dilute in 1 L of water (0.5%); mix thoroughly and apply with an appropriate sprayer at a rate of 40 mL of solution per 1 m².  Porous surfaces: application rate in terms of active substance is 52.7 mg t.g.a.i./m2.  Non-porous surfaces: application rate in terms of active substance is 21 mg t.g.a.i./m2.  Residuality: 4 weeks  Treatment can be performed up to 2 times per year. |
| **Category(ies) of users** | Trained professional and professional. |
| **Pack sizes and packaging material** | HDPE bottle with measuring cap: 100, 250, 500, 1000, 2000 ml.  HDPE bottle with measuring chamber (double neck bottle): 500, 1000 ml.  HDPE Jerrycan: 5, 10, 20 L. |

#### Use-specific instructions for use

|  |
| --- |
| The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, where insects usually hide. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply to areas susceptible to routine wet cleaning. * Avoid contact with treated surfaces. * Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). * A protective coverall (at least type X, EN XXXXX) shall be worn. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #2

Table 2. Use # 2 – Indoor spot application against crawling insects-General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Spot application |
| **Target organism (including development stage)** | Crawling insects  *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Spot application by spraying |
| **Application rate(s) and frequency** | In the case of porous surfaces (e.g. concrete, bricks, woods plastic etc.) (52.7 mg t.g.a.i./m2)   * Bottle with measuring window : measure 1 mL of product and pour in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 40 spray per m2 * Single use pack 1 mL: open the sealage and pour the content in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 40 spray per m2 * Ready to Dilute System: shake well and perform 40 spray per m2 * Cartridge system: shake well and perform 40 spray per m2   In the case of non porous surfaces (e.g. plastic, metal, ceramics etc.) (21 mg t.g.a.i./ m2):   * Bottle with measuring window: measure 0.5 mL of product and pour in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 32 spray per m2. * Single use pack 1 mL: open the sealage and pour the content in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 16 spray per m2. * Ready to Dilute System: shake well and perform 16 spray per m2. * Cartridge system: shake well and perform 16 spray per m2.   Residuality: 4 weeks  Treatment can be performed up to 2 times per year. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Bottle with measuring window (20ml)  Single use pack: 1 mL  Ready to Dilute System: 5mL  Cartridge system: 5mL |

#### Use-specific instructions for use

|  |
| --- |
| The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, where insects usually hide.  In the case of Ready to Dilute System, strip the collar, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of the Cartridge System, add 500ml of tap water in the bottle, position the cartridge in the neck of the bottle, position the trigger, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of Bottle with measuring window and Single use pack, the application is performed *via* trigger sprayer with a spray rate of 1.25 ml/spray. The appropriate volume of product is added to the required volume of water and agitated.  For the non-professional users the following limitation is proposed to be included : “Knockdown of cockroaches is expected 4 hours after exposure of insects to the treated surfaces”. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply to areas susceptible to routine wet cleaning. * Avoid contact with treated surfaces. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #3

Table 3. Use # 3 – Indoor application in crack & crevice against crawling insects-Professional users

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Application in cracks and crevices |
| **Target organism (including development stage)** | Crawling insects  *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Crack and crevice treatment by spraying |
| **Application rate(s) and frequency** | In the case of porous surfaces (e.g. concrete, bricks, woods plastic etc.) (52.7 mg t.g.a.i./m2): Use 10 g of concentrated product and dilute in 1 L of water (1%); mix thoroughly and apply with an appropriate sprayer at a rate of 50 mL of solution per 1 m².  In the case of non-porous surfaces (e.g. plastic, metal, ceramics etc.) (21 mg t.g.a.i./ m2): Use 5 g of concentrated product and dilute in 1 L of water (0.5%); mix thoroughly and apply with an appropriate sprayer at a rate of 40 mL of solution per 1 m².  Residuality: 4 weeks  Treatment can be performed up to 2 times per year. |
| **Category(ies) of users** | Trained professional and professional. |
| **Pack sizes and packaging material** | HDPE bottle with measuring cap: 100, 250, 500, 1000, 2000 ml.  HDPE bottle with measuring chamber (double neck bottle): 500, 1000 ml.  HDPE Jerrycan: 5, 10, 20 L. |

#### Use-specific instructions for use

|  |
| --- |
| Apply in cracks and crevices of surfaces such as: ceramic tile, marble, granite and other hard stone surfaces, metals (steel, iron, etc …), plastic, glass (ex: window panes), painted plywood. Apply the product directly into cracks and crevices from a distance of 40 cm.  The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harbourage for cockroaches and ants. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply to areas susceptible to routine wet cleaning. * Avoid contact with treated surfaces. * Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). * A protective coverall (at least type X, EN XXXXX) shall be worn. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #4

Table 4. Use # 4 – Indoor application in crack & crevice against crawling insects-General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | Application in cracks and crevices |
| **Target organism (including development stage)** | Crawling insects  *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Crack and crevice treatment by spraying |
| **Application rate(s) and frequency** | In the case of porous surfaces (e.g. concrete, bricks, woods plastic etc.) (52.7 mg t.g.a.i./m2)   * Bottle with measuring window: measure 1 mL of product and pour in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 40 spray per m2 * Single use pack 1 mL: open the sealage and pour the content in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 40 spray per m2 * Ready to Dilute System: shake well and perform 40 spray per m2 * Cartridge system: shake well and perform 40 spray per m2   In the case of non porous surfaces (e.g. plastic, metal, ceramics etc.) (21 mg t.g.a.i./ m2):   * Bottle with measuring window: measure 0.5 mL of product and pour in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 32 spray per m2. * Single use pack 1 mL: open the sealage and pour the content in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 16 spray per m2. * Ready to Dilute System: shake well and perform 16 spray per m2. * Cartridge system: shake well and perform 16 spray per m2.   Residuality: 4 weeks  Treatment can be performed up to 2 times per year. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Bottle with measuring window (20ml)  Single use pack: 1 mL  Ready to Dilute System: 5mL  Cartridge system: 5mL |

#### Use-specific instructions for use

|  |
| --- |
| Apply in domestic premises in crack and crevices, on surfaces such as: ceramic tile, marble, granite and other hard stone surfaces, metals (steel, iron, etc …), plastic, glass (ex: window panes), painted plywood. Apply the product directly onto the surface from a distance of 40 cm from the treated surface.  The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater, in all cracks and crevices that can be a harbourage for cockroaches and ants.  For the non-professional users the following limitation is proposed to be included: “Knockdown of cockroaches is expected 4 hours after exposure of insects to the treated surfaces”  In the case of Ready to Dilute System , strip the collar, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of the Cartridge System, add 500ml of tap water in the bottle, position the cartridge in the neck of the bottle, position the trigger, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of Bottle with measuring window and Single use pack, the application is performed *via* trigger sprayer with a spray rate of 1.25 ml/spray. The appropriate volume of product is added to the required volume of water and agitated. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply to areas susceptible to routine wet cleaning. * Avoid contact with treated surfaces. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #5

Table 5. Use # 5 – Surface residual treatment around the building against tiger mosquito-Professional users

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor around buildings in rural areas to control mosquitoes. |
| **Target organism (including development stage)** | *Aedes albopictus* |
| **Field of use** | Outdoor in rural areas |
| **Application method(s)** | Spray, surface treatment |
| **Application rate(s) and frequency** | Treat around building starting from a height of about 50cm, up to 150cm, treating a band of about one meter in height.  Use 2 g of concentrated product and dilute in 1 L of water (0.2%); mix thoroughly and apply with an appropriate sprayer at a rate of 50 mL of solution per 1 m².  Application rate in terms of active substance is 10.5 mg t.g.a.i. /m2.  Treatment can be performed up to 2 times per year.  The residual action of the product is 3 days |
| **Category(ies) of users** | Trained professional and professional. |
| **Pack sizes and packaging material** | HDPE bottle with measuring cap: 100, 250, 500, 1000, 2000 ml.  HDPE bottle with measuring chamber (double neck bottle): 500, 1000 ml.  HDPE Jerrycan: 5, 10, 20 L. |

#### Use-specific instructions for use

|  |
| --- |
| Dilute the product in water to 0.2% w/w, mix thoroughly and using a knapsack spray or an appropriate device, applying 50 mL of insecticide solution per m2.  The product should be applied uniformly over the selected area from a distance of 50 cm. The product acts against tiger mosquitoes by contact and vapour. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product on areas connected or near sewer system, drain water, manholes. * Do not apply during rainy or windy weather. Prevent exposure of non-target organisms (e.g., consider night application when pollinators including bees are not active, no treatment of plants during blooming period). * Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). * A protective coverall (at least type X, EN XXXXX) shall be worn. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #6

Table 6. Use # 6 – Surface residual treatment around the building against tiger mosquito-General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor around buildings in rural areas to control mosquitoes. |
| **Target organism (including development stage)** | *Aedes albopictus* |
| **Field of use** | Outdoor in rural areas |
| **Application method(s)** | Spray, surface treatment |
| **Application rate(s) and frequency** | Treat around building starting from a height of about 50cm, up to 150cm, treating a band of about one meter in height.   * Bottle with measuring window : measure 2 mL of product and pour in 1 L of water into an appropriate container with trigger spray. Shake well and perform 40 spray per m2 * Single use pack 2 mL: open the sealage and pour the content in 1 L of water into an appropriate container with trigger spray.Shake well and perform 40 spray per m2 * Ready to Dilute System: shake well and perform 8 spray per m2 * Cartridge system: shake well and perform 8 spray per m2   Application rate in terms of active substance is 10.5 mg t.g.a.i./m2)  Treatment can be performed up to 2 times per year.  The residual action of the product is 3 days |
| **Category(ies) of users** | Non-professional. |
| **Pack sizes and packaging material** | Bottle with measuring window: 20mL  Single use pack: 2 mL  Ready to Dilute System: 5mL  Cartridge system: 5mL |

#### Use-specific instructions for use

|  |
| --- |
| The product should be applied uniformly over the selected area from a distance of 50 cm. The product acts against tiger mosquitoes by contact and vapour.  In the case of Ready to Dilute System , strip the collar, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of the Cartridge System, add 500ml of tap water in the bottle, position the cartridge in the neck of the bottle, position the trigger, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of Bottle with measuring window and Single use pack, the application is performed *via* trigger sprayer with a spray rate of 1.25 ml/spray. The appropriate volume of product is added to the required volume of water and agitated. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply the product on areas connected or near sewer system, drain water, manholes. * Do not apply during rainy or windy weather. Prevent exposure of non-target organisms (e.g., consider night application when pollinators including bees are not active, no treatment of plants during blooming period). |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #7

Table 7. Use # 7 – Ant nest eradication-Professional users

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor for ant nest eradication. |
| **Target organism (including development stage)** | Scientific name*: Lasius niger*  Common name: Garden ant  Development stage: Adults |
| **Field of use** | Outdoor |
| **Application method(s)** | Application around and at the entrance of the nest by spraying.  One single nest application to eradicate the nest |
| **Application rate(s) and frequency** | Concentrated product has to be diluted in water to 0.5% w/w before use. The quantity of insecticide solution (diluted) to be applied to each nest is 25 g/nest.  (Application rate in terms of active substance is 13.2 mg t.g.a.i./nest). |
| **Category(ies) of users** | Trained professional and professional. |
| **Pack sizes and packaging material** | HDPE bottle with measuring cap: 100, 250, 500, 1000, 2000 ml.  HDPE bottle with measuring chamber (double neck bottle): 500, 1000 ml.  HDPE Jerrycan: 5, 10, 20 L. |

#### Use-specific instructions for use

|  |
| --- |
| Dilute the product in water at the recommended rate, mix thoroughly and apply using an appropriate sprayer to distribute the solution. Application must be done at a rate of 25 mL of insecticide solution per nest, applied around and at the entrace of the nest. To optimize the treatment efficacy, do not apply in case of rain or wind. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Treatment of one single nest per application.  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).  A protective coverall (at least type X, EN XXXXX) shall be worn. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### Use description #8

Table 8. Use # 8 – Ant nest eradication-General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor for ant nest eradication. |
| **Target organism (including development stage)** | Scientific name: *Lasius niger*  Common name: Garden ant  Development stage: Adults |
| **Field of use** | Outdoor |
| **Application method(s)** | Application around and at the entrance of the nest by spraying.  One single nest application to eradicate the nest. |
| **Application rate(s) and frequency** | * Single use pack 1 mL: open the sealage and pour the content in 100 mL of water into an appropriate container with trigger spray. Shake well and perform 10 spray per nest. * Ready to Dilute System: shake well and perform 10 spray per nest * Cartridge system: shake well and perform 10 spray per nest.   Application rate in terms of active substance is 13.2 mg t.g.a.i./nest. |
| **Category(ies) of users** | General public (non-professional). |
| **Pack sizes and packaging material** | Single use pack: 1 mL  Ready to Dilute System: 5 mL  Cartridge system: 5 mL |

#### Use-specific instructions for use

|  |
| --- |
| In the case of Ready to Dilute System , strip the collar, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger.  In the case of the Cartridge System, add 500ml of tap water in the bottle, position the cartridge in the neck of the bottle, position the trigger, screw down the ferrule, shake the container. The application has to be performed using the specific container, equipped with the appropriated trigger  In the case of Single use pack, the application is performed *via* trigger sprayer with a spray rate of 1.25 ml/spray. The appropriate volume of product is added to the required volume of water and agitated.  Application must be done at recommended rate around and at the entrance of the nest. To optimize the treatment efficacy, do not apply in case of rain or wind. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Treatment of one single nest per application. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

#### 

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

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

|  |
| --- |
| Please, refer to section 2.1.5 General directions for use. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Always read the label or leaflet before use and follow all the instructions provided. |

#### 

#### Risk mitigation measures

|  |
| --- |
| - The product should be applied in such a way that children, farm animals and pets, especially cats, do not come into contact with the product.  - Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.  - Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.  - Keep out of reach of children and pets.  - Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.  - Do not spray onto people and pets.  For applications indoor to control crawling insects:  - N-122 Cover all surfaces and facilities likely to be in contact with food, feed and drinking water.  - N-127 Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.  - N-132 Do not apply directly to surfaces or rooms on which food or feed is stored, prepared or eaten.  - N-301 Do not store near food, drink and feed.  See use-specific risk mitigation measures detailed above. |

#### 

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

|  |
| --- |
| - Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation).  If symptoms persist: Get medical advice.  - 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.  - Do not release the product or its empty containers in the environment. |

#### 

#### 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 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.  Shelf-life: 2 years, in original container at room temperatures. Avoid extreme temperatures and exposure to direct sunlight. Protect from frost |

### 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** | **Intended user (e.g. professional, non-professional)** | **Intended Uses** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle with measuring cap | 100, 250, 500, 1000, 2000 ml | HDPE | HDPE | professional | 1-3-5-7 | yes |
| Bottle with measuring chamber.  (Double nek) | 500, 1000 ml | HDPE | HDPE | professional | 1-3-5-7 | yes |
| Jerry can | 5, 10, 20 L | HDPE | HDPE | professional | 1-3-5-7 | yes |
| Cartridge (ready to dilute system and cartridge system) | 5 ml | HDPE | HDPE | non-professional | 2-4-6-8 | yes |
| Bottle with measuring window | 20 ml | HDPE | HDPE | non-professional | 2, 4, 6 | yes |
| Single Use pack | 1 ml  2 ml | HDPE | HDPE | non-professional | 2-4-6-8 | yes |

More information, photos and specification of the packaging are available in IUCLID.

### Documentation

#### Data submitted in relation to product application

In relation to product application, the following data have been submitted:

* 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
* Storage stability test – long term storage at ambient temperature (in progress)
* Emulsion characteristics and re-emulsification properties
* Persistent foam
* Surface tension
* Viscosity
* Explosives: BAM FALLHAMMER and KOENEN TUBE
* Closed Cup Flash Point
* Oxidising liquids
* Corrosive to metals
* Auto-ignition temperature
* Methods for detection and identification
* Efficacy studies

#### Access to documentation

The applicant Activa submits the Letter of Access granted by Limaru (acting on behalf of Tagros) for the active substance cypermethrin as well as copy of the Letter of Access granted by the main notifier Arysta (formerly Agriphar) to Tagros for the studies used for the inclusion of cypermethrin in the Union list of approved active substances under the Biocidal Products Regulation.

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

## Assessment of the biocidal product

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

#### Use description #1

Table 5. Use # 1 – Indoor spot application in not wet cleaned areas

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Application of the product must be performed in areas that are not wet cleaned.  Total area treated in a standard house = 2 m2  Total area treated in a large building = 9.3 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 1% w/w before use.  Application rate of diluted product is 50 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | Trained professional and professional. |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #2

Table 6. Use # 2 – Indoor spot application in not wet cleaned areas

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Application of the product must be performed in areas that are not wet cleaned.  Total area treated in a standard house = 2 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 1% w/w before use.  Application rate of diluted product is 50 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | Non-professional. |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #3

Table 7. Use # 3 – Indoor spot application in crack & crevice

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Total area treated in a standard house = 2 m2  Total area treated in a large building = 9.3 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Periplaneta Americana*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use. Therefore, the final concentration of cypermethrin in in-use product is 0.05% w/w.  Application rate of diluted product is 20 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | trained professional and professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #4

Table 8. Use # 4 – Indoor spot application in crack & crevice

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Total area treated in a standard house = 2 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Periplaneta Americana*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use. Therefore, the final concentration of cypermethrin in in-use product is 0.05% w/w.  Application rate of diluted product is 20 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | non-professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #5

Table 9. Use # 5 – Indoor barrier application in crack & crevice

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Application of the product must be performed in areas that are not wet cleaned.  Total area treated in a standard house = 20 m2  Total area treated in a large building = 93 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Periplaneta Americana*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use.  Application rate of diluted product is 20 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | trained professional and professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #6

Table 10. Use # 6 – Indoor barrier application in crack & crevice

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | Application of the product must be performed in areas that are not wet cleaned.  Total area treated in a standard house = 20 m2 |
| **Target organism (including development stage)** | *Blattella germanica*  *Blatta orientalis*  *Periplaneta Americana*  *Lasius niger* |
| **Field of use** | Indoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use. Therefore, the final concentration of cypermethrin in in-use product is 0.05% w/w.  Application rate of diluted product is 20 mg a.i./m2.  Application up to 2 times per year. |
| **Category(ies) of users** | non-professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #7

Table 11. Use # 7 – Indoor flying wasp control

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | The product is applied directly on a single wasp when it is laid on a surface. |
| **Target organism (including development stage)** | *Vespula germanica* |
| **Field of use** | Indoor |
| **Application method(s)** | Pump spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 5% w/w before use.  Dose of application is 20 mg a.i./insect.  Application up to 2 times per year. |
| **Category(ies) of users** | non-professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #8

Table 12. Use # 8 – Targeted residual treatment around the building against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor around buildings in rural areas to control flying insects. |
| **Target organism (including development stage)** | *Aedes albopictus*  *Culex pipiens* |
| **Field of use** | Outdoor, only in rural area |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.2% w/w before use. Quantity of insecticide solution (diluted) applied is 50 g/m2.  Application rate of diluted product is 10 mg/m2. |
| **Category(ies) of users** | Trained professional and professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #9

Table 13. Use # 9 – Targeted residual treatment around the building against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor around buildings in rural areas to control flying insects. |
| **Target organism (including development stage)** | *Aedes albopictus*  *Culex pipiens* |
| **Field of use** | Outdoor, only in rural area |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.2% w/w before use. Quantity of insecticide solution (diluted) applied is 50 g/m2.  Application rate of diluted product is 10 mg/m2. |
| **Category(ies) of users** | non-professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### XXXXXXXXXXXXXXX

Table 14. Use # 10 – XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

|  |  |
| --- | --- |
| **Product Type** | XXXXX |
| **Where relevant, an exact description of the authorised use** | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX |
| **Target organism (including development stage)** | *XXXXXXXXX*  *XXXXXXXXXXXXX* |
| **Field of use** | XXXXXXXXXXXXXXXXXXX |
| **Application method(s)** | XXXXXXXX |
| **Application rate(s) and frequency** | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  - XXXXXXXXXXXXXXXXXXXXXXXXXXX  - XXXXXXXXXXXXXXXXXXXXXXXXXXX  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  XXXXX  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX |
| **Category(ies) of users** | XXXXXXXXXXXXXXXXXXXXXXXX |
| **Pack sizes and packaging material** | XXXXXXXXXXXXXXXXXXXXXXX |

#### Use description #11

Table 15. Use # 11 – Ant nest eradication

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor for ant nest eradication. |
| **Target organism (including development stage)** | *Lasius niger* |
| **Field of use** | Outdoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use. Quantity of insecticide solution (diluted) applied is 40 g/m2.  Application rate is 20 mg a.i./nest |
| **Category(ies) of users** | Trained professional and professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use description #12

Table 16. Use # 12 – Ant nest eradication

|  |  |
| --- | --- |
| **Product Type** | PT 18 |
| **Where relevant, an exact description of the authorised use** | The product is applied outdoor for ant nest eradication. |
| **Target organism (including development stage)** | *Lasius niger* |
| **Field of use** | Outdoor |
| **Application method(s)** | Knapsack spray |
| **Application rate(s) and frequency** | Concentrated product (i.e. FREE LAND 10 EC) have to be diluted to 0.5% w/w before use. Quantity of insecticide solution (diluted) applied is 40 g/nest.  Application rate of diluted product is 20 mg a.i./nest. |
| **Category(ies) of users** | non-professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

### Physical, chemical and technical properties

All the formulation test items (XXXXXXXXXXXXXXXXXXXXXX) have the same composition with the one described in the Confidential Section.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **Acceptability / eCA comment** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830.6302 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | Liquid at 20°C. | GLP Study  No. CH – 0004/2020. | Acceptable |
| Colour at 20 °C and 101.3 kPa | OPPTS 830.6303 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number:  XXXX | Clear yellow at 20°C. | GLP Study  No. CH – 0004/2020. | Acceptable |
| Odour at 20 °C and 101.3 kPa | OPPTS 830.6304 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | Characteristic odour at 20°C. | GLP Study  No. CH – 0004/2020. | Acceptable |
| Acidity / alkalinity | CIPAC method MT 75.3 and OECD Test No 122 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | pH value of the neat test item without dilution was 7.7 (rounded mean value of two measurements) and the pH value of a 1 % w/v aqueous emulsion of the test item sample was 4.9 (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. | GLP Study  No. CH – 0004/2020. | Acceptable |
| Relative density / bulk density | Guideline A.3 in Council Regulation (EC) No 440/2008 part A, CIPAC method MT 3.2 and OECD Test No 109 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | Test item density is 0.9772 g/mL at 20°C, the relative density (𝐷2020) is 0.9789 and the relative density (𝐷420) is 0.9772. | GLP Study  No. CH – 0004/2020. | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical Methods for Technical and Formulated Pesticides:  - MT 46 “Accelerated storage procedure”  - MT 18 “Standard waters”  - MT 36.3 “Emulsion characteristics and re-emulsification properties”  - MT 47.3 “Persistent foam”  - MT 75.3 “Determination of pH values” Note: since the pH value ranged from 4 to 10, the acidity or alkalinity test (CIPAC MT 31 or 191) was not performed. | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | After 8 weeks of storage at 40°C, the Cypermethrin active ingredient content and the physico-chemical properties of the test item were comparable to the relevant values obtained in the initial characterisation.  Packaging  Initial characterisation: HDPE bottle  After 8 weeks of storage at 40°C: HDPE bottles, labelled as “A” and “B”  Weight variation (%)  Initial characterisation: -  After 8 weeks of storage at 40°C: A: -0.01 %; B: 0.00 %  Cypermethrin active ingredient content  Initial characterisation: 9.32 ± 0.06 % w/w; Cis: 3.77 ± 0.03 % w/w; Trans: 5.55 ± 0.04 % w/w  After 8 weeks of storage at 40°C: 9.42 ± 0.03 % w/w; Cis: 3.80 ± 0.01 % w/w; Trans: 5.63 ± 0.02 % w/w  Appearance (Colour, odour and physical state)  Initial characterisation: Clear yellow liquid with characteristic odour  After 8 weeks of storage at 40°C: Amber liquid with characteristic odour  Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)  Initial characterisation: -  After 8 weeks of storage 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: 7.7  After 8 weeks of storage at 40°C: 7.6  pH value (1% w/v aqueous dilution)  Initial characterisation: 4.9  After 8 weeks of storage at 40°C: 4.8  Persistent foam  Initial characterisation: Foam after 1 minute: 0.2 % w/v = 4 mL; 1.0 % w/v = 6 mL  After 8 weeks of storage at 40°C: Foam after 1 minute: 0.2 % w/v = 6 mL; 1.0 % w/v = 8 mL  Emulsion characteristics and re-emulsification properties  Initial characterisation: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.2 % w/v and 1.0 % w/v)  After 8 weeks of storage at 40°C: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.2 % w/v and 1.0 % w/v)  From the above reported data, it can be concluded that the FREE LAND 10 EC formulation sample is stable in its commercial packaging under the tested accelerated storage conditions (8 weeks of storage at 40°C). | GLP Study  No. CH – 0006/2020. | Acceptable  No significant variation of physicochemical and technical properties appears during storage.  The biocidal product Free Land 10 EC is considered stable when stored in its initial commercial packaging from HDPE under the tested accelerated storage conditions (40°C for 8 weeks). |
| Test item: FREE LAND 10 EC  Cypermethrin: 10.18 % w/w  Batch number: XXXXXXXXXX | After 14 days of storage at 54°C, the Cypermethrin active ingredient content and the physico-chemical properties of the test item were comparable to the relevant values obtained in the initial characterisation.  Packaging  Initial characterisation: HDPE bottle  After 14 days of storage at 54°C: HDPE bottles, labelled as “A” and “B”  Weight variation (%)  Initial characterisation: -  After 14 days of storage at 54°C: A: -0.01 %; B: -0.02 %  Cypermethrin active ingredient content  Initial characterisation: 9.77 ± 0.05 % w/w; Cis: 3.96 ± 0.03 % w/w; Trans: 5.81 ± 0.03 % w/w  After 14 days of storage at 54°C: 9.77 ± 0.05 % w/w; Cis: 3.96 ± 0.02 % w/w; Trans: 5.81 ± 0.03 % w/w  Appearance (Colour, odour and physical state)  Initial characterisation: Clear yellow liquid with characteristic odour  After 14 days of storage at 54°C: Clear yellow liquid with characteristic odour  Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally)  Initial characterisation: -  After 14 days of storage at 54°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: 7.7  After 14 days of storage at 54°C: 5.4  pH value (1% w/v aqueous dilution)  Initial characterisation: 4.9  After 14 days of storage at 54°C: 4.9  Persistent foam  Initial characterisation: Foam after 1 minute: 0.01 % w/v = 0 mL; 1.0 % w/v = 6 mL  After 14 days of storage at 54°C: Foam after 1 minute: 0.01 % w/v = 0 mL; 1.0 % w/v = 4 mL  Emulsion characteristics and re-emulsification properties  Initial characterisation: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.01 % w/v and 1.0 % w/v)  After 14 days of storage at 54°C: Complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (0.01 % w/v and 1.0 % w/v)  From the above reported data, it can be concluded that the FREE LAND 10 EC formulation sample is stable in its commercial packaging under the tested accelerated storage conditions (14 days of storage at 54°C). | GLP Study  No. CH – 0451/2021 | Acceptable  No significant variation of physicochemical and technical properties appears during storage.  The biocidal product Free Land 10 EC is considered stable when stored in its initial commercial packaging from HDPE under the tested accelerated storage conditions (54°C for 14 days). |
| **eCA comment on Substance of concern:** (2-methoxymethyl-ethoxy) propanol has been considered a substance of concern in the formulation Free Land 10 EC.  No storage data and method of analysis of the substance of concern is required, since SoC cannot be formed during storage and its concentration remains unchanged as applicant stated. | | | | | |
| 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  - EPA Product Properties Test Guidelines:  OPPTS 830.6302 (1996) “Color”;  OPPTS 830.6303 (1996) “Physical State”;  OPPTS 830.6304 (1996) “Odor”.  - CIPAC:  MT 18 “Standard waters”  MT 36.3 “Emulsion characteristics and re-emulsification properties”  MT 47.3 “Persistent foam”  MT 75.3 “Determination of pH values”  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, July 2013 “Determination of pH, Acidity and Alkalinity”.  - Cypermethrin active ingredient content with the Internal Analytical Method No. 0005/2020  adjusted and validated in GLP Study CH – 0005/2020.  - 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: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | |  |  | | --- | --- | | Test | Initial characterisation | | Cypermethrin active ingredient content | 9.32 ± 0.06 % w/w  Cis: 3.77 ± 0.03 % w/w  Trans: 5.55 ± 0.04 % w/w | | Appearance (Colour, odour and physical state) | Clear yellow liquid with characteristic odour | | pH value (neat test item) | 7.7 | | pH value (1% w/v aqueous dilution) (1) | 4.9 | | Persistent foam | Foam after 1 minute:  0.01 % w/v = 0 mL  0.2 % w/v = 4 mL  1.0 % w/v = 6 mL | | Emulsion characteristics and re- emulsification properties | Complete initial emulsification (0h); complete re- emulsification (24h) for all application rates (0.01 % w/v, 0.2% w/v  and 1.0% w/v) |  |  |  |  |  | | --- | --- | --- | --- | | Test | After 6 months storage | After 12 months storage | After 24 months storage | | Packaging | HDPE bottle, labelled “C” | HDPE bottle, labelled “D” | HDPE bottles, labelled “E” and “F” | | Weight variation (%) | “C”: 0.01 % | “D”: 0.00 % | “E”: 0.02 %  “F”: 0.02 % | | Cypermethrin active ingredient content (all in % w/w) | 9.28 ± 0.02  (-0.46% from T0)  Cis: 3.72 ± 0.03  Trans: 5.56 ± 0.02 | 9.10 ± 0.03  (-2.36% from T0)  Cis: 3.69 ± 0.02  Trans: 5.41 ± 0.01 | 9.24 ± 0.03  (-0.81% from T0)  Cis: 3.71 ± 0.02  Trans: 5.54 ± 0.02 | | Appearance (Colour, odour and physical state) | Clear yellow liquid with characteristic odour | Clear yellow liquid with characteristic odour | Clear yellow liquid with characteristic odour | | Compatibility (resistance) of the packaging material (Visual examination of packaging both externally and internally) | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident  corrosion phenomena | The container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident  corrosion phenomena | 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) | 7.3 | 7.3 | 7.2 | | pH value (1% w/v aqueous dilution) (1) | 5.1 | 5.5 | 5.5 | | Persistent foam (Standard Water D) | Foam after 1 minute:  0.2 % w/v = 4 mL  1.0 % w/v = 6 mL | Foam after 1 minute:  0.2 % w/v = 6 mL  1.0 % w/v = 6 mL | Foam after 1 minute:  0.01% w/v = 0 mL  0.2 % w/v = 1 mL  1.0 % w/v = 3 mL | | Emulsion characteristics and re-emulsification properties (Standard Water D and A) | Complete initial emulsification (0h); complete re- emulsification (24h) for both application rates  (0.2 % w/v and  1.0 % w/v) | Complete initial emulsification (0h); complete re- emulsification (24h) for both application rates  (0.2 % w/v and  1.0 % w/v) | Complete initial emulsification (0h); complete re- emulsification (24h) for all application rates  (0.01 % w/v,  0.2 % w/v and  1.0 % w/v) |   From the obtained results, it can be concluded that no significant change was found in the Cypermethrin active ingredient content for the sample stored in the HDPE bottle with a screw cap for 24 months of storage at ambient warehouse temperature, comparing the obtained results at the beginning of the storage stability, that it complies with the tolerance and it is in accordance with the declared value.  No change in the sample appearance, colour or odour, was found in the test item formulation sample stored in HDPE bottle with a screw for 24 months of storage at ambient warehouse temperature and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena.  Moreover, no significant changes in physical properties (pH value, persistent foam, emulsion characteristics and re-emulsification properties) were found for the test item stored in the HDPE bottle with a screw cap for 24 months of storage at ambient warehouse temperature, comparing the initial characterisation.  From the above reported data, it can be concluded that the FREE LAND 10 EC formulation sample is stable in its commercial packaging during 24 months storage at ambient warehouse temperature. | GLP Study No. CH – 0007/2020 | Acceptable  No significant variation of physicochemical and technical properties appears during storage.  The biocidal product Free Land 10 EC is considered stable for two years when stored in its initial commercial packaging from HDPE at ambient temperature. |
| **eCA comment on Substance of concern:** (2-methoxymethyl-ethoxy) propanol has been considered a substance of concern in the formulation Free Land 10 EC.  No storage data and method of analysis of the substance of concern is required, since SoC cannot be formed during storage and its concentration remains unchanged as applicant stated. | | | | | |
| Storage stability test – **low temperature stability test for liquids** | - | - | Data on low temperature storage stability are not available.  According to Guidance on BPR Volume I, Part A Chapter III version 1.1 Novembre 2014, in the label of the product there is steated that the product must not be stored under conditions of ≤0°C (e.g. protect from frost). | - | Acceptable  Labeling ”Protect from frost” should be applied. |
| 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. | IUCLID section 3.4.2.1 | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical  Methods for Technical and Formulated Pesticides: MT 46 “Accelerated storage procedure” | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | No significant change was found in the Cypermethrin active ingredient content for the sample stored in the HDPE bottle with a screw cap for 8 weeks of storage at 40°C and 2 weeks at 54°C, comparing the obtained results at the beginning of the storage stability, that it complies with the tolerance and it is in accordance with the declared value.  A slight change of colour was noted from light yellow to amber and no change in the sample appearance or odour, was found in the test item formulation sample stored in HDPE bottle with a screw cap for 8 weeks of storage at 40°C and no variation on the packaging was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena.  Moreover, no significant changes in physical properties (pH value, persistent foam, emulsion characteristics and re-emulsification properties) were found for the test item stored in the HDPE bottle with a screw cap for 8 weeks of storage at 40°C and 2 weeks at 54°C, comparing the initial characterisation. | GLP Study No. CH – 0006/2020 | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical  Methods for Technical and Formulated Pesticides: MT 46 “Accelerated storage procedure” | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: 4633  Cypermethrin: 10.18 % w/w  Batch number: XXXXXXXXXX | No variation on the packaging was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena after 8 weeks of storage at 40°C and 2 weeks at 54°C. | GLP Study No. CH – 0006/2020 | Acceptable |
| Wettability | Justification for the non-submission of data | - | Data waiving since the data are required only for solid preparations which are to be dispersed in water. | - | - |
| Suspensibility, spontaneity and dispersion stability | Justification for the non-submission of data | - | Data waiving, since applicability depends on the formulation type (nature) of the biocidal product. FREE LAND 10 EC is a an emulsifiable concentrate, not a suspension concentrate. | - | - |
| Wet sieve analysis and dry sieve test | Justification for the non-submission of data | - | Data waiving, since applicability depends on the formulation type (nature) of the biocidal product. FREE LAND 10 EC is a an emulsifiable concentrate; therefore, this endpoint is not relevant. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | MT 36.3 “Emulsion characteristics and re-emulsification properties” | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX  Test item: FREE LAND 10 EC  Cypermethrin: 10.18 % w/w  Batch number: XXXXXXXXXX | From the experimental data obtained according to CIPAC method MT 36.3 in Standard Water D and Standard Water A, it can be concluded that for FREE LAND 10 EC formulation sample, a complete initial emulsification was noted after a single inversion and waiting for 30 seconds either for 0.002 kg/L (0.2 % w/v) and 0.01 kg/L (1.0 % w/v) emulsion.  Moreover, a complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds either for 0.002 kg/L (0.2 % w/v) and 0.01 kg/L (1.0 % w/v) emulsion.  New test has been done at 0.01% w/v.  A complete initial emulsification was noted after a single inversion and waiting for 30 seconds for 0.001 kg/L (0.01 % w/v) suspension.  Moreover, a complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds for 0.001 kg/L (0.01 % w/v) suspension | GLP Study No. CH – 0004/2020  GLP Study No. CH – 0450/2021 | Acceptable |
| Disintegration time | Justification for the non-submission of data | - | 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 | - | - | FREE LAND 10 EC is not a powder biocidal product and it cannot generates aerosols. | - | - |
| Persistent foaming | MT 47.3 “Persistent foam”  CIPAC MT 18 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX  Test item: FREE LAND 10 EC  Cypermethrin: 10.18 % w/w  Batch number: XXXXXXXXXX | 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 4 mL for 0.2 % w/v emulsion and 6 mL for 1.0 % w/v emulsion, as mean of two determinations.  New test has been done at 0.01% w/v.  It can be concluded that, after 1 minute, the persistent foam of test item formulation sample is 0 mL for 0.01 % w/v suspension. | GLP Study No. CH – 0004/2020  GLP Study No. CH – 0450/2021 | Acceptable |
| Flowability/Pourability/Dustability | Justification for the non-submission of data | - | Data waiving, since applicability depends on the formulation type (nature) of the biocidal product. FREE LAND 10 EC is an emulsifiable concentrate, not a suspension concentrate. | - | - |
| Burning rate — smoke generators | Justification for the non-submission of data | - | Data waiving since the preparation is not applied as a smoke. | - | - |
| Burning completeness — smoke generators | Justification for the non-submission of data | - | Data waiving since the preparation is not applied as a smoke. | - | - |
| Composition of smoke — smoke generators | Justification for the non-submission of data | - | Data waiving since the preparation is not applied as a smoke. | - | - |
| Spraying pattern — aerosols |  |  | FREE LAND 10 EC is not an aerosol; therefore, this endpoint is not relevant. |  | - |
| Physical compatibility | Justification for the non-submission of data | - | Not required. The product is not intended to be used with other products (including other biocidal products). | - | - |
| Chemical compatibility | Justification for the non-submission of data | - | Data waiving. Data to address the physical and chemical compatibility must not be provided since the biocidal product can not co-apply with other substances, mixtures or biocidal or non-biocidal products. | - | - |
| Degree of dissolution and dilution stability | Justification for the non-submission of data | - | Data waiving. The product is not used in a water soluble bag or tablets. The dilution stability is not determined since the product is not a water-soluble preparations. | - | - |
| Surface tension | Guideline A.5 in Council Regulation (EC) No 440/2008 part A and OECD Guideline No. 115 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX  Test item: FREE LAND 10 EC  Cypermethrin: 10.18 % w/w  Batch number: XXXXXXXXX | Surface tension at 20°C of the undiluted test item is 26.2 mN/m and the surface tension at 20°C of 0.002 kg/L (0.2 % w/v) and 0.01 kg/L (1.0 % w/v) test item aqueous solutions is 35.9 mN/m and 32.1 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.  New test has been done at 0.01% w/v.  Surface tension at 20°C of the undiluted test item is 32.5 mN/m and the surface tension at 20°C of 0.001 kg/L (0.01 % w/v) test item aqueous solutions is 43.0 mN/m.  According to the interpretation of the results suggested in the A.5 method, the test item should be regarded as a surface-active material. | GLP Study No. CH – 0004/2020  GLP Study No. CH – 0450/2021 | Acceptable |
| Viscosity | CIPAC method MT 192 and OECD Guideline No. 114 | Test item: FREE LAND 10 EC  Cypermethrin: 9.97 % w/w  Batch number: XXXX | The test item is a Newtonian liquid and its dynamic viscosity doesn’t change with the shear rate.  The mean values of dynamic and kinematic viscosities 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 14.39 cP (mPa\*s)  - kinematic viscosity 14.73 cSt (mm2/s)  - shear-rate range (sec-1) from 15.84 to 132.00 sec-1 (from 12 to 100 rpm, spindle SC4-18)  at 40°C  - dynamic viscosity 7.28 cP (mPa\*s)  - kinematic viscosity 7.45 cSt (mm2/s)  - shear-rate range (sec-1) from 15.84 to 132.00 sec-1 (from 12 to 100 rpm, spindle SC4-18). | GLP Study No. CH – 0004/2020 | Acceptable |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Physical-chemical properties:  The preparation is a clear yellow liquid with characteristic odour at 20°C, containing 10.0 % w/w (pure) cypermethrin. The pH value of the neat test item without dilution was 7.7 and the pH value of a 1 % w/v aqueous emulsions of the test item sample was 4.9 at a temperature of 20°C. It density is 0.9772 g/mL at 20°C. The product is surface active since the surface tension of the undiluted test item is 26.2 mN/m. It is a Newtonian liquid and has a dynamic viscosity of 14.39 mPa\*s at 20°C. Its emulsion characteristics and persistent of foaming are acceptable.  Storage stability:  After storage at 40°C for 8 weeks, for 2 weeks at 54°C and for 24 months at ambient temperature (in HDPE bottle), the test item did not show any significant difference in terms of active ingredient content, pH value, persistent of foam, emulsion characteristics and re-emulsification properties, compared to the initial conditions. The product FREE LAND 10 EC is stable for two years when stored in its initial commercial packaging.  The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. |

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| **Conclusion on the packaging of the biocidal product** |
| Accelerated storage stability test for 8 weeks at 40°C, for 2 weeks at 54°C and for 24 months at ambient temperature demonstrated compatibility with the packaging material HDPE (1L bottle).  Extrapolation between different packaging size of the same material is acceptable. Therefore, the proposed packaging for the product Free Land 10 EC is considered acceptable for commercial use.  EL CA note: According to the applicant for the packaging stated as Cartridge (ready to dilute system and cartridge system): “The output of the trigger is 1,25 ml per each hit and at the proposed dosages the amount of a.i. released in each spray is 1,25 mg (0,00125 g).” |

### Physical hazards and respective characteristics

All the formulation test items (xxxxxxxxxxxxxxxx) have the same composition with the one described in the Confidential Section.

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **Acceptability** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Tests performed according to EU Method A.14 (Explosive properties) | Free Land 10 EC. Batch number xxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxx | Differential Scanning Calorimetry (DSC)  The test sample is charged to either a high pressure gold / steel crucible (sealed) or an aluminium crucible (open or pierced lid). An empty crucible of the same type is used as a reference. The sample and reference crucibles are placed into a furnace which is heated to the required start temperature (typically 25°C). Once the crucibles have equilibrated with the furnace, they are heated at a constant rate (of up to 20 K.min-1) up to 500°C or set to an isothermal set point. The heat flow from the sample crucible and the reference crucible are recorded throughout the test. Any exothermic activity within the sample will result in a larger heat flow out of the sample crucible relative to the reference crucible. For closed cell tests, the crucible is weighed before and after the test in order to determine if mass loss occurred (i.e. to confirm that the crucible remained sealed during the test).  The total heat of decomposition has been determined to be 673.6 J g-1.  There are not inorganic substances in the FREE LAND 10 EC and in all the organic substances in the formulation there are no chemical groups associated with explosive properties. In this respect it is possible to waive the trials as described in point 2.1.4.2. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures.  Anyway, not all the substances in the formulation are known, there is a small percentage of polymers with not complete structural formula know. It was preferable to make other investigation. After the trials is possible to consider the high heat of decomposition linked to a high concentration of molecules with long chains and not to unstable chemicals groups.  UN Test series 1 have been performed.  Tests are conducted in accordance with the procedure described in EU Regulation (EC) 440/2008, Annex Part A test A.14 and it are described also in Manual of test and Criteria of United Nation and in the Guidance on the Application of the CLP Criteria Version 5.0 – July 2017.  *BAM FALLHAMMER*  The sample of Free Land 10 EC was observed to exhibit no reaction at 40 J. The test result is therefore considered negative (-) (according to the EC Classification, Packaging & Labelling of Dangerous Substances in the European Union Part 2, Testing Methods, Jan 97).  *KOENEN TUBE*  The sample did not exhibit an explosion during any of the tests. The test result is therefore considered negative (-) (according to the EC Classification, Packaging & Labelling of Dangerous Substances in the European Union Part 2, Testing Methods, Jan 97). | Report number S3016007067AR1/2020  GLP study | Acceptable  From the available data, the biocidal product Free Land 10 EC is not expected to have explosive properties. |
| Flammable gases | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not a gas. | - |  |
| Flammable aerosols | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not an aerosol. | - |  |
| Oxidising gases | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not a gas. | - |  |
| Gases under pressure | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not a gas under pressure. | - |  |
| Flammable liquids | A.9 method (Flash point) in Council Regulation (EC) No 440/2008 of 30 May 2008  Pensky Martens closed cup method (test was performed with standard EN ISO 2719) | Free Land 10 EC. Batch number xxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxx | Closed Cup Flash Point Temperature: 82.0°C (corrected due to barometric pressure). | Report number S3016007067AR1/2020  GLP study | Acceptable |
| Flammable solids | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not solid. | - |  |
| 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.  Differential Scanning Calorimetry (DSC)  The total heat of decomposition has been determined to be 673.6 J g-1.  There are not inorganic substances in the FREE LAND 10 EC and in all the organic substances in the formulation there are no chemical groups associated with explosive properties.  Anyway, not all the substances in the formulation are known, there is a small percentage of polymers with not complete structural formula know. It was preferable to make other investigation.  After the trials is possible to consider the high heat of decomposition linked to a high concentration of molecules with long chains and not to unstable chemicals groups. | - | Acceptable |
| 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). | - | Acceptable |
| Pyrophoric solids | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not solid. | - |  |
| Self-heating substances and mixtures | Justification for the non-submission of data | - | 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 | - | Acceptable |
| 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). | - | Acceptable |
| Oxidising liquids | UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Test O.2. | Free Land 10 EC. Batch number xxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxx | The 1:1 mixture of the sample and cellulose was observed to have a mean pressure rise time greater than that of a 1:1 mixture of 65 % nitric acid and cellulose. The sample is therefore exempt from classification as an oxidising liquid of UN Class 5, Division 5.1. | Report number S3016007067AR1/2020  GLP study | Acceptable |
| Oxidising solids | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not solid. | - |  |
| Organic peroxides | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC does not contain organic peroxides. | - | Acceptable |
| Corrosive to metals | Test performed according to UN Manual of Tests and Criteria: Part III, 37.4: Test methods for corrosion to metals | Free Land 10 EC. Batch number xxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxx | The percentage mass losses on steel and aluminium were found to be < 13.5 % over 7 days and the maximum pit depth on the aluminium / steel coupons was < 120 μm. The sample is therefore exempt from classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations). | Report number S3016007067AR1/2020  GLP study | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) | Test performed according to EU Method A.15 (Auto-Ignition Temperature (Liquids and Gases)) | Free Land 10 EC. Batch number xxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxx | The autoignition temperature of Free Land 10 EC has been determined to be 200°C. | Report number S3016007067AR1/2020  GLP study | Acceptable |
| Relative self-ignition temperature for solids | Justification for the non-submission of data | - | Data waiving since FREE LAND 10 EC is not solid. | - |  |
| Dust explosion hazard | Justification for the non-submission of data | - | Data waiving sinceFREE LAND 10 EC is not a powder and does not contain (nor is able to produce) dust. | - | Acceptable |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product Free Land 10 EC is not expected to have explosive or oxidising properties, nor to be self-heating, self-reactive or flammable. None of the components is known to evolve any flammable gases in contact with water/humid air or to be pyrophoric. The product is not expected to be corrosive to metals. Thus, has no classification according to CLP criteria. |

### Methods for detection and identification

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.

Equipment used:

HPLC mod. 1200 equipped with UV detector, autosampler, managed by Chemstation software

HPLC column, Zorbax RX-SIL, 5 μm, 150 x 4.6 mm i.d.

Reference material: Cypermethrin, PESTANAL® analytical standard

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 FREE LAND 10 EC) | HPLC/UV  (HPLC mod. 1200 equipped with UV detector, autosampler, managed by Chemstation software).  detector wavelength 278 nm | Spike A:  Cypermethrin added 100.06 g/kg  Spike B:  Cypermethrin added 100.65 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: 51.48 – 308.88 μg/mL  Linearity Range: 2.57 – 15.44 % w/w  Cypermethrin Cis isomer  Injected range: 22.93 – 137.59 μg/mL  Linearity Range: -  Cypermethrin Trans isomer  Injected range: 28.55 – 171.29 μg/mL  Linearity Range: -  Cypermethrin  y = 15814x - 10513  r = 0.99982 | Specific  Cyper Cis I RT = 12.037 min  Cyper Cis II RT = 13.687 min  Cyper Trans I RT = 17.463 min  Cyper Trans II RT = 19.939 min | Spike A:  Cypermethrin added 100.06 g/kg  Cypermethrin found 97.74 g/kg  Cypermethrin recovery 97.69%  Spike B:  Cypermethrin added 100.65 g/kg  Cypermethrin found 99.61 g/kg  Cypermethrin recovery 98.96% | Total mean recovery 98.3% | Cypermethrin  Mean value (% w/w) = 9.32  Standard deviation (% w/w) = 0.06  Relative Standard Deviation (RSD%) = 0.62  Horrat value = 0.32  Cypermethrin Cis isomer  Mean value (% w/w) = 3.77  Standard deviation (% w/w) = 0.03  Relative Standard Deviation (RSD%) = 0.67  Horrat value = 0.31  Cypermethrin Trans isomer  Mean value (% w/w) = 5.55  Standard deviation (% w/w) = 0.04  Relative Standard Deviation (RSD%) = 0.67  Horrat value = 0.32 | Not required | FREE LAND 10 EC: Validation of the Analytical Method for the Determination of the Active Ingredient Content. GLP Study No. CH – 0005/2020. March 03, 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 | 51.48 – 308.88 | 2.57 – 15.44 |
| Cypermethrin Cis isomer | 5 | 22.93 – 137.59 | - |
| Cypermethrin Trans isomer | 5 | 28.55 – 171.29 | - |

(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 | 9.32 | 0.076 | 0.62 | 1.92 | 0.32 |
| Cypermethrin Cis isomer | 5 | 3.77 | 0.03 | 0.67 | 2.19 | 0.31 |
| Cypermethrin Trans isomer | 5 | 5.55 | 0.04 | 0.67 | 2.07 | 0.32 |

(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**

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

in the range 97 to 103 % for active ingredient content ≥ 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.

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| --- | --- | --- | --- | --- |
| **Active ingredient** | **Level** | **Tests No.** | **Recovery value** (%) | |
| Cypermethrin | Spike A | 1 det. | 97.69 | |
| Spike B | 1 det. | | 98.96 |

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| **Conclusion on the methods for detection and identification of the product** |
| The HPLC-UV analytical method was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of Cypermethrin (including its isomers), in Free Land 10 EC formulation. |

**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). |

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.

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

**Analytical methods for substances of concern**

According to ECHA "Guidance on the BPR: Volume I Parts A+B+C (version 2.0 May 2018)" in cases where the substances of concern cannot possibly increase on storage of the biocidal product then they do not need to be included in the storage stability/shelf life study.

(2-methoxymethylethoxy) propanol cannot increase during storage, since its vapor pressure is higher than vapor pressure of the others substances in the product. Vapor pressure of all ingredients is detailed in Confidential Annex.

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| **Conclusion on the methods for Substances of Concern in the product.** |
| An analytical method for the determination of the identified Substance of Concern in the formulation Free Land 10 EC is not required since SoC cannot be formed during storage and its concentration remains unchanged during storage as applicant stated. |

### Efficacy against target organisms

#### 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

FREE LAND 10EC is a emulsifiable concentrate (EC) insecticide (PT 18) product, containing 10% w/w cypermethrin (as pure active substance), corresponding to 10.5 % w/w. The product is intended for use, indoor or / and outdoor, by both professional and non-professional users to control German (*Blattella germanica*), Oriental (*Blatta orientalis*) and American (*Periplaneta americana*) cockroaches, 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.

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

The product Free Land 10 ECis an insecticide intended to be used for the control of German (*Blattella germanica*) and Oriental (*Blatta orientalis*) cockroaches, Black garden ants (*Lasius niger*) and mosquitoes (the tiger mosquito *Aedes albopictus* and the house mosquito *Culex pipiens*).

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

Efficacy of FREE LAND 10 EC has been assessed in terms of KD, mortality and population reduction, as detailed in section 2.2.5.5.

Free Land 10 EC is intended to be used by both professionals and non-professionals, indoors or/ and outdoors. Free Land 10 EC acts on harmful organisms by contact resulting in death.

#### 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 are presented in the following table:

| **Experimental data on the efficacy of the biocidal product against crawling insects** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blattella germanica* German cockroach  25 adults mixed sex (2-4 weeks aged) and 25 nymphs 3rd instar | Laboratory test (forced contact test on porous and non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile on its smooth side) and porous (concrete) tiles.  Adults and nymphs were placed for 60 min on the treated tiles (30 x 30 cm), under a Petri dish (14 cm in diameter) to prevent escaping and thus ensuring contact with the treated surface.  4 replicates / treatment (25 adults / replicate and 25 nymphs 3rd instar). Untreated tiles were also used as controls.  The product was applied at a dose of 50g/m2 of a 1% solution. Specifically, 10 gr of concentrated product was diluted in 1 liter of water (1%); then 50 gr of the solution was spread on 1 m² of surface, equal to a dosage of 4,5 gr per tile. The product was applied directly onto the tile from a distance of 40 cm from the treated surface.  Knockdown was recorded at 5, 10, 15, 30 and 60 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, T2, T3 and T4 (1, 2, 3 and 4 weeks after treatment respectively). | **Porous surface**  T0 (+ 2h) and T1  Knockdown (adults, nymphs):  ≥ 5 min: 100.00±0.00%  T2  Knockdown (adults):  - ≥ 10 min: 100.00±0.00%  Knockdown (nymphs):  ≥ 5 min: 100.00±0.00%  T3  Knockdown (adults):  ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 15 min: 100.00±0.00%  T4  Knockdown (adults):  - ≥ 20 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 15 min: 100.00±0.00%  Non-Porous surface  T0 (+ 2h) and T1  Knockdown (adults, nymphs):  ≥ 5 min: 100.00±0.00%  T2  Knockdown (adults):  - ≥ 10 min: 100.00±0.00%  Knockdown (nymphs):  ≥ 5 min: 100.00±0.00%  T3  Knockdown (adults):  ≥ 15 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 15 min: 100.00±0.00%  T4  Knockdown (adults):  - 5 min: 19.00±2.0%  - 10 min: 88.00±3.3%  - ≥ 15 min: 100.00±0.00%  Knockdown (nymphs):  - 5 min: 41.00±5.0%  - 10 min: 99.00±2.0%  - ≥ 15 min: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0% and 0-1 % respectively.  Mortality:  In both types of surfaces, mortality (adults and nymphs) was 100% 24 hours after the treatment in fresh and 4 weeks deposits. | Xxxxxxxx (2019),  Report No: 2493-LAB-BG/0819 |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blattella germanica* German cockroach  25 adults mixed sex (2-4 weeks aged) and 25 nymphs 3rd instar | Laboratory test (forced contact test on non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile on its smooth side) tiles.  Adults and nymphs were placed for 60 min on the treated tiles (30 x 30 cm), under a Petri dish (14 cm in diameter) to prevent escaping and thus ensuring contact with the treated surface.  4 replicates / treatment (25 adults / replicate and 25 nymphs 3rd instar). Untreated tiles were also used as controls.  The product was applied at a dose of 40 g/m2 of a 0.5% solution. Specifically, 5 g of concentrated product was diluted in 1 liter of water (0.5%). Then 40 g of the solution was spread on 1 m² of surface. The product was applied directly onto the tile from a distance of 40 cm from the treated surface.  Knockdown was recorded at 5, 15, 30, 60, 120 and 240 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, T2, T3 and T4 (1, 2, 3 and 4 weeks after treatment respectively). | Non-Porous surface  T0  Knockdown (adults):  - ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 15 min: 100.00±0.00%  T1  Knockdown (adults):  - ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 15 min: 100.00±0.00%  T2  Knockdown (adults):  - ≥ 60 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 30 min: 100.00±0.00%  T3  Knockdown (adults):  - 5,15 min: 00.00±0.00%  - 30 min: 11.00±2.00%  - 60 min: 55.00±0.00%  -120 min: 79.00±19.00%  Knockdown (nymphs):  - ≥ 60 min: 100.00±0.00%  T4  Knockdown (adults and nymphs):  - 5-60 min: 00.00±0.00%  Mortality (adults and nymphs) was 100% 24 hours after the treatment in fresh and 4 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2019),  Report No: 2532f-LAB-BG/0120 |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blatta orientalis* Oriental cockroach  25 adults mixed sex (2-4 weeks aged) and nymphs 3rd instar | Laboratory test (forced contact test on porous and non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile on its smooth side) and porous (concrete) tiles.  Adults and nymphs were placed for 60 min on the treated tiles (30 x 30 cm), under a Petri dish (14 cm in diameter) to prevent escaping and thus ensuring contact with the treated surface.  4 replicates / treatment (25 adults / replicate and 25 nymphs 3rd instar). Untreated tiles were also used as controls.  The product was applied at a dose of 50g/m2 of a 1% solution. Specifically, 10 gr of concentrated product was diluted in 1 liter of water (1%); then 50 gr of the solution was spread on 1 m² of surface, equal to a dosage of 4,5 gr per tile. The product was applied directly onto the tile from a distance of 40 cm from the treated surface.  Knockdown was recorded at 5, 10, 15, 30 and 60 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, T2, T3 and T4 (1, 2, 3 and 4 weeks after treatment). | Porous surface  T0 and T1  Knockdown (adults, nymphs):  ≥ 5 min: 100.00±0.00%  T2  Knockdown (adults):  ≥ 10 min: 100.00±0.00%  Knockdown (nymphs):  ≥ 5 min: 100.00±0.00%  T3  Knockdown (adults):  ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 5 min: 100.00±0.00%  T4  Knockdown (adults):  - ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 10 min: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0% and 0-1 % respectively.  Non-Porous surface  T0 (+ 2h) and T1  Knockdown (adults, nymphs):  ≥ 5 min: 100.00±0.00%  T2  Knockdown (adults):  - ≥ 10 min: 100.00±0.00%  Knockdown (nymphs):  ≥ 5 min: 100.00±0.00%  T3  Knockdown (adults):  ≥ 15 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 5 min: 100.00±0.00%  T4  Knockdown (adults):  - ≥ 30 min: 100.00±0.00%  Knockdown (nymphs):  - ≥ 10 min: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%.  Mortality: In both types of surfaces, mortality (adults and nymphs) was 100% 24 hours after the treatment in fresh and 4 weeks deposits. | Xxxxxxxx (2019),  Report No. 2493-LAB-BO/0819 |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blatta orientalis* Oriental cockroach  10 adults mixed sex and 10 nymphs | Laboratory test (forced contact test on non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (vitrified side of ceramic tile) surfaces.  Adults and nymphs were placed for 60 min on the treated tiles (30 x 30 cm), under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  3 replicates / treatment (10 adults / replicate and 10 nymphs 3rd instar). Untreated tiles were also used as controls.  The product was applied at a dose of 40g/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 at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 6 weeks. Seven assessments were carried out: T0 (after treatment), T1, T2, T3, T4, T5 and T6 (1,2,3,4, 5 and 6 weeks respectively after treatment). | Non-Porous surface  T0  Knockdown:  - ≥ 30 min: 100.00±0.00%  T1  Knockdown:  - ≥ 50 min: 100.00±0.00%  T2  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 18.33±6.01%  - 20 min: 38.33±8.33%  - 25 min: 75.00±18.03%  - 30 min: 83.33±16.67%  - 35 min: 86.67±13.33%  - 40 min: 86.67±13.33%  - 50 min: 91.67±8.33%  - 60 min: 96.67±3.33%  T3  Knockdown :  ≥ 50 min: 100.00±0.00%  T4  Knockdown:  ≥ 40 min: 100.00±0.00%  T5  Knockdown:  - 2,5,7 min: 00.00±0.00%  - 10 min: 5.00±5.00%  - 15 min: 10.00±5.00%  - 20 min: 25.00±12.58%  - 25 min: 55.00±22.55%  - 30 min: 68.33±20.48%  - 35 min: 83.33±12.02%  - 40 min: 85.00±10.41%  - 50 min: 96.67±3.33%  - 60 min: 98.33±1.67%  T6  Knockdown:  - ≥ 30 min: 100.00±0.00%  Mortality: Mortality was 100%, 24 hours after the treatment in fresh and 6 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2020) Report No.:  Q12-19-02 |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Peripalneta americana* American cockroach  10 adults mixed sex and 10 nymphs | Laboratory test (forced contact test on porous and non-porous surface) | Laboratory conditions.  Direct contact to treated porous (marble) and non-porous (ceramic tile-side up) tiles.  Adults and nymphs were placed for 60 min on porous surface and 30 min on non-porous treated tiles (30 x 30 cm), under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  3 replicates / treatment for porous and 5 replicates / treatment for non-porous tiles. Untreated tiles were also used as controls.  The product was applied at a dose of 53.75 g/m2 of a 0.4% solution on porous surface and at 26.78 g/m2 of a 0.4% solution on non 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 - 40 min and at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 3 weeks (for non-porous) and up to 4 weeks (for porous). Assessments were carried out: T0 (after treatment), T1, T2, T3, and T4 (1,2,3 and 4 weeks respectively after treatment). | Non-Porous surface  T0  Knockdown:  - ≥ 50 min: 100.00±0.00%  T1  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 10.00±3.16%  - 20 min: 34.00±7.65%  - 25 min: 78.00±3.00%  - 30 min: 82.00±3.00%  - 35 min: 86.00±1.87%  - 40 min: 90.00±1.58%  - 50 min: 92.00±1.22%  - 60 min: 99.00±1.00%  T2  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 2.00±2.00%  - 20 min: 43.00±2.00%  - 25 min: 67.00±3.74 %  - 30 min: 80.00±7.58%  - 35 min: 86.00±6.96%  - 40 min: 91.00±5.57%  - 50 min: 97.00±2.00%  - 60 min: 98.00±1.22%  T3  Knockdown :  - 2-10 min: 00.00±0.00%  - 15 min: 36.00±6.00%  - 20 min: 45.00±2.24%  - 25 min: 58.00±2.00%  - 30 min: 68.00±3.39%  - 35 min: 73.00±1.22%  - 40 min: 83.00±1.22%  - 50 min: 97.00±2.00%  - 60 min: 99.00±1.00%  Mortality: In non-porous surface, mortality was 100%, 24 hours after the treatment in fresh and 3 weeks deposits.  Porous surface  T0  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 13.33±1.67%  - 20 min: 38.33±1.67%  - 25 min: 43.33±1.67%  - 30 min: 51.67±1.67%  - 35 min: 65.00±5.00%  - 40 min: 70.00±2.89%  - 50 min: 85.00±2.89%  - 60 min: 91.67±1.67%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 8.33±8.33%  - 20 min: 26.67±9.28%  - 25 min: 45.00±10.41%  - 30 min: 65.00±18.03%  - 35 min: 76.67±13.33%  - 40 min: 86.67±8.33%  - 50 min: 88.33±9.28%  - 60 min: 91.67±8.33%  Mortality:  - 24h: 100.00±0.00%  T2  Knockdown:  - 2-10 min: 00.00±0.00%  - 15 min: 1.67±1.67%  - 20 min: 11.67±1.67%  - 25 min: 66.67±4.41%  - 30 min: 76.67±6.01%  - 35,40 min: 91.67±4.41%  - 50,60 min: 95.00±2.89%  Mortality:  - 24h: 100.00±0.00%  T3  Knockdown:  - 2-15 min: 00.00±0.00%  - 20 min: 8.33±1.67%  - 25 min: 26.67±8.82%  - 30 min: 33.33±3.33%  - 35 min: 58.33±3.33%  - 40 min: 61.67±1.67%  - 50 min: 91.67±4.41%  - 60 min: 93.33±3.33%  Mortality:  - 24h: 96.67±3.33%  T4  Knockdown:  - 2-15 min: 00.00±0.00%  - 20 min: 3.33±1.67%  - 25 min: 16.67±8.82%  - 30 min: 35.00±8.66%  - 35 min: 46.67±6.67%  - 40 min: 65.00±5.00%  - 50 min: 91.67±3.33%  - 60 min: 95.00±5.00%  Mortality:  - 24h: 98.33±1.67%  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2019) Report No.: Q27 0519-Q141 119 -01. |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w as pure active substance) | *Lasius niger* Black garden ant  25 adult workers- | Laboratory test (forced contact test on porous and non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic tile on its smooth side) and porous (concrete) tiles.  Adults were placed for 60 min on the treated tiles (30 x 30 cm), under a Petri dish (14 cm in diameter) to prevent escaping and thus ensuring contact with the treated surface.  4 replicates / treatment (25 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 50g/m2 of a 1% solution. Specifically, 10 gr of concentrated product was diluted in 1 liter of water (1%); then 50 gr of the solution was spread on 1 m² of surface, equal to a dosage of 4,5 gr per tile. The product was applied directly onto the tile from a distance of 40 cm from the treated surface.  Knockdown was recorded at 5, 10, 15, 30 and 60 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, T2, T3 and T4 (1, 2, 3 and 4 weeks after treatment respectively). | Porous surface  T0, T1,T2  Knockdown:  ≥ 5 min: 100.00±0.00%  T3  Knockdown:  ≥ 10 min: 100.00±0.00%  T4  Knockdown:  - ≥ 15 min: 100.00±0.00%  Non-Porous surface  T0, T1,T2, T3  Knockdown:  ≥ 5 min: 100.00±0.00%  T4  Knockdown:  - ≥ 10 min: 100.00±0.00%  Mortality: mortality was 100%, 24 hours after the treatment in fresh and 4 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2020),  Report No.  2493-LAB-LN/0819 |
| Insecticide (PT18)  Indoor application against crawling insects | Indoor applications  Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w as pure active substance) | *Lasius niger* Black garden ant  25 adult workers | Laboratory test (forced contact test on non-porous surface) | Laboratory conditions.  Direct contact to treated non-porous (ceramic) tiles.  Adults were placed for 60 min on the treated tiles (30 x 30 cm), under plastic cups (12 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring contact with the treated surface.  4 replicates / treatment (25 adults / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40g/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 at 50 and 60 min. Mortality was recorded every 24 hours.  The same observations were carried out every week, up to 6 weeks. Seven assessments were carried out: T0 (after treatment), T1, T2, T3, T4, T5 and T6 (1,2,3,4, 5 and 6 weeks respectively after treatment). | Non-Porous surface  T0  Knockdown:  ≥ 25 min: 100.00±0.00%  T1  Knockdown:  ≥ 40 min: 100.00±0.00%  T2  Knockdown:  ≥ 35 min: 100.00±0.00%  T3  Knockdown:  - ≥ 40 min: 100.00±0.00%  T4  Knockdown:  ≥ 30 min: 100.00±0.00%  T5  Knockdown:  - ≥ 30 min: 100.00±0.00%  T6  Knockdown:  - ≥ 20 min: 100.00±0.00%  Mortality: mortality was 100%, 24 hours after the treatment in fresh and 6 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2020),  Report No:  Q12-19-01 |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w)  Batch No.: XXXXXXXXXXX | *Blatta orientalis* Oriental cockroach  10 adults mixed sex and 10 nymphs | Simulated use test  Choice test | Choice test.  The trial was caried out in a test chamber of 12m3 (6m2 floor, 3 m long x 2 m wide x 2 m high) in porous and non-porous surfaces.  Inside the test chamber, a device simulating “cracks and crevices” was set containing the treated tiles. The “cracks and crevices device” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/ crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture") some ceramic tiles 15 cm x 15 cm are set and they are the treated materials.  Food and water sources were placed on the corners of the test chamber but not on the treated surfaces. The pests were able to reach water and food sources without being in contact with the treated surfaces.  5 replicates / treatment (25 cockroaches (adults and nymphs / replicate) were placed in the test arenas after the treatment. Untreated harbourages were also used as controls.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 8 h light.  The product was applied directly onto the harborages at 40 gr /m2 on the non porous treated side and at 50 gr /m2 on the porous treated side. The treatment was carried out on an area of max. 2m2 simulating real coditions. Assessments of knockdown were carried out at 4 hours after exposure. Mortality was recorded 24 hours later.  The same observations were carried out on treated tiles every week, up to 4 weeks: T0 (after treatment), T1, T2, T3, T4 (1,2,3, 4 weeks respectively after treatment). | knockdown  In both types of surfaces (porous and non-porous), knockdown of adults and nymphs was 100% within 4 hours on fresh and 4 weeks deposits.  Mortality:  In both types of surfaces (porous and non-porous), mortality of adults and nymphs was 100% at 24 hours after the treatment on fresh and 4 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2022) Report No: 2532d-SIM-BO/0120 |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w)  Batch No.: XXXXXXXXXXX | *Blattella germanica* German cockroach  10 adults mixed sex and 10 nymphs | Simulated use test  Choice test | Choice test.  The trial was caried out in a test chamber of 12m3 (6m2 floor, 3 m long x 2 m wide x 2 m high) in porous and non-porous surfaces.  Inside the test chamber, a device simulating “cracks and crevices” was set containing the treated tiles. The “cracks and crevices device” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/ crevices. On the first 15 cm of these cracks/crevice (entry of the "furniture") some ceramic tiles 15 cm x 15 cm are set and they are the treated materials.  Food and water sources were placed on the corners of the test chamber but not on the treated surfaces. The pests were able to reach water and food sources without being in contact with the treated surfaces.  5 replicates / treatment (25 cockroaches (adults and nymphs / replicate) were placed in the test arenas after the treatment. Untreated harbourages were also used as controls.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 8 h light.  The product was applied directly onto the harborages at 40 gr /m2 on the non porous treated side and at 50 gr /m2 on the porous treated side. The treatment was carried out on an area of max. 2m2 simulating real coditions. Assessments of knockdown were carried out at 4 hours after exposure. Mortality was recorded 24 hours later.  The same observations were carried out on treated tiles every week, up to 4 weeks: T0 (after treatment), T1, T2, T3 and T4 (1,2,3 and 4 weeks respectively after treatment). | knockdown  In both types of surfaces (porous and non-porous), knockdown of adults and nymphs was 100% within 4 hours on fresh and 4 weeks deposits.  Mortality:  In both types of surfaces (porous and non-porous), mortality of adults and nymphs was 100% at 24 hours after the treatment on fresh and 4 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2022) Report No: 2532e-SIM-BG/0120 |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w)  Batch No.: XXXXXXXXXXX | *Lasius niger* Black garden ant  Adult workers 1-2 weeks aged and queens | Simulated use test  Choice test | Choice test.  The trial was caried out in a test chamber of 12m3 (6m2 floor, 3 m long x 2 m wide x 2 m high) in porous and non-porous surfaces.  Inside the test chamber, a device simulating “cracks and crevices” was set containing the treated tiles. The “cracks and crevices device” is a pile of 5 non-porous lacquer wood boards of 1 m x 1 m (usual dimensions of kitchen furniture), assembled together but letting a 3 cm space between each other in order to create the cracks/ crevices. On these cracks/crevice (entry of the "furniture") some ceramic tiles 15 cm x 15 cm were set and they were the treated materials.  Food and water sources were placed on the corners of the test chamber but not on the treated surfaces. The pests had the choice not to come into contact with the product and weren’t forced to be in contact with the treatment to reach water and food sources.  4 replicates. Four (4) batches of 25 adult workers were placed in the test arenas after the treatment. Untreated harbourages were also used as controls.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 8 h light.  The product was applied directly onto the harborages at 40 gr /m2 on the non porous treated side and at 50 gr /m2 on the porous treated side. The treatment was carried out on an area of max. 2m2 simulating real coditions. Assessments of knockdown were carried out at 4 hours after exposure. Mortality was recorded 24 hours later.  The same observations were carried out on treated tiles up to 1 week: T0 (after treatment) and T1, (1 week after treatment). | knockdown  knockdown of adult workers and queens was not assessed on fresh and 1 week deposits.  Mortality:  In both types of surfaces (porous and non-porous), mortality of adult workers and queens was 100% on 1 week deposits.  In the untreated controls, mortality of adult workers was 3.4% (on non porous) and 4.2% (on porous) whereas mortality of queens was 100% (on porous and non-porous surface). | Xxxxxxxx (2020) Report No: 2532i-SIM-ANT/0120. |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blattella germanica* German cockroach  adults | Field test  Indοor application in cracks and crevices. | Field conditions.  Field conditions in occupied public housing for the elderly with infestation of German cockroaches. Three sites of 25m2 each (replicates) were treated and another 3 apartments were used as untrteated controls. The presence of cockroaches was evaluated using sticky traps for three nights, before treatment.  Then the product was applied with a pressure pump into cracks and crevices at 40 gr of a 0.5% solution on a max. area of 2 m2/.  The presence of cockroaches was evaluated 1 day, 1, 2, 3 and 4 weeks after the treatment using sticky traps for three nights for each assessment. | The mean % population reduction of *B. germanica* was: 96% at 1 day after treatment and 96.7% and 92.1% at 1 and 2 weeks after treatment.  100% population reduction was recorded after 3 and 4 weeks.  Untreated control  Pre-treatment assessment: the mean number of the German cockroaches was 13.  Post-treatment assessment: the mean number of the German cockroaches was 9.0, 10, 7.5, 11.5 and 14.5 at 1 day, 1, 2, 3 and 4 weeks respectively. | Xxxxxxxx (2020) Report No:  Q081-20-01 |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Blatta orientalis*  Oriental cockroach  adults | Field test  Indοor application in cracks and crevices. | Field conditions.  Field conditions in occupied public housing for the elderly with infestation of oriental cockroaches. Three sites of 25m2 each (replicates) were treated and another 3 apartments were used as untrteated controls. The presence of cockroaches was evaluated using sticky traps for three nights, before treatment.  Then the product was applied with a pressure pump into cracks and crevices at 40 gr of a 0.5% solution on a max. area of 2 m2/.  The presence of cockroaches was evaluated 1 day, 1, 2, 3 and 4 weeks after the treatment using sticky traps for three nights for each assessment. | The mean % population reduction of *B. orientalis* was: 100% at 1 day after treatment, 90.4% and 90.2% at 1 and 2 weeks after treatment.  98.2% and 98.1% population reduction was recorded at 3 and 4 weeks, after treatment.  Untreated control  Pre-treatment assessment: the mean number of the German cockroaches / replicate was 15, 12.5 and 16.  Post-treatment assessment: the mean number of the German cockroaches / replicate was 9.5/11 /12 (1 day), 10.5/15.5/7.5 (1 week), 7.58/9.5/10 (2 weeks), 7/10.5/11.5 (3 weeks) and 11.5/11.5/9.5 (4 weeks). | Xxxxxxxx (2020) Report No: Q080-20-01 |
| Insecticide (PT18)  Indoor application in crack and crevice | Indoor application in crack & crevice, Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w)  Batch No: XXXXXXXXXXX | *Lasius niger*  Black garden ant  Adults, larvae and queen | Field test  Indoor application against ant colony | Field conditions.  Field conditions in occupied public housing for the elderly with infestation of ants. Three sites of 25-32 m2 each (replicates) were treated and another 3 apartments were used as untrteated controls. The presence of ants was evaluated using sticky traps.  Then the product was applied into cracks and crevices at 40 gr of a 0.5% solution on 1 m2/, with a maximum of 80 ml per room.  The presence of ants was evaluated 24 hours, 1, 2,3 and 4 weeks after the treatment using sticky traps. | The mean % reduction *in L. niger* population were 91.3% at 1 day after treatment, 99.5% at 1 week and 100% population reduction was achieved after 2- 4 weeks.  Untreated control:  Pre-treatment assessment: the mean number of ants was 146.7.  The mean population increase of ants was 0.6% (1 day), 4.1% (1 week), 7.4% (2 weeks), 6.9% (3 weeks) and 13.5% (4 weeks). | Xxxxxxxx (2021) Report No: 2683-EC/0621R |
| Insecticide (PT18)  Ant nest eradication | Ant nest eradication Trained professionals and professionals/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w)  Batch No: XXXXXXXXXX | *Lasius niger*  Black garden ant  Adults, larvae and queen | Field test  Outdoors  Ant nests | Ant nests outdoors in house gardens, terraces were treated.  The product was applied using a spray pump directly onto the nest and the surrounding area, at 25 gr on 1 m2 of surface surrounding the nest and at the entrance of the nest. These 25 gr of solution were distributed as follows: 10 gr at the entrance of the nest and 15 gr covering the square meter around the nest.  The number of ants walking around the nest was assessed for 5 minutes on 1 m2 surface around the nest entrance.  Assessments were carried out 1 day before treatment and 1, 3, 7, 14, 21 and 28 days after treatment.  28 days (4 weeks) post treatment the nests were opened to check for any dead/ living adults and larvae.  5 untreated nests were also used for control.  5 treated and 5 untreated nests were used as replicates. | The mean % population reduction after treatment was 92.4% (T+1 day), 98.6% (T+3 days) and 100% (T+1 and 2 weeks respectively).  100% population reduction was recorded against ants after 3 and 4 week.  In the untreated nests a population increase was recorded after 1 and 3 days(3.7 and 5.2% respectively) and after 1, 2, 3 and 4 weeks (8.7, 4.5, 7.0 and 11.7% respectively). | Xxxxxxxx (2020) Report No: 2532g-FIELD-ANT/0120 |

The individual trials are presented in the following table:

| **Experimental data on the efficacy of the biocidal product against mosquitoes** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Aedes albopictus*  (tiger mosquito)  (20 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.  Mosquitoes 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. The the insects were then moved to a healthy environment.  3 replicates (20 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 g/m2 of a 0.5% solution on both surfaces.  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 6 weeks. T0 (after treatment), T1, T2, T3, T4,T5 and T6 (1,2,3,4,5 and 6 weeks after treatment). | Non - porous surface  T0, T2  Knockdown:  - ≥ 10 min: 100.00±0.00%  T1, T3 and T6  Knockdown:  ≥ 15 min: 100.00±0.00%  T4  Knockdown:  ≥ 7 min: 100.00±0.00%  T5  Knockdown:  ≥ 50 min: 100.00±0.00%  Porous surface (marble)  T0  Knockdown:  ≥ 20 min: 100.00±0.00%  T1  Knockdown:  ≥ 35 min: 100.00±0.00%  T2, T3  Knockdown:  ≥ 40 min: 100.00±0.00%  T4  Knockdown:  ≥ 30 min: 100.00±0.00%  T5  Knockdown:  -25 min: 85.00±0.00%  - 30 min: 93.33±3.33%  -35-40 min: 96.67±1.67%  ≥ 50 min: 100.00±0.00%  T6  Knockdown:  ≥ 50 min: 100.00±0.00%  Mortality: In both types of surfaces (porous and non-porous) mortality of was 100% on fresh and 6 weeks deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2019), Report No: Q02 9-20-Q012-19-01 |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Culex pipiens* (house 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.  Mosquitoes 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. The insects were then moved to a healthy environment.  3 replicates (20 females / replicate). Untreated tiles were also used as controls.  The product was applied at a dose of 40 g/m2 of a 0.5% solution on both surfaces.  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 6 weeks. T0 (after treatment), T1, T2, T3, T4,T5 and T6 (1,2,3,4,5 and 6 weeks after treatment).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 6 weeks: T0 (after treatment), T1, T2, T3, T4,T5 and T6 (1,2,3,4,5 and 6 weeks after treatment). | Non-Porous surface  T0  Knockdown:  ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  ≥ 35 min: 100.00±0.00%  Mortality:  - 24h: 98.33±1.67%  T2  Knockdown:  -15 min: 90.00±5.77%  - 20 min: 96.67±3.33%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T3  Knockdown:  -10 min: 83.33±4.41%  -15 min: 96.67±1.67%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T4  Knockdown:  -5 min: 88.33±4.41%  -7 min: 95.00±2.89%  ≥ 10 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T5  Knockdown:  -10 min: 83.33±16.67%  -15 min: 93.33±6.67%  -15 min: 96.67±3.33%  ≥ 25 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  T6  Knockdown:  -7 min: 81.67±6.01%  -15 min: 93.33±4.41%  -15 min: 96.67±3.33%  ≥ 20 min: 100.00±0.00%  Mortality:  - 24h: 100.00±0.00%  In the untreated controls, knockdown and mortality was 0%.  Porous surface  T0  Knockdown:  -30 min: 81.67±15.90%  - 35 min: 85.00±12.58%  -40 min: 88.33±11.67%  - 50 min: 91.67±8.33%  -60: min: 96.67±3.33%  Mortality:  - 24h: 100.00±0.00%  T1  Knockdown:  -25 min: 85.00±2.89%  -30-40 min: 95.00±2.89%  -50-60 min: 98.33±1.67%  Mortality:  - 24h: 96.67±1.67%  T2  Knockdown:  -40 min: 86.67±1.67%  -50 min: 96.67±1.67%  -60 min: 98.33±1.67%  Mortality:  - 24h: 95.00±0.00%  T3  Knockdown:  -30 min: 95.00±5.00%  -35 min: 96.67±3.33%  ≥ 40 min: 100.00±0.00%  Mortality:  - 24h: 98.33±1.67%  T4  Knockdown:  -35 min: 86.67±6.01%  -40 min: 90.00±2.89%  -50 min: 96.67±1.67%  -60 min: 98.33±1.67%  Mortality:  - 24h: 93.33±4.41%  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2020), Report No: Q02 9-20-Q012-19- 02 |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Aedes albopictus,* (tiger mosquito)  (20 females, 5 - 10 days old) | Laboratory test Non choice test | Laboratory conditions.  In a room of 30 m3, plants of *Photinia fraseri* were placed against the wall to simulate a hedge of about 2 m2. Three (3) cylindrical cages containing 20 females of *Aedes albopictus* were placed inside the hedge, among the leaves. Each cage (4 cm in diameter and 8 cm in height) was made of 1 mm-mesh metallic net.  The product was applied uniformly on the hedge at 50 g/m2 (0.2% solution). Knockdown was evaluated for 60 minutes, then the insects were moved to a healthy environment.  3 replicates (20 females / replicate). Untreated tiles were also used as controls.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Some treated leaves were taken to perform a forced contact test. Another forced contact test was performed on a tile with 1 m2 of area.  Forced contact on leaves: a certain number of leaves was removed from the plants and glued on a tile, using a double-sticky tape. The treated surface of the leaves was positioned upwards. On each tile, 20 females were placed under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring the contact with the treated leaves.  Forced contact on non-porous tile: In the same room of the hedge test, a tile (1x1m) was hung on the wall. The tile was made of ceramic (non-porous) surface and was treated with the product. Mosquitoes were placed on the treated tile, under WHO cones to prevent escaping and thus ensuring contact with the treated surface.  Knockdown was recorded at 2, 5 and 7 minutes, then every 5 minutes from 10 to 40 minutes and at 50 and 60 minutes. Mortality was recorded every 24 hours.  The same observations were carried out at T0, and at 1 and 5 days after treatment. | Hedge  T0  Knockdown:  ≥ 10 min: 100.00±0.00%  1 day after application  Knockdown:  ≥ 20 min: 100.00±0.00%  5 days after application  Knockdown:  ≥ 10 min: 100.00±0.00%  Mortality: mortality was 100% on all deposits.  Forced contact on leaves:  T0  Knockdown:  ≥ 15 min: 100.00±0.00%  1 and 5 days after application  Knockdown:  ≥ 20 min: 100.00±0.00%  Mortality: mortality was 100% on all deposits.  Forced contact on tile:  T0  Knockdown:  ≥ 10 min: 100.00±0.00%  1 and 5 days after application  Knockdown:  ≥ 15 min: 100.00±0.00%  Mortality: mortality was 100% on all deposits.  In the untreated controls, knockdown and mortality was 0%. | Xxxxxxxx (2020)  Report No: Q074-20-01 |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Culex pipiens* (house mosquito)  (20 females, 5-10 days old) | Laboratory test Non choice test | Laboratory conditions.  In a room of 30 m3, plants of *Photinia fraseri* were placed against the wall to simulate a hedge of about 2 m2. Three (3) cylindrical cages containing 20 females of *Culex pipiens* were placed inside the hedge, among the leaves. Each cage (4 cm in diameter and 8 cm in height) was made of 1 mm-mesh metallic net.  The product was applied uniformly on the hedge at 50 g/m2 (0.2% solution). Knockdown was evaluated for 60 minutes, then the insects were moved to a healthy environment.  3 replicates (20 females / replicate). Untreated tiles were also used as controls.  Room conditions: temperature of T= 25±1°C, rel. humidity= 60±5%. Light conditions: 12 h light.  Some treated leaves were taken to perform a forced contact test. Another forced contact test was performed on a tile with 1 m2 of area.  Forced contact on leaves: a certain number of leaves was removed from the plants and glued on a tile, using a double-sticky tape. The treated surface of the leaves was positioned upwards. On each tile, 20 females were placed under WHO cones (8.8 cm in diameter and 6 cm in height) to prevent escaping and thus ensuring the contact with the treated leaves.  Forced contact on non-porous tile: In the same room of the hedge test, a tile (1x1m) was hung on the wall. The tile was made of ceramic (non-porous) surface and was treated with the product. Mosquitoes were placed on the treated tile, under WHO cones to prevent escaping and thus ensuring contact with the treated surface.  Knockdown was recorded at 2, 5 and 7 minutes, then every 5 minutes from 10 to 40 minutes and at 50 and 60 minutes. Mortality was recorded every 24 hours.  The same observations were carried out at 1 and 5 days after treatment. | Hedge  T0  Knockdown:  ≥ 15 min: 100.00±0.00%  1 day after application  Knockdown:  ≥ 15 min: 100.00±0.00%  5 days after application  Knockdown:  ≥ 20 min: 100.00±0.00%  Mortality: mortality was 100% on all deposits.  Forced contact on leaves:  T0  Knockdown:  --2-7 min: 0.00±0.00%  -10 min: 13.33±1.67%  -15 min: 58.33±8.33%  -20 min: 75.00±2.89%  -25 min: 83.33±3.33%  -30-40 min: 93.33±3.33%  -50 min: 95.00±2.89%  -60 min: 98.33±1.67%  Mortality:  24h: 96.67±3.33%  1 day after application  Knockdown:  --2-5 min: 0.00±0.00%  -7 min: 1.67±1.67%  -10 min: 30.00±5.00%  -15 min: 81.67±6.67%  -20 min: 93.33±4.41%  -25 min: 96.67±3.33%  -30-60 min: 98.33±1.67%  Mortality:  24h: 90.00±2.89%  5 days after application  Knockdown:  --2-5 min: 0.00±0.00%  -7 min: 3.33±1.67%  -10 min: 15.00±5.00%  -15 min: 51.67±13.02%  -20 min: 85.00±2.89%  -25 min: 88.33±3.33%  -30 min: 93.33±3.33%  -35-60 min: 96.67±1.67%  Mortality:  24h: 96.67±1.67%  Forced contact on tile:  T0  Knockdown:  ≥ 25 min: 100.00±0.00%  Mortality:  24h: 100.00±0.00%  1 day after application  Knockdown:  ≥ 15 min: 100.00±0.00%  Mortality:  24h: 100.00±0.00%  5 days after application  Knockdown:  --2-5 min: 0.00±0.00%  -7 min: 6.67±1.67%  -10 min: 10.00±2.89%  -15 min: 36.67±16.91%  -20 min: 43.33±13.33%  -25 min: 68.33±14.81%  -30 min: 71.67±11.67%  -35 min: 85.00±5.00%  -40 min: 91.67±6.01%  -50 min: 91.67±6.01%  -60 min: 98.33±1.67%  Mortality:  24h: 98.33±1.67%. | Xxxxxxxx (2020)  Report No:  Q02 8-20-01 |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Aedes albopictus,* (tiger mosquito)  (15 females, 5 - 10 days old) | Field test. Outdoor application | Field conditions (outdoor areas).  Test performed in 3 private gardens surrounded by hedges and/or bushes and some trees. All gardens were naturally infested by *Aedes albopictus*.  In each garden, a control and a treated area (20 m2) were chosen, corresponding to the control and the treated replicate.  In each area, 4 cylindrical cages containing 15 females of *Aedes albopictus* were hung at 50 cm height from the ground. 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 inside the hedge, at 50 cm height from the ground. In each treated parcel, the product was applied uniformly with a pressure sprayer along the perimeter, from a distance of 50 cm from hedges and walls. The product was applied uniformly covering a band of about 1 m (0.5-1.5 m height) at a dose of 50 g/m2 of a 0.2% solution. The treatment did not include direct application onto the mosquitoes. knockdown was evaluated after 60 minutes. The mosquitoes were moved to the laboratory in a healthy environment to check mortality after 24 hours.  The ability of the product to provide protection from mosquitoes was evaluated by assessing the wild tiger mosquito population with the Human Landing Technique. The number of landings on exposed legs skin in each replication was counted for 5 minutes. One volunteer per replication has been used. Along the test, the same volunteer was used to maintain the same conditions.  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. Population reduction was evaluated at different time intervals after treatment: 10 minutes, 1 hour, 3 days, 7 days and 10 days  A forced contact test was also performed on a wall in each garden. For each replication, 4 sub-replications were performed. A sub-replication was made of a WHO cone containing 15 female mosquitoes (2 -5 days old). The cones were placed on the wall and knockdown was evaluated. Then the mosquitoes were moved in laboratory in a healthy environment to check mortality after 24 hours.  Finally, a forced contact test was performed on leaves taken from each garden. The leaves were brought to the lab and glued on a tile. For each replication, 4 sub-replications were performed. A sub-replication was made of a WHO cone containing 15 female mosquitoes 2 - 5 days old placed on a group of leaves. Knockdown and mortality after 24 hours were evaluated.  Evaluation of efficacy was performed by HL, counting the number of probings on the same volunteers for 5 minutes at 1 hour after treatment.  Forced contact tests: Knockdown was recorded at 2 - 5 and 7 min, then every 5 min between 10 - 40 min and then at 50 and 60 min. Mortality was recorded after 24 hours. | Cages in hedge:  100% knockdown and mortality  Forced contact on wall:  T0 and T3  Knockdown:  ≥ 25 min: 100.00±0.00%  Mortality:  24h: 100.00±0.00%  Forced contact on leaves:  T0  Knockdown:  -2 min: 0.00±0.00%  -5 min: 1.11±0.43%  -7 min: 16.67±5.99%  -10 min: 38.33±6.69%  -15 min: 67.22±10.58%  -20 min: 80.00±8.56%  -25 min: 86.67±5.71%  -30 min: 92.22±2.58%  -35 min: 97.22±1.05%  -40-50 min: 98.89±0.75%  -60 min: 99.44±0.37%  Mortality:  24h: 96.11±2.39%  T3  Knockdown:  ≥ 40 min: 100.00±0.00%  Mortality:  24h: 93.89±1.54%  In the untreated controls, knockdown and mortality was 0%.  The reduction of landings of *Aedes albopictus* was as follows: 100% after 10 minutes, 100% after 1 hour, 3 and 7 days. | Xxxxxxxx (2020)  Report No: Q076D-20-01 |
| Insecticide (PT18)  Surface treatment around building - Mosquitoes | Surface treatment around the building against mosquitoes  Professional/  Non-professionals | Free Land 10 EC (cypermethrin 10.0% w/w) | *Culex pipiens* (house mosquito)  (15 females, 5– 10 days old) | Field test. Outdoor application | Field conditions (residential areas).  Test performed in 3 private gardens surrounded by hedges and/or bushes and some trees. All gardens were naturally infested by *Culex pipiens*.  In each garden, a control and a treated area (20 m2) were chosen, corresponding to the control and the treated replicate.  Before the treatment, in each area 4 cylindrical cages containing 15 females (5- 10 days old) were placed inside the hedge at 50 cm height from the ground. The cages were made of 1 mm-mesh metallic net measuring 5.5 cm in diameter and 5.5 cm tall. The cages were placed inside the hedge, at 50 cm height from the ground. In each treated parcel, the product was applied uniformly with a pressure sprayer along the perimeter, from a distance of 50 cm from hedges and walls. The product was applied uniformly covering a band of about 1 m (0.5-1.5 m height) at a dose of 50 g/m2 of a 0.2% solution. The treatment did not include direct application onto the mosquitoes. knockdown was evaluated after 60 minutes. The mosquitoes were moved to the laboratory in a healthy environment to check mortality after 24 hours.  A forced contact test was also performed on a wall in each garden. For each replication, 4 sub-replications were performed. A sub-replication was made of a WHO cone containing 15 female mosquitoes (2 -5 days old). The cones were placed on the wall and knockdown was evaluated. Then the mosquitoes were moved in laboratory in a healthy environment to check mortality after 24 hours.  Finally, a forced contact test was performed on leaves taken from each garden. The leaves were brought to the lab and glued on a tile. For each replication, 4 sub-replications were performed. A sub-replication was made of a WHO cone containing 15 female mosquitoes 2 - 5 days old placed on a group of leaves. Knockdown and mortality after 24 hours were evaluated.  Adult mosquito monitoring pre- and post- treatment was carried out with CDC traps to capture adult mosquitoes. The CDC traps were positioned inside the test area at a distance of about 1 m from the treated hedges. The CDC traps were provided with CO2 as attractant and left working 1 night. The efficacy of the product was evaluated only the night of the treatment placing again the CDC traps, then the test was interrupted. The percentage of reduction was calculated.  The % mean population reduction was recorded 24h after treatment. Forced contact tests: Knockdown was recorded at 2 - 5 and 7 min, then every 5 min between 10 - 40 min and then at 50 and 60 min. Mortality was recorded after 24 hours. | Pre and Post-treatment results (population reduction) for adults indoor  Site 1  Pre - treatment: 21 adults  Post - treatment: 13 adults  Site 2:  Pre - treatment: 31 adults  Post - treatment: 15 adults  Site 3  Pre - treatment: 91 adults  Post - treatment: 33 adults  24h: The mean % population reduction was 26.2%.  Cages in hedge:  100% knockdown and mortality  Forced contact on wall:  At T0 and 3 days knockdown and mortality were 100% (in 20 min) and 100% mortality in 24h. At 7 days knockdown was 100% (in 40 min) and mortality 86.7% in 24 h. At 10 days knockdown was 93.33% (in 60 min) and mortality 53.9% in 24h.  Forced contact on leaves:  At T0 knockdown was 100% (in 20 min) and mortality 100% in 24h.  At 3 days knockdown was 98.9% (in 50 min) and mortality was 94.4% in 24 h. At 7 days, knockdown was 100% (in 40 min) and mortality 80% (in 24h). At 10 days knockdown was 95.6% (in 60 min) and mortality 81.7% in 24h. | Xxxxxxxx (2020)  Report No: Q076D-20-02 |
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| **Conclusion on the efficacy of the product** |
| Several efficacy studies (laboratory, simulated and field studies) were submitted by the applicant to support the intended uses of Free Land 10EC (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:   * Spot treatment by professionals and non-professionals, indoors for the control of German (*Blattella germanica*), Oriental (*Blatta orientalis*) cockroaches and Black garden ant (*Lasius niger*) at 40 g /m2 of a 0.5% solution (for non-porous surfaces) and 50 g /m2 of 1% solution (for porous surfaces).The product has a residual period of 4 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches is expected 4 hours after after exposure of insects to the treated surfaces” (Intended Uses # 1 and 2, as applied for by the applicant). * Crack and crevice treatment by professionals and non-professionals, indoors for the control of German (*Blattella germanica*) and Oriental (*Blatta orientalis*) cockroaches and Black garden ant (*Lasius niger*) at 40 g /m2 of a 0.5% solution (for non-porous surfaces) and 50 g /m2 of 1% solution (for porous surfaces).The product has a residual period of 4 weeks. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of cockroaches is expected 4 hours after after exposure of insects to the treated surfaces” (Intended Uses # 3 and 4, as applied for by the applicant). * Surface outdoor treatment around buildings against tiger mosquito (*Aedes albopictus*) by professionals and non-professionals at 50 g /m2 of a 0.5% solution. The product has 3 days residual action against mosquitoes. The product provides sufficient control of mosquitoes when applied at a distance of 50 cm from the treated surfaces (Intended Uses # 8 and 9, as applied for by the applicant). * XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX * Direct application around and at the entrance of the ant nest, outdoors, at 25 gr/ nest, by professionals and non-professionals. (Intended Uses # 11 and 12, as applied for by the applicant). |

#### 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.

#### Known limitations

According to the efficacy trials on FREE LAND 10 EC and to cypermethrin properties, no limitations of the product are known.

#### Evaluation of the label claims

**Intended Uses # 1 & 2 for professionals and non-professionals: Indoor spot application in not wet cleaned areas**

The product is intended to be used for the control of crawling insects *Blattella germanica* (German cockroach), *Blatta orientalis* (oriental cockroach) and *Lasius niger* (Black garden ant) indoors as spot treatment on non porous at 40 g/m2 of a 0.5% insecticide solution and on porous surface at 50 g/m2 of 1% insecticide solution.

**Intended Uses # 3 & 4 for professionals and non-professionals: Indoor spot application in crack & crevice against crawling insects**

The product is intended to be used for the control of crawling insects *Blattella germanica* (German cockroach), *Blatta orientalis* (oriental cockroach), *Periplaneta americana* (American cockroach) and *Lasius niger* (Black garden ant) indoors as crack and crevice treatment on non porous at 40 g/m2 of a 0.5% insecticide solution and on porous surface at 50 g/m2 of 1% insecticide solution.

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

Lab study – XXXXXXXX (2019), Report No: 2493-LAB-BG/0819

In the lab study by XXXXXXXX (2019), the product was applied as surface treatment in a forced contact test on non-porous surfaces (ceramic tile –smooth side) and porous surface (concrete) against adults of the German cockroach (*Blattela germanica*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic spatula) at 50 g/m2 of a 1% solution. To evaluate the residual activity, the cockroaches were exposed to 4 weeks aged treated tiles. According to the results,the product provided 100% knockdown in 5-15 minutes after exposure of the insects to the non-porous treated surfaces and 100% knockdown in 5-30 minutes after exposure of the insects to the porous treated surfaces. The product also resulted in 100% mortality 24h after exposure of the insects to treated non-porous and porous surfaces.

Lab study – XXXXXXXX (2019), Report No: 2532f-LAB-BG/0120

In the lab study by XXXXXXXX (2019), the product was applied as surface treatment in a forced contact test on non porous (ceramic tile –smooth side) 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 40 g/m2 of a 0.5% solution. To evaluate the residual activity, the cockroaches were exposed to 4 weeks aged treated tiles. According to the results,the product provided 100% knockdown in 15-60 minutes in fresh and up to 2 weeks aged treated tiles and 100% mortality in 24h after exposure of the insects to fresh and 4 weeks aged porous treated surfaces.

Lab study – XXXXXXXX (2019), Report No. 2493-LAB-BO/0819

In the lab study by XXXXXXXX (2019), the product was applied as surface treatment in a forced contact test on porous (concrete) and non-porous 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 spatula) at 50 g/m2 of a 1% solution. To evaluate the residual activity, the cockroaches were exposed to 4 weeks aged treated tiles. According to the results,the product provided 100% knockdown in 5-30 minutes after exposure of the insects to the non-porous and porous treated surfaces. The product also resulted in 100% mortality 24h after exposure of the insects to fresh and 4 weeks aged non-porous and porous treated surfaces.

Lab study – XXXXXXXX (2020) Report No.: Q12-19-02

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a forced contact test on non porous (ceramic tiles) 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 g/m2 of a 0.5% solution. To evaluate the residual activity, the cockroaches were exposed to 6 weeks aged treated tiles. According to the results,the product provided 100% knockdown in 30-50 minutes after exposure of the insects to fresh and to 1, 3, 4 and 6 weeks aged treated tiles. The product also resulted in 100% mortality 24h after exposure of the insects to fresh and 6 weeks aged non-porous and porous treated surfaces.

Lab study – XXXXXXXX (2019) Report No.: Q27 0519-Q141 119 -01.

In the lab study by XXXXXXXX (2019), 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 American 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 53.75 g/m2 of a 0.4% solution (on porous surface) and 26.78 g/m2 of a 0.4% solution (on non porous surface). To evaluate the residual activity, the cockroaches were exposed to fresh and up to 3 weeks aged non porous and up 4 weeks aged porous treated tiles. According to the results,the product provided 100% knockdown in 50 minutes after exposure of the insects to fresh non-porous treated surfaces and 91.67-95% knockdown in 35-60 minutes after exposure of the insects to the porous treated surfaces. The product also resulted in 100% mortality 24h after exposure of the insects to non-porous treated surfaces and 96.67-100% mortality 24h after exposure of the insects to fresh and 4 weeks aged porous treated surfaces.

It should be noted that in the study report, the product was applied against American cockroaches at different doses (53.75 g/m2 of a 0.4% solution on porous surface and 26.78 g/m2 of a 0.4% solution on non porous surface) than the claimed (50 g/m2 of 1% solution and 40 g/m2 of a 0.5 % solution on non porous surface).

Lab study – XXXXXXXX (2020), Report No. 2493-LAB-LN/0819

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a forced contact test on porous (concrete) and non porous (ceramic tiles –smooth side) surfaces against adult workers of the Black garden ant (*Lasius niger*). The product was applied (by using a pipette and was then smeared on the whole surface with a plastic brush) at a dose of 50 g/m2 of a 1% solution on porous and non-porous surface. To evaluate the residual activity, the ants were exposed to 4 weeks aged non porous and porous treated tiles. According to the results,the product provided 100% knockdown in 5-10 minutes after exposure of the insects to non-porous treated surfaces and 100% knockdown in 5-15 minutes after exposure of the insects to the porous treated surfaces. The product also resulted in 100% mortality 24h after exposure of the insects to fresh and 4 weeks aged non-porous and porous treated surfaces.

Lab study – XXXXXXXX (2020), Report No: Q12-19-01

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a forced contact test on non-porous (ceramic) tiles 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 g/m2 of a 0.5% solution. To evaluate the residual activity, the ants were exposed to 6 weeks aged treated tiles. According to the results,the product provided 100% knockdown in 20-40 minutes after exposure of the insects to non-porous treated surfaces. The product also resulted in 100% mortality 24h after exposure of the insects to fresh and 6 weeks aged non-porous treated surfaces.

Simulated use test- XXXXXXXX (2022) Report No: 2532d-SIM-BO/0120

In the simulated use test (choice test) by XXXXXXXX (2022) the product was applied as crack and crevice at 40 g /m2 (on non-porous surface) and 50 g/m2 (on porous surface) against the Oriental cockroach (*Blatta orientalis*) on fresh and 4 weeks deposits. According to the results,the product provided 100% knockdown within 4 hours and 100% mortality 24 hours after exposure of the cockroach to fresh and 4-week aged porous and non-porous treated surfaces.

Simulated use test- XXXXXXXX (2022), Report No: 2532e-SIM-BG/0120

In the simulated use test (choice test) by XXXXXXXX (2022) the product was applied as crack and crevice at 40 g /m2 (on non-porous surface) and 50 g /m2 (on porous surface) against the German cockroach (*Blattela germanica*) on fresh and 4 weeks deposits. According to the results,the product provided 100% knockdown within 4 hours and 100% mortality 24 hours after exposure of the cockroach to fresh and 4-week aged porous and non-porous treated surfaces.

In the simulated use tests 2532d-SIM-BO/0120 and 2532e-SIM-BG/0120, 100% knockdown against *Blatta orientalis* and *Blattela germanica* was achieved in 4 hours. However, according to the efficacy guidance, for non-professional users *≥ 90% knockdown within a few minutes after contact with the product (or according to the claim), direct after spray and at the end of the residual period claimed* is required. For non-professional users the following limitation is proposed to be included in the specific instructions for use: “Knockdown of the German and Oriental cockroaches is expected 4 hours after after exposure of insects to the treated surfaces.

Simulated use test- XXXXXXXX (2020) Report No: 2532i-SIM-ANT/0120.

In the simulated use test (choice test) by XXXXXXXX (2020) the product was applied as crack and crevice at 40 ml final solution /m2 (0.5% dilution in water) (on non-porous surface) and 50 ml final solution /m2 (1% dilution in water) (on porous surface) against the black garden ants (*Lasius niger*) on fresh and 1 week deposits. Knockdown of adult workers and queens was not assessed on fresh and 1 week deposits. The product resulted in 100% mortality 24 hours after exposure of the ants to 1-week aged porous and non-porous treated surfaces.

In the simulated use test 2532i-SIM-ANT/0120, 100% knockdown against *Lasius niger* Knockdown was not assessed on fresh and 1 week deposits. According to the efficacy guidance, for non-professional users *≥ 90% knockdown in 5 -10 minutes (or according to the claim), direct after spraying the ants and at the end of the residual period,* is required.

Field study – XXXXXXXX (2020) Report No: Q081-20-01

In the field study by XXXXXXXX (2020) the effectiveness of the product was evaluated in naturally infested areas by *Blattella germanica*. The product was applied indoors, as a crack and crevice treatment, at 40 g/m2 of a 0.5% solution (on a max. area of 2 m2). According to the results, the product provided 92.1-100% mean population reduction of the German cockroach, up to 4 weeks after treatment.

Field study – XXXXXXXX (2020) Report No: Q080-20-01

In the field study by XXXXXXXX (2020) the effectiveness of the product was evaluated in naturally infested areas by *Blatta orientalis*. The product was applied indoors, as a crack and crevice treatment, at 40 g/m2 of a 0.5% solution (on a max. area of 2 m2). According to the results, the product provided 90.2-100% mean population reduction of the oriental cockroach, up to 4 weeks after treatment.

Field study – XXXXXXXX (2021) Report No: 2683-EC/0621R

In the field study by XXXXXXXX (2021) 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 40 g/m2 of a 0.5% solution (i.e. 20 mg a.s./m2). According to the results, the product provided 91.3-100% mean population reduction of the ants, up to 4 weeks after treatment.

The submitted simulated use and field tests where the product was applied as crack and crevice treatment can be used to support the claimed spot application (intended uses 1 & 2) considering crack and crevice treatment as worse case treatment (applied in smaller scale) than spot treatment in terms of efficacy against crawling insects. According to the guidance, the spot application, is defined as an application “to limited areas on which insect pests are likely to occur” and thus includes crack and crevice treatment which is defined as treatment onto places “where insects hide and harbourage, or through which they may enter the building”.

The intended Uses # 3 and 4 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 # 4 (non-professional users) against cockroaches, the requirements of the guidance for surface treatment for non-professionals should normally be fulfilled, i.e. in lab and simulated-use tests ≥ 90% knockdown within a few minutes after contact with the product (or according to the claim) for cockroaches. Mortality according to the label claim, should preferably be ≥90% in 24 hour. According to the submitted simulated-use tests the exposure of the German and Oriental cockroaches to porous and non-porous treated surfaces for up to 4-weeks resulted in 100% knockdown in 4 hours after exposure of cockroaches to the treated surfaces.Hence, the intended Use # 4 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 the German and Oriental cockroaches is expected 4 hours after exposure of insects to the treated surfaces”.

**Intended Uses # 5 and 6 for professionals and non-professionals: Targeted residual treatment around the building against mosquitoes**

The product is intended to be used outdoor, around buildings in rural areas against mosquitoes *Culex pipiens* (house mosquito) and *Aedes albopictus* (tiger mosquito) at 50 ml /m2 of a 0.2% insecticide solution. The residual action of the product is 3 days. Treat around building starting from a height of about 50 cm, up to 150 cm, treating a band of about one meter in height. The product should be applied uniformly over the selected area from a distance of 50 cm.

XXXXXXXX (2019), Report No: Q02 9-20-Q012-19-01

In the lab study by XXXXXXXX (2019), 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 g/m2 of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 6 weeks aged treated tiles. According to the results,the exposure of mosquitoesto non-porous surfaces up to 6 weeks resulted in 100% knockdown in 7-50 min and 100% mortality in 24h after exposure of the insects to the treated surfaces. The exposure of mosquitoesto porous surfaces up to 6 weeks resulted in 100% knockdown in 20-50 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.*

XXXXXXXX (2020), Report No: Q02 9-20-Q012-19- 02

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a forced contact test on on non-porous (ceramic tiles – side up) and porous (marble) 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 g/m2 of a 0.5% solution. To evaluate the residual activity, the adults were exposed to 6 weeks aged treated tiles. According to the results,the exposure of mosquitoesto non-porous surfaces up to 6 weeks resulted in 100% knockdown in 10-35 min and 98.33-100% mortality in 24h after exposure of the insects to the treated surfaces. According to the results,the exposure of mosquitoesto porous surfaces up to 6 weeks resulted in 91.67-100% knockdown in 40-60- minutes and 93.33-100% mortality in 24h after exposure of the insects to the treated surfaces*.*

XXXXXXXX (2020), Report No: Q074-20-01

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a hedge (of about 2 m2) of *Photinia fraseri* plants, inside of which cylindrical cages containing 20 females of *Aedes albopictus* were placed. The product was also applied as surface treatment in a forced contact test on *Photinia fraseri* treated leaves and on non-porous (ceramic tiles) surfaces against female adults of *Aedes albopictus*. The product was applied at a dose of 50 g/m2 of a 0.2% solution. To evaluate the residual activity, the adults were exposed to 5 days aged treated tiles. According to the results,the exposure of mosquitoesto the hedge up to 5 days provided 100% knockdown in 10-20 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto the treated leaves up to 5 days resulted in 100% knockdown in 15-20 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto non- porous surfaces up to 5 days resulted in 100% knockdown in 10-15 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.*

XXXXXXXX (2020), Report No: Q02 8-20-01

In the lab study by XXXXXXXX (2020), the product was applied as surface treatment in a hedge (of about 2 m2) of *Photinia fraseri* plants, inside of which cylindrical cages containing 20 females of *Culex pipiens* were placed. The product was also applied as surface treatment in a forced contact test on *Photinia fraseri* treated leaves and on non-porous (ceramic tiles) surfaces against female adults of *Culex pipiens*. The product was applied at a dose of 50 g/m2 of a 0.2% solution. To evaluate the residual activity, the adults were exposed to 5 days aged treated tiles. According to the results,the exposure of mosquitoesto the hedge up to 5 days provided 100% knockdown in 15-20 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto the treated leaves up to 5 days provided 93-33-98.33%% knockdown in 20-60 minutes and 90-96.67% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto non- porous surfaces up to 5 days provided 91.67-100% knockdown in 15-40 minutes and 98.33100% mortality in 24h after exposure of the insects to the treated surfaces*.*

XXXXXXXX (2020), Report No: Q076D-20-01

In the field study by XXXXXXXX (2020) the effectiveness of the product was evaluated in 3 private gardens, naturally infested by *Aedes albopictus*. The product was applied outdoors onto the selected area (walls up to 1.5 m) from a distance of 50 cm as a surface treatment (on a band of 1 m, from 0.5-1.5 m height). The product was applied at a dose of 50 g /m2 of a 0.2% solution. The treatment did not include direct application onto the mosquitoes. A forced contact test was also performed on a wall in each garden following the WHO cone method containing 15 female mosquitoes. Knockdown after exposure of mosquitoes to the treated wall surface was evaluated as well as mortality after 24 hours in the laboratory. A forced contact test was performed on leaves taken from each garden. The leaves were brought to the lab and glued on a tile. Following the WHO cone method female mosquitoes were exposed to the treated leave surfaces. Knockdown and mortality after 24 hours were evaluated.

According to the results,the exposure of mosquitoesto the hedge up to 3 days provided 100% knockdown in 60 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto treated wall up to 3 days provided 100%% knockdown in 25 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto treated leaves provided 92.22-99.44% knockdown in 30-60 minutes and 96.11% mortality in 24h just after exposure of the insects to the treated surfaces (T0) and 100% knockdown in 40 minutes and 93.89% mortality in 24h just after exposure of the insects to the treated surfaces at 3 days after application (T3).

Protection from mosquitoes was evaluated by assessing the wild tiger mosquito population with the Human Landing Technique. The number of landings on exposed legs skin in each replication was counted for 5 minutes. The % reduction of landings of *Aedes albopictus* was 100% after 10 minutes, 1 hour, 3 days and 7 days.

XXXXXXXX (2020), Report No: Q076D-20-02

In the field study by XXXXXXXX (2020) the effectiveness of the product was evaluated in 3 private gardens naturally infested by *Culex pipiens*. Before the treatment, in each area 4 cylindrical cages containing 15 females were placed inside the hedge at 50 cm height from the ground. In each treated parcel, the product was applied uniformly with a pressure sprayer along the perimeter, from a distance of 50 cm from hedges and walls. The product was applied as a surface treatment (on a band of 1 m, from 0.5-1.5 m height) at a dose of 50 g /m2 of a 0.2% solution. The treatment did not include direct application onto the mosquitoes. A forced contact test was also performed on a wall in each garden following the WHO cone method containing 15 female mosquitoes. Knockdown after exposure of mosquitoes to the treated wall surface was evaluated as well as mortality after 24 hours in the laboratory.

A forced contact test was performed on leaves taken from each garden. The leaves were brought to the lab and glued on a tile. Following the WHO cone method female mosquitoes were exposed to the treated leave surfaces. Knockdown and mortality after 24 hours were evaluated. Adult mosquito monitoring pre- and post- treatment was carried out with CDC traps to capture adult mosquitoes. The CDC traps were provided with CO2 as attractant and left working 1 night. The efficacy of the product was evaluated only the night of the treatment placing again the CDC traps, then the test was interrupted. The percentage of reduction was calculated.

According to the results,the exposure of mosquitoesto the hedge up to 3 days provided 100% knockdown in 60 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto treated wall up to 3 days provided 100%% knockdown in 20 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces*.* According to the results,the exposure of mosquitoesto treated leaves provided 100% knockdown in 20 minutes and 100% mortality in 24h just after exposure of the insects to the treated surfaces (T0) and 98.9% knockdown in 50 minutes and 94.4% mortality in 24h just after exposure of the insects to the treated surfaces at 3 days after application (T3). The mean % population reduction was 26.2%.

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:

* The intended Uses # 5 and 6 against mosquitoes, are accepted from an efficacy point of view, with the following limitations to be added in the PAR and SPC:

“The product provides sufficient control of mosquitos when appled at a distance 0,5 m from the treated surfaces”.

For the intended uses 5 & 6 (surface treatment around buildings against mosquitoes) and taking into consideration the low population reduction (26,2%) against *Culex* sp. in the field study by XXXXXXXX 2020, the claimed target mosquito *Culex* sp. and consequently the general claim against mosquitoes are not sufficiently proved and is proposed to be removed from the target organisms.

For the intended uses 5 & 6 (surface treatment around buildings against mosquitoes) sufficient knockdown and killing effect against tiger mosquitoes through the vapour of the product (applied as surface treatment) is demonstrated for up to 3 days in the field study by XXXXXXXX 2020. Hence, the results of that study support a 3 days residual action of the product against tiger mosquitoes,

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**Intended Uses # 8 and 9 for professionals and non-professionals: – Ant nest eradication**

The results of the laboratory studies 2493-LAB-LN/0819 and Q12-19-01 and the simulated use test 2532i-SIM-ANT/0120 have been presented above.

XXXXXXXX (2020) Report No: 2532g-FIELD-ANT/0120

The results of the field study by XXXXXXXX (2020) showed that the product was effective when applied outdoors, directly onto the ant nests and the surrounding area at at 25 gr on 1 m2 of surface surrounding the nest and at the entrance of the nest. These 25 gr of solution were distributed as follows: 10 gr at the entrance of the nest and 15 gr covering the square meter around the nest. Study results showed that the product provided 92.4% and 98.6% mean population reduction of ants at 1 and 3 days after treatment respectively. The mean population reduction of ants was 100% at 1, 2, 3 and 4 weeks after treatment.

Based on the results of the aforementioned efficacy studies, the intended uses 8 and 9, from an efficacy point of view, are acceptable as applied for by the applicant.

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

FREE LAND 10 EC is not intended to be authorised for use in mixture with other biocidal products.

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### Risk assessment for human health

**General information**

The assessment of effects on human health for FREE LAND 10 EC 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 FREE LAND 10 EC contains only not hazardous co-formulants. Cypermethrin, is the only hazardous ingredient in the product. Available toxicological information for the active substance and all co-formulants are deemed sufficient for the hazard assessment of the biocidal product FREE LAND 10 EC.

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

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

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritant to skin. |
| Justification for the value/conclusion | No data on skin corrosion/irritation are available for the biocidal product FREE LAND 10 EC.  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.  Neither the active substance nor the co-formulants of FREE LAND 10 EC are classified for skin corrosion/irritation, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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

***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 FREE LAND 10 EC.  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.  Neither the active substance nor the co-formulants of FREE LAND 10 EC are classified for eye damage/irritation, 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. |

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| **Data waiving** | |
| Information requirement | Eye irritation.  According to the information requirement of BPR, testing on the product does not 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 laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Since the available data on each of the components allow to estimate the classification of the product, data waiving is acceptable and the classification of the product can be estimated by calculation method considering all the components relevant for this endpoint. |

***Respiratory tract irritation***

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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 TG available for respiratory tract irritation and there is no testing requirement for this endpoint under the BPR.  There are no animal studies or human data for the biocidal product FREE LAND 10 EC that could be used to assess respiratory tract irritation.  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.  Cypermethrin is the only ingredient of the biocidal product FREE LAND 10 EC, classified as STOT SE Cat. 3, H335 (RAC opinion, December 2019).  However, as its concentration in the product (10.53%) 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 FREE LAND 10 EC, 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/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | The available information is sufficient to assess this hazard and no additional studies are required.  On the basis of BPR information requirements for this endpoint data, waiving is acceptable. |

***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 FREE LAND 10 EC.  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.  Neither the active substance nor the co-formulants of FREE LAND 10 EC are classified as skin 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. |

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| **Data waiving** | |
| Information requirement | Skin sensitization.  Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | According to the specific adaptation rules described in Annex III of BPR, the available information on the components in the mixture is sufficient to allow the classification according to the rules of CLP Regulation (EC). No additional testing ofa the product is required to assess this hazard. |

***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 FREE LAND 10 EC.  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.  Neither the active substance nor the co-formulants of FREE LAND 10 EC are classified as repiratory 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. |

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| **Data waiving** | |
| Information requirement | Respiratory sensitization.  There are currently no standard tests and no OECD test guidelines available for respiratory tract sensitization and there is no testing requirement for this endpoint under the BPR. |
| Justification | There are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  None of the components of the biocidal product is classified for this endpoint. Therefore, the biocidal product does not meet the criteria for classification for respiratory sensitization according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Non-toxic *via* the oral route. |
| Justification for the selected value | Acute oral toxicity data are not available for the biocidal product FREE LAND 10 EC.  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 is the only ingredient of the product FREE LAND 10 EC classified for acute oral toxicity.  The classification of cypermethin is Acute Tox. Cat. 4, H302 with oral ATE of 500 mg/kg bw (RAC opinion, December 2019). The concentration of the a.s. in the biocidal product is 10.53 % w/w.  Calculation of acute oral toxicity for FREE LAND 10 EC is:  100/ATEmix = 10.53/500; ATEmix = 4748 mg/kg bw  Based on the calculated ATEmix, the biocidal product FREE LAND 10 EC is not classified for acute oral toxicity. |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | Acute oral toxicity.  According to the specific adaptation rules described in Annex III of BPR, the available information on the components in the mixture is sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). No additional testing on the product is required to investigate this hazard. |

*Acute toxicity by inhalation*

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| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Non-toxic *via* the inhalation route. |
| Justification for the selected value | Acute inhalation toxicity data are not available for the biocidal product FREE LAND 10 EC.  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 is the only ingredient of the product FREE LAND 10 EC classified for acute inhalation toxicity.  The classification of cypermethin is Acute Tox. Cat. 4, H332 with inhalation ATE of 3.3 mg/L (RAC opinion, December 2019). The concentration of the a.s. in the biocidal product is 10.53 % w/w.  Calculation of acute inhalation toxicity for FREE LAND 10 EC is:  100/ATEmix = 10.53/3.3; ATEmix = 31.34 mg/L  Based on the calculated ATEmix the biocidal product FREE LAND 10 EC is not classified for acute inhalation toxicity. |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Acute inhalation toxicity.  Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | According to the specific adaptation rules described in Annex III of BPR, the available information on the components in the mixture is sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). No additional testing on the product is required to investigate this hazard. |

*Acute toxicity by dermal route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Non-toxic *via* the dermal route. |
| Justification for the selected value | No acute dermal toxicity data are available for the biocidal product FREE LAND 10 EC.  Classification of the product for this endpoint 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).  Neither the active substance nor the co-formulants of FREE LAND 10 EC are classified for acute dermal toxicity hazard. Therefore, the biocidal product does not meet the criteria for classification for acute dermal toxicity according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Acute dermal toxicity.  Testing on the product does not to be conducted if there are valid data available on each of the components sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | According to the specific adaptation rules described in Annex III of BPR, the available information on the components in the mixture is sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). No additional testing on the product is required to investigate this hazard. |

***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 FREE LAND 10 EC (10.53%), is above 10%, which is the generic concentration limit triggering classification of a product for STOT RE Cat. 2.  Therefore, **FREE LAND 10 EC 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***

*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 (xxxxxxxxxxxx) 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). 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.*

In the Assessment Report of cypermethrin as PT08 (2013)[[1]](#footnote-1), in the elements to be taken into account when authorising products, it is stated that *dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using default values*.

Based on the above and considering the characteristics of all products under assessment, the value derived in the CAR and used for the 25 mg/L cypermethrin dilution of the skin sensitizer EC formulation is considered as a worst-case. Thus, for the assessment of the human internal dermal exposure to the biocidal product FREE LAND 10 EC, **a value of 13% is used.**

The above conclusion is in line with the assessment included in the CAR for cypermethrin as PT18[[2]](#footnote-2) for the EW formulation, and the following has been concluded:

*The in vivo dermal absorption study in rats performed with the Cypermethrin 500 g/L EC formulation provided 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). The solvents used in the EC 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).*

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | cypermethrin |
| Value(s) | 13% |
| Justification for the selected value(s) | EC formulation is an organic solvent-based formulation and the concentration of cypermethrin is 10.53%.  There is no experimental data available on the dermal absorption of the biocidal product FREE LAND 10 EC; no study has been conducted so far.  However, the dermal absorption of cypermethrin has been reviewed in detail in the CAR of the active substance as PT08 taking into account all relevant data available, *in vitro* studies, *in vivo* rat data and human data from the open literature.  Based on the data reviewed a 13% dermal absorption value has been concluded for the assessment of the human internal dermal exposure to the EC formulation examined in the CAR. The concluded value has been based on the outcome of an in vivo study in rats with an EC formulation for the tested concentration of 25 mg a.s./L.  The composition of the EC formulation used in the *in vivo* dermal absorption study included in the CAR of cypermethrin, is not specified in detail. The only information reported in the CAR is that the solvents used in the EC formulation are considered to be more likely to carry the active substance through the skin due to the more lipophilic nature.  Although the detailed composition is not known, we are of the opinion that sufficient information is available to support the use of the 13% value in the exposure assessment of FREE LAND 10 EC:  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).  According to EFSA Guidance on dermal absorption (2017), p. 20, "substances not contained in the reference formulation might be acceptable up to a concentration of ≤ 0.5%, but only if it is shown or scientifically justified that this minor change does not have an impact on physical–chemical or toxicological properties of the formulation".  FREE LAND 10EC is diluted 1:100 in water. Therefore, in the diluted product the only relevant co-formulant above 0.5% is dipropylen glycol with a concentration of about 0.54% w/w (54% w/w in concentrated product).  The remaining co-formulants are less than 0.5% w/w and it is considered that they have no impact on the physical–chemical or toxicological properties of the formulation.  Dipropylen glycol has a logKow = 0.004; as such, it can be considered less lipophilic than solvents used in the formulation of the CAR (as reported in the CAR: "the solvents used in the EC formulation are considered to be more likely to carry the active substance through the skin due to the more lipophilic nature").  The applicability of the dermal absorption value derived in the CAR of cypermethrin on the FREE LAND 10EC has been verified also using the EFSA Flow chart 6 (EFSA Journal, 2017; 15(6): 4873) on read across between different formulations:  EFSA Flow chart 6:  - Were data on active substance generated with water as a vehicle? Yes  - Is formulation under consideration water based without surfactants? Yes  - Is active of same or greater skin irritancy/sensitisation than formulation? Yes  - Is level of active in formulation similar/greater than in tested solution? Yes  In addition to the above, it should be kept in mind that the dermal absorption study is an *in vivo* study which is a worst case as rat skin is more permeable than human skin.  Therefore, the dermal absorption value of 13% has been used in the exposure assessment of FREE LAND 10 EC. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption. |
| Justification | No data on dermal absorption are available for FREE LAND 10 EC, data of the CAR of cypermethrin can be used since the product is similar (i.e. about 10% a.s.). |

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

The biocidal product FREE LAND 10 EC contains the co-formulant (2-methoxymethylethoxy) propanol (CAS No. 34590-94-8). Based on the submitted MSDS of the supplier and the REACH registration dossier, (2-methoxymethylethoxy)propanol is not classified as hazardous according to CLP Regulation, therefore there is no impact on the classification of the biocidal product FREE LAND 10 EC.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health–Part B and C Risk Assessment–Version 4.0–December2017), (2-methoxymethyl ethoxy) propanol should be considered as a Substance of Concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit of (2-methoxymethylethoxy)propanol is 308 mg/m3 (<https://echa.europa.eu/el/substance-information/-/substanceinfo/100.047.353>) with a skin note (a skin notation assigned to the OEL identifies the possibility of significant uptake through the skin).

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

However, in case of (2-methoxymethylethoxy)propanol, a dermal quantitative risk assessment has not been performed as a dermal NOAEC value for this co-formulant has not been peer reviewed and agreed under the BPR. Therefore, only an inhalation quantitative risk assessment has been undertaken for this co-formulant.

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

Mixtures are not present in the biocidal product FREE LAND 10 EC.

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

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product FREE LAND 10 EC has been performed according to the instructions described in the document agreed in the Coordination Group (CG-39-2020-11 AP 16.4 e-c ED co-formulant assessment by MS).

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

The sources of information, the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product FREE LAND 10 EC are presented in detail in the Confidential Annex of this PAR.

Overall, based on available information it is concluded that the product FREE LAND 10 EC does not contain co-formulants with endocrine-disrupting properties for human.

Please, refer to the Confidential Annex for further details.

***Other***

Not applicable.

#### Exposure assessment

**Introduction**

The biocidal product FREE LAND 10 EC is an emulsifiable concentrate (EC) formulation containing cypermethrin (CAS No. 52315-07-8) as active substance and 2-methoxymethyl-ethoxy propanol (CAS No. 34590-94-8) as Substance of Concern.

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 FREE LAND 10 EC 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 FREE LAND 10 EC are reported in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Use** | **User** | **Type of applicator** | **Dilution** | **Application rate\*** |
| **Indoor uses** | | | |  |
| Use #1  Spot application  Crawling insects | Professional | Spray | Porous surfaces: dilute 10 ml of concentrated product in 1 L of water (1%).  Non-porous surfaces: dilute  5 ml of concentrated product in 1 L of water (0.5%). | Porous surfaces:  50 ml product/m²;  52.7 mg a.s./m2  Non-porous surfaces:  40 ml product/m²;  21 mg a.s./m2 |
| Use #2  Spot application  Crawling insects | Non- professional | Spray | Porous surfaces: dilute 1 ml of concentrated product in 100 ml of water (1%).  Non-porous surfaces: dilute  0.5 ml of concentrated product in 100 ml of water (0.5%). | Porous surfaces:  40 spray/m2;  1.25 ml product/spray;  50 ml product/m²;  52.7 mg a.s./m2  Non-porous surfaces:  32 spray/m2;  1.25 ml product/spray;  40 ml product/m²;  21 mg a.s./m2 |
| Use #3  Cracks & crevices  Crawling insects | Professional | Spray | Porous surfaces: dilute 10 ml of concentrated product in 1 L of water (1%).  Non-porous surfaces: dilute  5 ml of concentrated product in 1 L of water (0.5%). | Porous surfaces:  50 ml product/m²;  52.7 mg a.s./m2  Non-porous surfaces:  40 ml product/m²;  21 mg a.s./m2 |
| Use #4  Cracks & crevices  Crawling insects | Non- professional | Spray | Porous surfaces: dilute 1 ml of concentrated product in 100 ml of water (1%).  Non-porous surfaces: dilute  0.5 ml of concentrated product in 100 ml of water (0.5%). | Porous surfaces:  40 spray/m2;  1.25 ml product/spray;  50 ml product/m²;  52.7 mg a.s./m2  Non-porous surfaces:  32 spray per m2;  1.25 ml product/spray;  40 ml product/m²;  21 mg a.s./m2 |
| **Outdoor uses** | | | |  |
| Use #5  Around buildings  Rural areas  Mosquitoes | Professional | Spray | Dilute 2 ml of concentrated product in 1 L of water (0.2%). | 50 mL product/m².  10.5 mg a.s./m2 |
| Use #6  Around buildings  Rural areas  Mosquitoes | Non- professional | Spray | Dilute 2 ml of concentrated product in 1 L of water (0.2%). | 40 spray per m2;  1.25 ml product/spray;  50 mL product/m².  10.5 mg a.s./m2 |
| Use #7  Ant nest eradication | Professional | Spray | Concentrated product has to be diluted in water to 0.5% w/w before use. | 25 gr product/nest;  12.5 mg a.s./nest |
| Use #8  Ant nest eradication | Non- professional | Spray | Dilute 1 ml of concentrated product in 100 ml of water (1%). | 10 spray/nest;  1.25 ml product/spray;  12.5 gr product/nest |

\* The application rate in terms of active substance is expressed as technical grade active substance.

**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. | No | Yes | n.a. |

n.a.: not applicable

***List of scenarios***

In order to estimate the exposure of professional and non-professional users in each task of use (e.g. mixing & loading, application) of the biocidal product, suitable models have to be selected in Biocides Human Health Exposure Methodology.

|  |  |  |
| --- | --- | --- |
| **Summary table: scenarios** | | |
| Scenario number | Scenario | Exposed group |
| 1. | Mixing and loading spot treatment | Professional users |
| 2. | Mixing and loading crack&crevice spot treatment | Professional users |
| 3. | Mixing and loading around the building | Professional users |
| 4. | Mixing and loading ant nest | Professional users |
|  | | |
| 5. | Mixing and loading spot treatment | Non-professional users |
| 6. | Mixing and loading crack&crevice spot treatment | Non-professional users |
| 7. | Mixing and loading around the building | Non-professional users |
| 8. | Mixing and loading ant nest | Non-professional users |
|  | | |
| 9. | Application spot treatment | Professional users |
| 10. | Application crack&crevice spot treatment | Professional users |
| 11. | Application around the building | Professional users |
| 12. | Application ant nest | Professional users |
|  | | |
| 13. | Application spot treatment | Non-professional users |
| 14. | Application crack&crevice spot treatment | Non-professional users |
| 15. | Application around the building | Non-professional users |
| 16. | Application ant nest | Non-professional users |
|  | | |
| 17. | Cleaning of spraying equipment | Professional users |
|  | | |
| 18. | Laundering of contaminated work clothes | Professional users |
| 19. | Secondary exposure | 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 phase.

***Professional exposure***

##### Scenario 1. Mixing and loading spot treatment – professional users

Primary exposure of professional users resulting from mixing and loading phase for this use is included in the application task i.e. in Scenario 9.

##### Scenario 2. Mixing and loading crack & crevice spot treatment – professional users

Primary exposure of professional users resulting from mixing and loading phase for this use is included in the application task i.e. in Scenario 10.

##### Scenario 3. Mixing and loading around buildings – professional users

Primary exposure of professional users resulting from mixing and loading phase for this use is included in the application task i.e. in Scenario 11.

##### Scenario 4. Mixing and loading ant nest – professional users

Primary exposure of professional users resulting from mixing and loading phase for this use is included in the application task i.e. in Scenario 12.

##### Scenario 9. Indoor spot application – professional users

Spraying Model 1 (TNsG part 2, p. 143) was used for assessing the scenario concerning indoor spot application of the biocidal product FREE LAND 10 EC 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 both spot and 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 FREE LAND 10 EC are summarised below, while the detailed calculations are presented in the Annex 3.2 of this document.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 9:** **Spot application of FREE LAND 10 EC 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 (coated 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 | Professionals | **-** |
| Scenario | Spot 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 (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product (technical grade active substance 10.53% diluted 100 times). |
| **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  coated coveralls: 20 | Default protection factor for coated coveralls is 80% for insecticides applied by spray, 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 HEEG Opinion “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 HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |

**Calculations for Scenario 9: Spot application 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 9  Spot application  Professional users | 1 / no PPE | 0.00456 | 0.07475 | **0.07931** |
| 2 / gloves, coated coveralls | 0.00456 | 0.00797 | **0.01253** |

**Further information and considerations on Scenario 9**

The biocidal product FREE LAND 10 EC contains the co-formulant (2-methoxymethylethoxy)propanol (CAS No.34590-94-8) at a concentration of 54.47% w/w.

As (2-methoxymethylethoxy)propanol has a European Union-agreed IOELV (308 mg/m3), a quantitative inhalation risk assessment for the professional operator against the IOELV has been conducted. Therefore, for scenario 10, the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol has been calculated.

The parameters used for the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol during spot application (Scenario 10) of FREE LAND 10 EC are summarised below, while the calculations are presented in the Annex 3.2 of this document.

***Scenario 9***

|  |  |  |
| --- | --- | --- |
| **Scenario 9: Inhalation exposure of professional users to (2-methoxymethylethoxy)propanol during spot application of FREE LAND 10 EC.** | | |
| **Parameters** | **Value** | **Comments** |
| Concentration of (2-methoxymethylethoxy)propanol in the concentrated product (%) | 54.47 | Concentration of (2-methoxymethylethoxy)propanol in the concentrated product. |
| Concentration of 2-methoxymethylethoxy)propanol in the in-use product (%) | 0.5447 | Final concentration of 2-methoxymethylethoxy)propanol in the in-use diluted product. |
| Body weight of adult (kg) | 60 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Inhalation rate of adult (m3/h) | 1.25 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Penetration through RPE (%) | 100 | As a worst-case scenario, it is assumed that no respiratory 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. |
| Indicative inhalation exposure (mg/m3) | 104 | Indicative exposure value for inhalation (Spraying Model 1, TNsG part 2, p. 143). |
| Inhalation absorption (%) | 100 | Worst-case assumption. |
| Application duration (min) | 120 | Median duration "using pesticides" according to an HSE survey of pest controllers (1994). |

**Calculations for Scenario 9 for (2-methoxymethylethoxy)propanol**

| **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 9 | 1/no PPE | 0.0236 | - | - | **0.0236** |

In addition to the above exposure assessment and in order to address the concerns raised during the bilateral discussions as regards exposure *via* inhalation to the SoC after evaporation, a worst-case approach calculation has been considered assuming that the whole amount of the SoC applied in a room evaporates at the same time while the professional user is still in the room.

The parameters used for the inhalation exposure of professional users to (2-methoxymethylethoxy)propanol and the estimated inhalation exposure are summarized below:

- Room volume = 20 m3

- Room height = 2.5 m

- Room surface = 8 m2

- Application rate of the in-use product = 0.5 g/m2

- Application rate of SoC = 54.47% x 0.5 g/m2 = 0.272 g/m2

- Total amount of SoC applied in the room = 8 m2 x 0.272 g/m2 = 2.176 g SoC

- SoC concentration in the room = 2.176 g/20 m3 = 0.1088 g/m3 = 108.8 mg/m3, i.e. **35.3%** of the respective IOELV.

##### Scenario 10. Application crack & crevice spot treatment – professional users

Exposure assessment for application in crack and crevice spot treatment by professional users is not necessary, since it is considered covered by the exposure assessment performed in Scenario 9 (spot application by professional users) that represents a worst-case scenario.

##### Scenario 11. Application around buildings – professional users

Exposure assessment for application around buildings by professional users is not necessary, since it is considered covered by the exposure assessment performed in Scenario 9 (spot application by professional users) that represents a worst-case scenario.

Outdoor use has been considered similar to the indoor use (i.e. both indoor and outdoor uses are covered by Spraying Model 1 of TNsG).

##### Scenario 12. Application ant nest - professional users

Exposure assessment for application on ant nests by professional users is not necessary, since it is covered by exposure assessment performed in Scenario 9 (spot application by professional users) that represents a worst-case scenario.

Outdoor use has been considered similar to the indoor use (i.e. both indoor and outdoor uses are covered by Spraying Model 1 of TNsG).

##### Scenario 17. Cleaning of spraying equipment - professional users

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 17: cleaning of spraying equipment by professional users** | | |
| Exposure to the product FREE LAND 10 EC 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 coated coveralls during cleaning of the spraying equipment.  The model and the parameters used for the professional exposure to FREE LAND 10 EC 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 (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product for spot application. |
| Density of the in-use product (g/ml) | 1 | The density of the in-use diluted product is considered to be 1 g/ml. |
| 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 HEEG Opinion “Default human factor values for use in exposure assessments of 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 tasks (Tier 2), the professional 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 (%) | 20 | According to the assumptions performed for application tasks (Tier 2), the professional user wears coated coveralls with protection factor 80% during cleaning of the spraying equipment. |

**Calculations for Scenario 17: 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 17  Cleaning spraying equipment after spot application  Professional users | 2 / gloves, coated coveralls | - | 3.32 x 10-4 | - | **3.32 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 9) and during cleaning of the spraying equipment (primary indirect exposure – Scenario 17).

**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** | | | |
| Spot application &  cleaning equipment.  Professional users  Scenarios  9 & 17 | 2 / gloves, coated coveralls | 4.56 x 10-3 | 7.97 x 10-3  +  3.32 x 10-4  =  8.3 x 10-3 | - | **1.29 x 10-2** |

***Non-professional exposure***

##### Scenario 5. Mixing and loading spot treatment - non-professional users

Exposure assessment for mixing and loading phase in spot treatment use by non professional has been performed using ConsExpo Web version 1.0.7.

Table. General input data for cypermethrin.

|  |  |
| --- | --- |
| **General input data ConsExpo Web version 1.0.7** | |
| Name of the substance | cypermethrin |
| CAS number | 52315-07-8 |
| Molecular weight | 416.3 g/mol |
| logKow | 5.45 |
| Vapour pressure (250C) | 6 x 10-7 |

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 5: Mixing and loading task in spot treatment use by non-professionals.** | | |
| Inhalatory exposure during mixing and loading can occur due to evaporation from the  bottle with the formulation. Dermal exposure can occur, due to liquid spills.  As reported in RIVM report 320005002/2006 - Pest Control Products Fact Sheet, a private user mixes and loads liquid into a plant sprayer filled with water to produce 2 litres of ready-for-use product. The active substance evaporates from the bottle with the formulation, a one-litre bottle with a not-too-small circular opening with a 5-cm diameter, resulting in a surface area of 20 cm2. During mixing and loading the user stays in the vicinity of the evaporating compound and it is therefore assumed that the user is present in a “personal volume” instead of a room volume. Further, there could be dermal exposure due to spillage. To calculate the exposure of the user during mixing and loading liquid, the “evaporation model” is used for inhalation exposure and the “instant application” model is used for dermal exposure.  Primary exposure of non-professional users for mixing and loading task 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 database | Pest control products | - |
| Product category | Mixing and loading | - |
| Product | Mixing and loading | - |
| Scenario | Mixing and loading, liquid | - |
| Frequency | 2 per year | According to the product label, the product is used 2 times per year. |
| Body weight (kg) | 60 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Concentration of a.s. in in-use product (%) | 10.53 | Final 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, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Application duration (min) | 1.33 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Product amount (g) | 500 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Room volume (m3) | 1 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Ventilation rate | 0.6 per hour | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Release area (m2) | 0.002 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Inhalation rate (m3/h) | 1.25 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Mass transfer rate | Langmuir | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Mol. weight matrix (g/mol) | 3000 | Default, 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 |  |
| Product amount (g) | 500 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 31). |
| Retention factor | 1 | Default, 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 5: Mixing and loading task in spot treatment use by non-professionals.**

| **Summary table: estimated exposure from non-professional uses: mixing and loading task in spot treatment use (internal dose on day of exposure).** | | | | |
| --- | --- | --- | --- | --- |
|  | **Inhalation dose** | **Dermal dose** | **Oral non-respirable dose** | **Total systemic dose** |
|  | mg/kg bw/day | | | |
| **Scenario 5** | 4.7 x 10-12 | 2.3 x 10-3 | - | **2.3 x 10-3** |

**Further information and considerations on Scenario 5**

No further information and considerations on this scenario.

##### Scenario 6. Mixing and loading crack & crevice spot treatment - non-professional users

Exposure assessment for mixing and loading in crack and crevice spot treatment by non-professional users is the same of previously calculated for spot treatment, i.e. Scenario 5.

##### Scenario 7. Mixing and loading around buildings - non-professional users

Exposure assessment for mixing and loading use around buildings by non-professional users is the same of previously calculated for spot treatment, i.e. Scenario 5.

##### Scenario 8. Mixing and loading ant nest - non-professional users

Exposure assessment for mixing and loading in ant nest treatment by non-professional users is the same of previously calculated for spot treatment, i.e. Scenario 5.

##### Scenario 13. Application spot treatment - non-professional users

Exposure assessment for application as spot 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 FREE LAND 10 EC are summarised below, while the detailed calculations are presented in the Annex 3.2 of this document.

| **Description of Scenario 13: Spot application of the biocidal product FREE LAND**  **10 EC by non-professional users.** | | |
| --- | --- | --- |
| Primary exposure for spot application by non-professional users 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 database | Pest control products | - |
| Product category | Sprays | - |
| Product | Targeted spot | - |
| Scenario | Application (trigger can) | - |
| Frequency | 2 per year | According to the product label, the product is used 2 times per year. |
| Body weight (kg) | 60 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Concentration of a.s. in in-use product (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product. |
| **Inhalation exposure** | | |
| Model | Exposure to spray | - |
| Mode of release | Spraying | - |
| Spray duration (min) | 6 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Inhalatory exposure duration (min) | 240 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Room volume (m3) | 20 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Room height (m) | 2.5 | Standard room height as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Ventilation rate | 0.6 per hour | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Inhalation rate (m3/h) | 1.25 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Mass generation rate (g/s) | 0.4 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Airborne fraction | 0.008 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Density non volatile  (g/cm3) | 1.8 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 21). |
| Inhalation cut off diameter (μm) | 15 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| Particle distribution - median diameter (μm) | 7.7 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Particle distribution - coefficient of variation. | 1.9 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Maximum diameter (μm) | 50 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| 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 |  |
| Dermal contact rate (mg/min) | 46 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (Table 13, p. 28). |
| Release duration (min) | 6 | Spray duration, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 37). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |

**Calculations for Scenario 13: Spot application by non-professional users**

| **Summary table: estimated exposure from non-professional uses: spot application**  **(internal dose on day of exposure)** | | | | |
| --- | --- | --- | --- | --- |
|  | **Inhalation dose** | **Dermal dose** | **Oral non-respirable dose** | **Total systemic dose** |
|  | mg/kg bw/day | | | |
| **Scenario 13** | 5.3 x 10-4 | 6.3 x 10-4 | 4.5 x 10-6 | **1.2 x 10-3** |

**Further information and considerations on Scenario 13**

No further information and considerations on this scenario.

##### Scenario 14. Application crack & crevice spot 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 FREE LAND 10 EC are summarised below, while the detailed calculations are presented in the Annex 3.2 of this document.

| **Description of Scenario 14: Crack and crevice spot application of the biocidal product FREE LAND 10 EC by non-professional users.** | | |
| --- | --- | --- |
| Primary exposure for crack and crevice spot application by non-professional users 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 database | Pest control products | - |
| Product category | Sprays | - |
| Product | Crack & crevice spot | - |
| Scenario | Application (trigger can) | - |
| Frequency | 2 per year | According to the product label, the product is used 2 times per year. |
| Body weight (kg) | 60 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Concentration of a.s. in in-use product (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product. |
| **Inhalation exposure** | | |
| Model | Exposure to spray | - |
| Mode of release | Spraying | - |
| Spray duration (min) | 4 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalatory exposure duration (min) | 240 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Room volume (m3) | 20 | Default, 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, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 42). |
| Inhalation rate (m3/h) | 1.25 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Mass generation rate (g/s) | 0.4 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Airborne fraction | 0.008 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Density non volatile  (g/cm3) | 1.8 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 21). |
| Inhalation cut off diameter (μm) | 15 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| Particle distribution - median diameter (μm) | 7.7 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Particle distribution – arithmetic coefficient of variation | 1.9 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Maximum diameter (μm) | 50 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| 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 |  |
| Dermal contact rate (mg/min) | 46 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (Table 13, p. 28). |
| 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 14: Crack and crevice spot application by non-professional users**

| **Summary table: estimated exposure from non-professional uses: crack and crevice spot application (internal dose on day of exposure)** | | | | |
| --- | --- | --- | --- | --- |
|  | **Inhalation dose** | **Dermal dose** | **Oral non-respirable dose** | **Total systemic dose** |
|  | mg/kg bw/day | | | |
| **Scenario 14** | 3.5 x 10-4 | 4.2 x 10-4 | 3.0 x 10-6 | **7.7 x 10-4** |

**Further information and considerations on Scenario 14**

No further information and considerations on this scenario.

##### Scenario 15. Application around buildings - non-professional users

Application around buildings by non-professional users has been considered as general surface treatment and the exposure assessment has been performed using ConsExpo Web version 1.0.7.

The model and the parameters used for the non-professional exposure to FREE LAND 10 EC are summarised below, while the detailed calculations are presented in the Annex 3.2 of this document.

| **Description of Scenario 15: Application around buildings of the biocidal product FREE LAND 10 EC by non-professional users.** | | |
| --- | --- | --- |
| Primary exposure of non-professional users for application around buildings 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 database | Pest control products | - |
| Product category | Sprays | - |
| Product | General surface | - |
| Scenario | Application (trigger can) | - |
| Frequency | 2 per year | According to the product label, the product is used 2 times per year. |
| Body weight (kg) | 60 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Concentration of a.s. in in-use product (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product. |
| **Inhalation exposure** | | |
| Model | Exposure to spray | - |
| Mode of release | Spraying | - |
| Spray duration (min) | 10 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 45). |
| Inhalatory exposure duration (min) | 240 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 45). |
| Room volume (m3) | 58 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (pp. 45). |
| Room height (m) | 2.5 | Standard room height as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 45). |
| Ventilation rate | 0.5 per hour | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 45). |
| Inhalation rate (m3/h) | 1.25 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Mass generation rate (g/s) | 0.8 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Airborne fraction | 0.008 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Density non volatile  (g/cm3) | 1.8 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 21). |
| Inhalation cut off diameter (μm) | 15 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| Particle distribution - median diameter (μm) | 7.7 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Particle distribution - coefficient of variation. | 1.9 | Default, as reported in “New default values for the spray model” RIVM, March 2010. |
| Maximum diameter (μm) | 50 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 25). |
| 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 |  |
| Dermal contact rate (mg/min) | 46 | Default, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (Table 13, p. 28). |
| Release duration (min) | 10 | Spray duration, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 44). |
| Dermal absorption (%) | 13 | Dermal absorption value established in the CAR of the active substance cypermethrin. |

**Calculations for Scenario 15: Application around buildings by non-professional users.**

| **Summary table: estimated exposure from non-professional uses: application around buildings (internal dose on day of exposure)** | | | | |
| --- | --- | --- | --- | --- |
|  | **Inhalation dose** | **Dermal dose** | **Oral non-respirable dose** | **Total systemic dose** |
|  | mg/kg bw/day | | | |
| **Scenario 15** | 6.6 x 10-4 | 1.0 x 10-3 | 5.2 x 10-6 | **1.7 x 10-3** |

**Further information and considerations on Scenario 15**

No further information and considerations on this scenario.

##### Scenario 16. Application ant nest - non-professional users

Due to the type of application and limited amount of product involved, this application can be deemed covered by aforementioned exposure scenarios (since they represent the worst case).

***Combined exposure***

Combined scenarios are relevant for non-professional adult users exposed to the active substance cypermethrin during mixing and loading phase (primary direct exposure – Scenario 5) and during application of the product (primary direct exposure – Scenario 13 or Scenario 14 or Scenario 15).

The following combinations are made:

* Scenario 5 + Scenario 13
* Scenario 5 + Scenario 14
* Scenario 5 + Scenario 15

| **Exposure scenario** | **Summary table: systemic acute exposure Total internal dose on day of exposure**  **mg/kg bw/day** |
| --- | --- |
| Spot treatment  Scenarios 5 + 13 | 0.0023 + 0.0012 = **0.0035** |
| Crack & crevice treatment  Scenarios 5 + 14 | 0.0023 + 0.00077 = **0.0031** |
| General surface treatment Scenarios 5 + 15 | 0.0023 + 0.0017 = **0.004** |

***Exposure of the general public***

##### Scenario 18. Laundering of contaminated work clothes - professional users

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 18:** **Adult professional users laundering contaminated work clothes at home.** | | |
| Exposure of adult professional users to the product FREE LAND 10 EC 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 | HEEG Opinion “Default human factor values for use in exposure assessments of 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 (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product for spot application. |
| Potential dermal exposure (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 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Total area of both hands of an adult (cm2) | 820 | HEEG Opinion “Default human factor values for use in exposure assessments of 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 18: 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 18  Laundering work clothes  Professional users | 1 / no PPE | - | 2.73 x 10-4 | - | **2.73 x 10-4** |

##### Scenario 19. Secondary exposure of the general public

Indoor uses (authorised uses #1, 2, 3 and 4) concern spot or crack and crevice treatment, while outdoor uses (authorised uses # 5 and 6) concern general surface treatment.

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.

Therefore, secondary exposure of the general public after general surface treatment outdoors is covered by the exposure assessment performed for the general public after spot treatment indoors.

Indirect secondary exposure could occur in the residential environment following the application of FREE LAND 10 EC. 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 public 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*

Tier-1 screening tool has been applied in order to assess whether inhalation exposure can be neglected or should be included into the risk assessment. The following screening test is based on the toddler, since represents the worst case, as proposed in HEEG Opinion 13.

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 bw of 10 kg) and using an AEL in mg a.s./kg bw/d, if

0.328 × [(mw x vp)/AELlong-term] ≤ 1

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Table. Screening tool of inhalation exposure for cypermethrin.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Active substance** | **MW (g/mol)** | **Vp (Pa) at 25°C** | **AELlong-term (mg/kg bw day)** | **0.328 × [(mw x vp)/AELlong-term]** | **Result** |
| Cypermethrin | 416.3 | 6 × 10-7 | 0.022 | 0.0037 | <1, then 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**

Dermal exposure is expected to occur for the general public in the domestic area *via* direct contact to deposits of the biocides 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 period and adults working around treated surfaces, thereby accidentally touching contaminated surfaces with their bare hands.

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 ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-to-mouth contact (RIVM report 320005002/2006).

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 19: Secondary dermal and oral exposure of the general public.** | | |
| The assessment for the dermal and oral exposure of the general public has been performed using ConsExpo Web, version 1.0.7.  Secondary exposure has been calculated for spot treatment using an application dose of 50 gr product/m² which is equivalent to 52.7 mg a.s./m2 (diluted product has a concentration of cypermethrin of 0.1053% w/w). | | |
| **Parameter** | **Value** | **Comments** |
| Exposed group | General public:  infant, toddler, child, adult | - |
| Product database | Pest control products | - |
| Product category | Sprays | - |
| Product | Spot treatment | - |
| Scenario | Post-application (child) | - |
| Application rate  (g/m2) | 50 gr product/m² | The actual application rate of the product for spot application. |
| Concentration of active substance (%) | 0.1053 | Final concentration of the active substance cypermethrin in the in-use diluted product. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Rubbing off | - |
| Exposure frequency | 28 per year | According to the product label, the product is used 2 times per year.  According to RIVM report 320005002/2006, the total contact time after application is defined to be 14 days.  Thus, the exposure frequency of the general public is: 2 x 14 days per year = 28 times per year. |
| Exposed area  (palms and backs of both hands) (cm2) | Infant: 196.8  Toddler: 230.4  Child: 427.8  Adult: 820 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Transfer coefficient (m2/hr) | Infant/toddler/child: 0.2  Adult: 0.78 | 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) | 2.25 | Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet”, using the actual application rate of the product for spot treatment.  According to RIVM report 320005002 (p.36), “It is assumed that 15% of the total amount sprayed ends up on the floor surface. The 30% of the amount on the floor surface is dislodgeable/wipeable, i.e., it can be brushed away. The floor surface in spot treatment is 2 m2.”  Therefore, dislodgeable amount for spot treatment is calculated as follows:  50 g/m2 x 15% x 30% = 2.25 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. 38). |
| Rubbed surface (m2) | 2 | Default value for rubbed surface, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 38). |
| 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  Adult: 60 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| **Oral exposure: hand-to mouth contact** | | |
| Model | Direct product contact | - |
| Loading | Constant rate | - |
| Ingestion rate od product (mg/min) | 0.75 | 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 FREE LAND 10 EC is calculated as follows: transfer coefficient x dislodgeable amount x 10% =  (0.2 m2/hr x 2.25 g/m2 x 1000 x 0.1) / 60 = 0.75 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 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

**Calculations for Scenario 19: Dermal and oral secondary exposure of infants, toddlers, children and adults**

| **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 19  Infants | - | 7.7 × 10⁻³ | 3.4 × 10⁻³ | **1.1 × 10⁻²** |
| Scenario 19  Toddlers | - | 6.1 × 10⁻³ | 2.7 × 10⁻³ | **8.8 × 10⁻³** |
| Scenario 19  Children | - | 2.6 × 10⁻³ | Not relevant for child | **2.6 × 10⁻³** |
| Scenario 19  Adults | - | 4.0 × 10⁻³ | Not relevant for adult | **4.0 × 10⁻³** |

**Further information and considerations on Scenario 19**

No further information and considerations on this scenario.

***Monitoring data***

No data available.

***Dietary exposure***

Information regarding residues in food/feedstuff or drinking water was not submitted by the applicant nor are required since no dietary exposure assessment is deemed necessary

The biocidal product FREE LAND 10 EC is not intended to be applied directly on food/feed, drinking water facilities or livestock premises and therefore it is not expected that consumer or livestock animals may be exposed to the product. In addition different mitigation measures are proposed in the label in order to avoid any accidental contamination on food/feedstuff from animal or vegetal origin such as described in “2.1.5.2 Risk mitigation measures” above.

#### Risk characterisation for human health

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

For Risk Characterisation AELs determined for cypermethrin have been used, as reported in the CAR of cypermethrin and as detailed in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 |

As indicated in the Technical Agreements for Biocidal Products for Human Health (TOX 22) version 2.0, the internal dose on the day of exposure is compared to the AEL long-term of the active substance for the primary exposure of professional users and compared to the AEL medium-term for the primary exposure of non-professional users and secondary exposure of the general public.

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.

Table. ADI and ARfD values for cypermethrin.

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

**Maximum residue limits or equivalent**

As to support the uses of Cypermethrin as a plant protection product, MRLs have been set for “*Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers))*” in plant and animal commodities with (Reg. (EU) 2017/626).

**Reference values to be used in Risk Characterisation for 2-methoxymethyl-ethoxy propanol (CAS No. 34590-94-8)**

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

The European IOELV (308 mg/m3) of 2-methoxymethyl-ethoxy propanol (CAS No. 34590-94-8) has been converted in the systemic inhalation uptake of 6.417 mg/kg bw/day, considering an inhalation rate of 1.25 m3/h, body weight of 60 kg, 100% inhalation absorption and 2 h exposure duration for the professional user:

308 mg/m3 x 1.25 m3/h x 2 h x 100% / 60kg = 12.833 mg/kg bw/day

***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/day)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| **cypermethrin** | | | | | |
| Spot application  Professionals  Scenario 9 | 1 | 0.022 | 0.07931 | 361% | **no** |
| 2 | 0.01253 | 57% | yes |
| Cleaning equipment - spot application  Professionals  Scenario 17 | 2 | 0.000332 | 1.51% | yes |
| **2-methoxymethyl-ethoxy propanol** | | | | | |
| Spot application  Professionals  Scenario 9 | 1 | 12.833 | 0.0236 | 0.2% | yes |

**Combined scenarios - cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AELlong-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Spot application, cleaning equipment,  Professional users  Scenarios 9 + 17 | 2 | 0.022 | 0.0129 | 58.64% | yes |

**Local effects**

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, the following instructions for use are proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 1053 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND 10 EC under product label instructions.

**Conclusion**

As a result of the risk assessment performed, the risk for trained professionals and professionals using the biocidal product FREE LAND 10 EC is considered acceptable, provided that the product is used according to instructions of use and professional users wear protective gloves and coated coveralls during application of the product and cleaning of the spraying equipment.

Also combined exposure of scenarios is considered acceptable for trained professional and professional users.

Therefore, there is no concern for trained professionals and professionals using the biocidal product FREE LAND 10 EC, provided that the product is used according to instructions of use and professional users wear protective gloves and coated coveralls.

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

**Systemic effects - cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Mixing and loading in spot treatment  Non-professionals  Scenario 5 | 1 | 0.055 | 0.0023 | 4.2% | yes |
| Mixing and loading in crack & crevice treatment  Non-professionals  Scenario 6 | 1 | 0.0023 | 4.2% | yes |
| Mixing and loading for application around buildings  Non-professionals  Scenario 7 | 1 | 0.0023 | 4.2% | yes |
| Mixing and loading for ant nest treatment  Non-professionals  Scenario 8 | 1 | 0.0023 | 4.2% | yes |
| Spot application  Non-professionals  Scenario 13 | 1 | 0.0012 | 2.2% | yes |
| Crack&crevice application  Non-professionals  Scenario 14 | 1 | 0.00077 | 1.4% | yes |
| Application around buildings  Non-professionals  Scenario 15 | 1 | 0.0017 | 3.1% | yes |

**Local effects**

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, the following instructions for use are proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 1053 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND 10 EC under product label instructions.

**Conclusion**

As a result of the risk assessment performed, the risk for the non-professionals using the biocidal product FREE LAND 10 EC is considered acceptable, provided that the product is used according to the instructions of use.

***Risk for the general public***

**Systemic effects - cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Scenario 18  Laundering  Adults | 1 | 0.022 | 0.000273 | 1.24% | yes |
| Scenario 19  Infants | 1 | 0.055 | 0.011 | 20% | yes |
| Scenario 19  Toddlers | 1 | 0.0088 | 16% | yes |
| Scenario 19  Children | 1 | 0.0026 | 4.73% | yes |
| Scenario 19  Adults | 1 | 0.004 | 7.3% | yes |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/d)** | **Estimated uptake**  **(mg/kg bw/d)** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Spot application, cleaning equipment, laundering clothes  Professional users  Scenarios  9 + 17 +18 | 2 | 0.022 | 0.01314 | 59.7% | yes |
| Mixing/loading, spot application, secondary  Non-professionals  Scenarios  5 + 13 + 19 | 1 | 0.055 | 0.0075 | 13.64% | yes |
| Mixing/loading, crack&crevice application, secondary  Non-professionals  Scenarios  5 + 14 + 19 | 1 | 0.00707 | 12.85% | yes |
| Mixing/loading, application around buildings, secondary  Non-professionals  Scenarios  5 + 15 + 19 | 1 | 0.008 | 14.55% | yes |

**Local effects**

Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, the following instructions for use are proposed:

- The biocidal product contains cypermethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of cypermethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of cypermethrin is assumed to be lower than 1053 ppm.

Therefore, no local effects are foreseen from the application of the biocidal product FREE LAND 10 EC under product label instructions.

**Conclusion**

As a result of the risk assessment performed, the risk for the secondary exposure of the general public is considered acceptable.

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

No combined exposure is foreseen.

### Risk assessment for animal health

Risk assessment for animal health is not necessary, since exposure of animals is not expected (i.e. FREE LAND 10 EC is not intended to be applied to animals). The product is not used on animals.

The following risk mitigation measures will be included in the product label in order to ensure the safety of animals:

- The product should be applied in such a way that children, farm animals and pets, especially cats, do not come into contact with the product.

- Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.

- Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.

- Keep out of reach of children and pets.

- Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.

- Do not spray onto people and pets.

### 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.

All ingredients of the biocidal product “FREE LAND 10 EC” are not classified according to CLP Regulation EU No 1272/2008 (i.e. not hazardous), except for the active substance cypermethrin.

Moreover, available toxicological information for the active substance (i.e. cypermethrin) and all co-formulants are deemed sufficient for the hazard assessment of FREE LAND 10 EC.

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

#### 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 | 0.0050 mg/Kg wwt (Cypermethrin, CAR, 2019) |
| Microorganisms in STP | 1.63 mg/l |
| Soil | 0.070 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)***

Not applicable.

**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, in the product only cypermethrin is classified as hazardous for the environment. |

|  |  |
| --- | --- |
| **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, in the product only cypermethrin is classified as hazardous for the environment. |

|  |  |
| --- | --- |
| **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 data available.

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

Screening of endocrine-distruptors 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 distruptor properties for environment.

Please, refer to the Annex of Confidential Data for further details.

#### Exposure assessment

According to the following request of e-CA Greece : “The minimum purity 93% of Tagros source reported in the PAR is not the one stated in the Technical equivalence for cypermethrin and ECHA decision on chemical equivalence (XXXXXXXXXXXXXXXXXXXX), where is it clearly indicating a min purity of 95%... the risk assessment of the product should be corrected (where needed) using the correct min. at 95%“.

The risk assessment calculations proposed are at 95% of purity. Therefore, TGAI is 10.5% w/w (i.e. 10.0 × 100/95).

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 FREE LAND 10 EC 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*  Scenario 1 – Indoor spot application  Scenario 2 – Indoor spot application in crack & crevice  Scenario 3 – Indoor barrier application in crack & crevice  *Outdoor*  Scenario 4 – Targeted residual treatment around the building against mosquitoes  XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX  XXXXX  Scenario 6 – Ant nest eradication |
| 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 appooach 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. |
| 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. |

Scenario 3 is related to Intended Uses# 5 (Indoor barrier application in crack & crevice, professional use) and #6 (Indoor barrier application in crack & crevice, non-professional use), which are not supported by the applicant.

Scenario 3 is presented for completeness reasons and should not be further considered for the risk characterisation.

***Emission estimation***

**Formulation of the product**

Production of FREE LAND 10 EC is an industrial formulation process. Exposure estimation for the formulation of FREE LAND 10 EC was not performed since:

* releases into the environment cannot 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".

##### Scenario 1 - Indoor spot treatment

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

This scenario cover uses of the product by trained professional, professional and non-professional users.

Table. Indoor spot treatment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment of TIER 1** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | FREE LAND 10 EC is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, surface | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot 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 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 | 10 g | g | 10 g of a solution at 10.5% of active substance (1 L) have to be diluted in a final volume of 1 L of water. |
| 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) |
| Number of preparations per day, large building | 3 | - |
| 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 | 0.5 | g/m2 | Dose expressed as pure active ingredient is 50 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.5 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.5 g/m2 x 10.5/100 = 52.5 mg a.i./m2. |
| 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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) | 0.5 | - | Default cleaning efficiency for surface spot treatment, 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 “Fraction emitted to treated surfaces during application” 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. In order to simulate in the exposure assessment, the application of this RMM, the “fraction emitted to treated surfaces during application” has been set to 0.** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | FREE LAND 10 EC is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, surface | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot 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 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 | 10 g | g | 10 g of a solution at 10.5% of active substance (1 L) have to be diluted in a final volume of 1 L of water. |
| 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) |
| Number of preparations per day, large building | 3 | - |
| 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 | 0.5 | g/m2 | Dose expressed as pure active ingredient is 50 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.5 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.5 g/m2 x 10.5/100 = 52.5 mg a.i./m2. |
| 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 | - | Default value for “fraction emitted to treated surfaces” is 0.85. A scenario with the default value has already been assessed (TIER 1) and, as a result, 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. In order to simulate the application of this RMM in the exposure assessment, the “fraction emitted to treated surfaces during application” has been set to 0. |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.50 | - | Default cleaning efficiency for surface spot treatment, 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 | - | - |

Calculations for Scenario 1 - Indoor spot treatment

**TIER 1**

| **Resulting local emission to relevant environmental compartments –Industrial use (standard houses and large buildings)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 5.92 x 10-4 | - |
| Air | 2.31 x 10-5 | - |

| **Resulting local emission to relevant environmental compartments – Private use (standard houses)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 4.48 x 10-4 | - |
| Air | 1.72 x 10-5 | - |

**TIER 2**

| **Resulting local emission to relevant environmental compartments – Industrial use (standard houses and large buildings)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 1.00 x 10-4 | - |
| Air | 2.31 x 10-5 | - |

| **Resulting local emission to relevant environmental compartments – Private use (standard houses)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 8.32 x 10-5 | - |
| Air | 1.72 x 10-5 | - |

##### Scenario 2 - Indoor spot application in crack & crevice

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

This scenario cover uses of the product by trained professional, professional and non-professional users.

Table. Indoor crack and crevice spot treatment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | FREE LAND 10 EC is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Spot, crack and crevice | - | - |
| Total area treated in a standard house | 2 | m2 | Default value for spot crack and crevice 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 | 10 g | g | 10 g of a solution at 10.5% of active substance (1 L) have to be diluted in a final volume of 1 L of water. |
| 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) |
| Number of preparations per day, large building | 3 | - |
| 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 | 0.5 | g/m2 | Dose expressed as pure active ingredient is 50 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.5 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.5 g/m2 x 10.5/100 = 52.5 mg a.i./m2. |
| 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 | - | Default value for “fraction emitted to treated surfaces” is 0.85. In this case, the product is applied only in areas not subject to wet cleaning. With this RMM emission to surface water will be reduced. In order to simulate the application of this RMM in the exposure assessment, the “fraction emitted to treated surfaces during application” has been set to 0. |
| **Cleaning** | | | |
| Cleaning efficiency (of treated surfaces and floor from application) | 0.25 | - | Default cleaning efficiency for spot crack and crevice treatment, 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 | - | - |

Calculations for Scenario 2 - Indoor spot application in crack & crevice

| **Resulting local emission to relevant environmental compartments – Industrial use (standard houses and large buildings)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 6.86 × 10-5 | - |
| Air | 2.31 x 10-5 | - |

| **Resulting local emission to relevant environmental compartments – Private use (standard houses)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 5.96 x 10-5 | - |
| Air | 1.72 x 10-5 | - |

##### Scenario 3 - Indoor barrier crack and crevice treatment

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

This scenario cover uses of the product by trained professional, professional and non-professional users.

Table. Indoor barrier crack and crevice treatment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of active substance in the commercial product | 0.105 | - | FREE LAND 10 EC is a biocidal product with 10.5% of cypermethrin. |
| Surface or air space treatment | Surface treatment (area) | - | - |
| Selected treatment | Barrier, crack and crevice | - | - |
| Total area treated in a standard house | 20 | m2 | Default value for barrier crack and crevice treatment for a domestic house is 20 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.1, ENV 142). |
| Total area treated in a large building | 93 | m2 | Default value for barrier 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) | 5.9 | m2 | Default value, ENV TAB 2.1 (2019). |
| Wet cleaning zone in a large building (leading to releases to the STP) | 27 | 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 | 10 g | g | 10 g of a solution at 10.5% of active substance (1 L) have to be diluted in a final volume of 1 L of water. |
| 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) |
| Number of preparations per day, large building | 3 | - |
| 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 | 0.5 | g/m2 | Dose expressed as pure active ingredient is 50 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.5 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.5 g/m2 x 10.5/100 = 52.5 mg a.i./m2. |
| 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 FREE LAND 10 EC is twice per year per premises. This results in an indoor simultaneity factor for FREE LAND 10 EC 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 barrier crack and crevice treatment, 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 | Dry cleaning of treated surfaces | - | As RMM dry cleaning of treated surfaces have been assumed. |

Calculations for Scenario 3 - Indoor barrier crack and crevice treatment

| **Resulting local emission to relevant environmental compartments – Industrial use (standard houses and large buildings)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 3.38 x 10-4 | - |
| Air | 2.31 x 10-4 | - |

| **Resulting local emission to relevant environmental compartments – Private use (standard houses)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 2.60 x 10-4 | - |
| Air | 1.72 x 10-4 | - |

##### Scenario 4 - Targeted residual treatment around the building against mosquitoes

Exposure assessment for treatment around building against flying insects by trained professionals, professionals and non-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.

This scenario cover uses of the product by trained professional, professional and non-professional users.

**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. Targeted residual treatment around the building against mosquitoes - Urban area.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| **General** | | | |
| Fraction of the substance in commercial product | 0.105 | - | i.e. 10.5% w/w (TGAI) |
| 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 | 2 | g | 2 mL of product have to be diluted in 1 L of water. Density of water used for calculation. |
| Number of preparations per day, standard house | 7 | d-1 | Dose is 10 mg active substance/m2.  Product is diluted before use to 0.02%.  Quantity of product = 10 x 100/0.02 = 50 g/m2  125 m2 x 50 g/m2 = 6250 g  About 7 preparation of 1 L. |
| Number of preparations per day, large buildings | 32 | d-1 | Dose is 10 mg active substance/m2.  Product is diluted before use to 0.02%.  Quantity of product = 10 x 100/0.02 = 50 g/m2  625 m2 x 50 g/m2 = 31250 g  About 32 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 | 0.1 | g/m2 | Dose expressed as pure active ingredient is 10 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.1 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.1 g/m2 x 10.5/100 = 10.5 mg a.i./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 4 - Targeted residual treatment around the building against mosquitoes – Urban area

| **Resulting local emission to relevant environmental compartments – Private use (standard house)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 5.36 x 10-3 | - |

| **Resulting local emission to relevant environmental compartments –Industrial use (standard houses and large building)** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Water | 8.58 x 10-3 | - |

**Rural 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. Targeted residual treatment around the building against mosquitoes - Rural area.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | | **Remarks** |
| **General** | | | | |
| Fraction of active substance in the commercial product | 0.105 | - | | FREE LAND 10 EC is a biocidal product with 10.5% w/w 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. |
| Solid-water partition coefficient | 1.73E+04 | m3/m3 | | Default value. |
| 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 | 0.1 | g/m2 | | Dose expressed as pure active ingredient is 10 mg a.i./m2. The amount of biocidal product per m2 (expressed as product before dilution) can be assumed 0.1 g/m2. Therefore, the amount of active substance expressed as technical grade active ingredient is 0.1 g/m2 x 10.5/100 = 10.5 mg a.i./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. |

Calculations for Scenario 4 - Targeted residual treatment around the building against mosquitoes – Rural area

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Local emission to soil, standard house | 0.00105 | - |
| Local emission to soil, large buildings | 0.00525 | - |

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|  |  |  |
| --- | --- | --- |
| **xxxxxxxxxx** | **xxxxxxxxxxxxxx** | **xxxx** |
| X | xx | xxxxxxxxxxxxxxxx |
| X | x | xxxxxxxxxxxxxxxx |
| X | x | xxxxxxxxxxxxxxxx |
| Xx | xxx | xxxxxxxxxxxxxxxx |
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| --- | --- | --- | --- |
| **Parameter** | **Description** | **Value** | **Unit** |
| xxx | Xxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxx  xxxxxxxxxxxxxxxxxx | Xxxxxxxxxxxxxxxx  xxxxxxxxxxx | - |
| xxx | Xxxxxxxxxxxxxxxxxxxxxxx  xxxxxxxxxxxxx | XXXXXXXXXXXXXXXX  XXXXXXXXX  XXXXXXXXXXXXXXXX  XXXXXXXXXXXX  XXXXXXXXXXXXXX  XX | xxxxxxxxxxx |
| Xxxxxxxxx  xxx | Xxxxxxxxxxxxxxxxxxxxxxxxx  xxxxxx | - | xxxxx |
| x | xxxxxxxxxxxxxxxxxxxxx | XXx | x |

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|  |  |  |  |
| --- | --- | --- | --- |
| **Distance (m)** | **Drift deposition (%)** | **PECwater, total (mg/L)**  **xxxxxxxxxxxxxxxxxx** | **PECwater, total (mg/L)**  **xxxxxxxxxxxxxxxxxxx** |
| X | Xx | xxxxxxx | xxxxxxx |
| X | X | xxxxxxx | xxxxxxx |
| X | x | xxxxxxx | xxxxxxx |
| Xx | xxx | xxxxxxxxx | xxxxxxxxx |
| Xx | Xxx | xxxxxxxxx | xxxxxxxxx |
| Xx | Xxx | xxxxxxxxx | xxxxxxxxx |
| xx | xxxx | xxxxxxxxx | xxxxxxxxx |

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(Eq. 2)

(Eq. 3)

Since *F*airsusp = 0 this equation reduces to

(Eq. 4)

(Eq. 5)

(Eq. 6)

(Eq. 7)

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| **Parameter** | **Description** | **Value** | **Unit** |
| --- | --- | --- | --- |
| *xxxxxxx* | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx | X | x |
| *xxxxxxxxx* | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx | xxx | Xxxxxx  ccccc |
| *xxxxxxx* | Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx  xxxxx | xxx | Xxxxxx |
| *xxxxxxxxx* | xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx | xxx | Xxxxxx  c |
| *K*air-water | air-water partition coefficient | - | - |
| *K*oc | organic carbon normalised partition coefficient | 575000 | L kg-1 |
| *K*psusp | partition coefficient between suspended matter and water | 0.1 × 575000 = 57500 | L kg-1 |
| *K*susp-water | suspended matter-water partition coefficient | 14375.9 | m3 m-3 |
| *PEC*sediment, dw | predicted environmental concentration in dry sediment | Not calculated at this stage. | mg kgdw-1 |
| *PEC*sediment, ww | predicted environmental concentration in wet sediment | - | mg kgww-1 |
| *R* | gas constant | 8.314 | Pa m3 mol-1 K-1 |
| *RHO*solid | density of the solid phase | 2500 | kgsolid msolid-3 |
| *RHO*susp | density of (wet) suspended matter | 1150 | kgww m-3 |
| *SUSP*water | concentration of suspended matter (dry weight) | 15 | mg L-1 |
| 1000 | conversion factor from m3 to L | - | L m-3 |

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|  |  |  |  |
| --- | --- | --- | --- |
| **Distance (m)** | **Drift deposition (%)** | **PECwater, diss (µg/L)**  **Xxxxxxxxxxx**  **xxxxx** | **PECwater, diss (µg/L)**  **Xxxxxxxxxxx**  **xxxxx** |
| X | Xx | xxxxx | xxxxx |
| X | X | xxxxx | xxxxx |
| X | x | xxxxx | xxxxx |
| Xx | xxx | Xxxxxxx | xxxxxxx |
| Xx | xxx | xxxxxxx | xxxxxxx |
| Xx | xxx | Xxxxxxx | Xxxxxxx |
| xx | xxxx | Xxxxxxx | Xxxxxxx |

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|  |  |  |  |
| --- | --- | --- | --- |
| **Distance (m)** | **Drift deposition (%)** | **PECsediment, ww (mg/kgwwt-1)**  **Xxxxxxxxxxx**  **xxxxx** | **PECsediment, ww (mg/kgwwt-1)**  **Xxxxxxxxxxx**  **xxxxx** |
| X | xx | xxxxx | xxxxx |
| X | X | xxxxx | xxxxx |
| X | X | xxxxx | xxxxx |
| xx | xxx | xxxxx | xxxxx |
| Xx | Xxx | Xxxxxxx | Xxxxxxx |
| Xx | Xxx | Xxxxxxx | Xxxxxxx |
| xx | Xxxx | Xxxxxxx | Xxxxxxx |

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where

MAF = Multiple Application Factor

n = number of applications

k = degradation rate constant = ln2/DT50 [d-1]

i = application interval [d]

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(Eq. 9)

with

PECsoil = Predicted Environmental Concentration in soil after one application [mg/kgdwt]

Dose = application rate [kg a.s./ha]

CONVkg🡪mg = conversion factor for kg to mg [xxxxxxx mg/kg]

Finterception = interception value [-]

RHOsoil = dry soil bulk density [xxxxx kg/m3]

Depth = soil depth [xxxx m]

CONVha🡪m2 = conversion factor from hectare to m2 [xxxxxx m2/ha]

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where

MAF = Multiple Application Factor

n = number of applications

k = degradation rate constant = ln2/DT50 [d-1]

I = application interval [d]

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(Eq. 9)

with

PECsoil = Predicted Environmental Concentration in soil after one application [mg/kgdwt]

Dose = application rate [kg a.s./ha]

CONVkg🡪mg = conversion factor for kg to mg [xxxxxxxxxxx mg/kg]

Finterception = interception value [-]

RHOsoil = dry soil bulk density [xxxxxx kg/m3]

Depth = soil depth [xxxx m]

CONVha🡪m2 = conversion factor from hectare to m2 [xxxxx0 m2/ha]

PECsoil = xxxxxxxxxxxx kg a.s./ha x xxxxxxxxx mg/kg x (xxxxx) / xxxx kg/m3 x xxxx m x xxxxxxxm2/ha = xxxxxxxxx mg/kgdwt

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(Eq. 9)

with

PECsoil = Predicted Environmental Concentration in soil after one application [mg/kgdwt]

Dose = application rate [kg a.s./ha]

CONVkg🡪mg = conversion factor for kg to mg [xxxxxxx mg/kg]

Finterception = interception value [-]

RHOsoil = dry soil bulk density [xxxx kg/m3]

Depth = soil depth [xxxxx m]

CONVha🡪m2 = conversion factor from hectare to m2 [xxxxx m2/ha]

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| --- | --- | --- |
|  | PEC soil (mg/kgdwt) | PEClocal,soil,porew  (mg/l) |
| Xxxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxx  Xxxxxxxxxxx  xxxxxxxxxxxxxxxxx | xxxxxxxxx | xxxxxxxxx |
| Xxxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxx | xxxxxxxxx | xxxxxxxxx |
| Xxxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxx | xxxxxxxxx | xxxxxxxxx |
| Xxxxxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxxxxxxx  Xxxxxxxxxxxxxxxxxxx | xxxxxxxxx | xxxxxxxxx |

##### Scenario 6 – Ant nest eradication

As reported in ESD PT18 the term of “spot application” is meant to cover the variety of situations in which local applications of insecticide are used on insect pathway or nest to control undesirable organisms.

The scenario “spot application” cover the use of powders in ant nest; however, it is deemed applicable even for liquid spray.

Input parameters for calculating the local emission.

|  |  |  |  |
| --- | --- | --- | --- |
| Input parameters for calculating the local emission | | | |
| Input | Value | Unit | Remarks |
| Quantity of commercial product applied per nest (Qprod) | 25 | g | 25 g/nest. |
| Fraction of active ingredient in the commercial product.  FAI | 0.000525 | - | Real fraction of active ingredient in commercial product is 0.105 (i.e. 10.5 % w/w); however, since the product is diluted before use to 0.05% (i.e. 0.0525% technical grade active ingredient), this value has been used as input, since in the previous line (i.e. 25 g) has been inserted the quantity of diluted product used in efficacy study. |
| Type of spot application | Liquid spray | - | - |
| Fraction emitted to soil during application | 0.9 | - | Default value ESD PT18 (p. 147) |
| Number of application sites | 1 | - | Default value ESD PT18 - (p. 147) |
| Number of applications during a campaign | 1 | - | Default value ESD PT18 - (p. 147) |
| Area treated - Single point of release | 0.250 | m2 | Default value ESD PT18 - (p. 148) |
| Depth of exposed soil | 0.5 | m | Default value ESD PT18 (p. 148) |
| Volume of soil exposed | 0.125 | m3 | Default value ESD PT18 (p. 148) |
| Bulk density of soil | 1700 | kgww/m3 | Default value ESD PT18 (p. 148) |
| Density of solid phase | 2500 | kg/m3 | [[[3]](#endnote-1) p.53] |
| Volume fraction of solids in soil | 0.6 | m3 /m3 | [8 p.53] |
| Soil-water partition coefficient | 17300 | m3 /m3 | Calculated with EUSES. |

Calculations for Scenario 6 - Ant nest eradication

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg]** | **Remarks** |
| Soil | 1.18 x 10-5 | - |

***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 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 |

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Fresh-water** | **Freshwater sediment** | **STP** | **Air\*** | **Soil** | **Ground-water** | **Other** |
| Scenario 1 | Yes | Yes | Yes | Yes | Yes | yes | No |
| Scenario 2 | Yes | Yes | Yes | Yes | Yes | yes | No |
| Scenario 3 | Yes | Yes | Yes | Yes | Yes | yes | No |
| Scenario 4  (urban areas) | Yes | Yes | Yes | Yes | Yes | yes | No |
| Scenario 4 (rural areas) | No | No | No | No | Yes | Yes | No |
| Scenario 5 | Yes | Yes | No | No | Yes | Yes | No |
| Scenario 6 | No | No | No | No | Yes | Yes | No |

\*negligible emissions

***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 PECs values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PECs values** | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/m3] |
| Scenario 1 –industrial use-TIER 1 | 2.47 x 10-5 | 1.33 x 10-6 | 0.017 | 5.68 x 10-4 | 1.33 x 10-8 | 3.52 x 10-11 |
| Scenario 1 private use– TIER 1 | 1.87 x 10-5 | 1.00 x 10-6 | 0.013 | 4.30 x 10-4 | 1.01 x 10-8 | 2.61 x 10-11 |
| Scenario 1 –industrial use -TIER 2 | 4.20 x 10-6 | 2.25 x 10-7 | 0.00282 | 9.64 x 10-5 | 2.25 x 10-9 | 3.52 x 10-11 |
| Scenario 1 private use – TIER 2 | 3.48 x 10-6 | 1.87 x 10-7 | 0.00233 | 7.98 x 10-5 | 1.87 x 10-9 | 2.61 x 10-11 |
| Scenario 2 –industrial use | 2.87 x 10-6 | 1.54 x 10-7 | 0.00192 | 6.58 × 10-5 | 1.54 x 10-9 | 3.52 x 10-11 |
| Scenario 2 –private use | 2.49 x 10-6 | 1.34 x 10-7 | 0.00167 | 5.72 x 10-5 | 1.34 x 10-9 | 2.61 x 10-11 |
| Scenario 3 –industrial use | 1.41 x 10-5 | 7.59 x 10-7 | 0.00949 | 3.25 x 10-4 | 7.60 x 10-9 | 3.52 x 10-10 |
| Scenario 3 - private use | 1.09 x 10-5 | 5.83 x 10-7 | 0.00729 | 2.49x 10-4 | 5.84 x 10-9 | 2.61 x 10-10 |
| Scenario 4 – Urban area –industrial use | 3.58 x 10-4 | 1.92 x 10-5 | 0.241 | 8.23 x 10-3 | 1.93 x 10-7 | 1.07 x 10-11 |
| Scenario 4 – Urban area –private use | 2.24 x 10-4 | 1.20 x 10-5 | 0.150 | 5.14 x 10-3 | 1.2 x 10-7 | 6.66 x 10-12 |
| Scenario 4 – Rural area - houses | not relevant | not relevant | not relevant | 0.048 | 4.68 x 10-6 | not relevant |
| Scenario 4 – Rural area – large buildings | not relevant | not relevant | not relevant | 0.049 | 4.83 x 10-6 | not relevant |
| Xxxxxxx  – application dose xxxxxxxx  xxxx  Drift deposition (%) & distance (m)  Xxxxx  xxxxx  xxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxxx | not relevant | xxxxxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxxxx  xxxxxxxxxx  xxxxxxxxxx  xxxxxxxxxxx | xxxxxx  xxxxxx  xxxxxx  xxxxxx  xxxxxxx  xxxxxx  xxxxxxxx | xxxxxxxx xx  xxxxxxxxxx  xxxxxxxx xx  xxxxxxxxxx | xxxxxxxx xx  xxxxxxxxxx  xxxxxxxx xx  xxxxxxxxxx | not relevant |
| Xxxxxxx  – application dose xxxxxxxx  xxxx  Drift deposition (%) & distance (m)  Xxxxx  xxxxx  xxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxxx | not relevant | xxxxxxxx  xxxxxxxx  xxxxxxxx  xxxxxxxxxx  xxxxxxxxxx  xxxxxxxxxx  xxxxxxxxxxx | xxxxxx  xxxxxx  xxxxxx  xxxxxx  xxxxxxx  xxxxxx  xxxxxxxx | xxxxxxxx xx  xxxxxxxxxx  xxxxxxxx xx  xxxxxxxxxx | xxxxxxxx xx  xxxxxxxxxx  xxxxxxxx xx  xxxxxxxxxx | not relevant |
| Scenario 6 – Ant nest eradication | not relevant | not relevant | not relevant | 0.056 | 5.48 x 10-6 | not relevant |

**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 6 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 scenario 1-Tier 2 for and scenario 6 for soil.

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Surface water** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsw (mg/L) |
| Cypermethrin | - | 416.3 | 2.25 × 10-7 |
| 3-PBA | 21 | 214.2 | 2.43 × 10-8 |
| DCVC | 38 | 209.1 | 4.29 × 10-8 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Sediment of surface water** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsed (mg/kg ww) |
| Cypermethrin | - | 416.3 | 0.00282 |
| 3-PBA | 29 | 214.2 | 4.21 × 10-4 |
| DCVC | 20 | 209.1 | 2.83 × 10-4 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Soil** | | | |
| Parent / metabolite | Max % AR | Molar mass | PECsoil (mg/kgww) |
| Cypermethrin | - | 416.3 | 5.60 × 10-2 |
| 3-PBA | 10.2 | 214.2 | 2.94 × 10-3 |
| DCVC | 17.5 | 209.1 | 4.92 × 10-3 |

Local concentrations of metabolites in groundwater were calculated based on TAB ENV10, according to the equation:

For the groundwater exposure of metabolites, the following parameters were used as inputs:

|  |  |
| --- | --- |
| **Parameter** | **Values** |
| Henry’s law constant (Pa m3 mole-1) \* | 3-PBA: 2.4 x 10-4 at 25°C |
| DCVC : 5.16 x 10-2 at 25°C |
| Koc\* | 3-PBA: 217.8 |
| DCVC: 59.47 |
| Kair-water | 3-PBA: 4.85 x 10-8 |
| DCVC : 1.04 x 10-5 |
| Ksoil-water | 3-PBA: 6.7 |
| DCVC: 2.0 |
| RHOsoil (kg/m3) | 1700 |

\*Input parameters have been estimated with EPIWEB4.1 tool, considering the smiles coding for the relevant compounds related to the CAS number.

|  |  |  |
| --- | --- | --- |
| **Groundwater** | | |
| **Metabolite** | **PECsoil [mg/kg]** | **PECgroundwater [mg/l]** |
| 3-PBA | 2.94 × 10-3 | 7.42× 10-4 |
| DCVC | 4.92× 10-3 | 4.22× 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 FREE LAND 10 EC 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 – Scenario 4 – Urban area – industrial use (worst case)*

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Definition** | **Value** |
| Local concentration of Cypermethrin in surface water [mg/L] | Clocal water | 1.92 x 10-5 |
| 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 | 8.01 x 10-2 |

Calculation for PECoral, predator as an indicator for possible secondary poisoning, resulted in a value of 0.0801 mg/kg.

PEC/PNEC ratio for fish eating birds

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **PECoral predator (mg/kg)** | **PNECoral (mg/kg)** | **PEC/PNEC** |
| Biota | 0.0801 | 33.3 | 2.40 x 10-3 |

PEC/PNEC ratio for fish eating mammals

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **PECoral predator (mg/kg)** | **PNECoral (mg/kg)** | **PEC/PNEC** |
| Biota | 0.0801 | 3.3 | 2.43 x 10-2 |

*Conclusion*

Comparing the PECoral predator with the respective PNECs, PEC/PNEC ratios are below one for birds and mammals, indicating no unacceptable risk for fish-eating birds and mammals.

**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.

**Cyermethrin**

All calculations below were performed only for Scenario 6 since it represent the worst case in term of PECS:

PEC porewater = 5.48 x 10-6 mg/l

PEC soil = 5.60 x 10-2 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 = 5.48 x 10-6 mg/l (EUSES 2.2.0)

Csoil = 5.60 x 10-2 mg/kg wwt corresponding to local PEC in agricultural 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 = 2.42 x 10-2 mg/kg wet earthworm (Cearthworm)

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 = 2.42 x 10-2 /33.3 = 7.27 x 10-4

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 = 2.42 x 10-2 /3.3 = 7.34 x 10-3

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Concentration** | **PECoral predator** | **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** |
| **Scenario: Application, Aquatic**  **compartment** | **PECsurface water**  **(mg/L)** | **(mg/kg wet**  **fish)** |  |  |
| Cypermethrin | 1.92 x 10-5 | 8.01 x 10-2 | 2.40 x 10-3 | 2.43 x 10-2 |
| **Scenario: Application, Terrestrial**  **compartment** | **PECporewater**  **(mg/L)** | **(mg/kg wet**  **earthworm)** |  |  |
| Cypermethrin | 5.48 x 10-6 | 2.42 x 10-2 | 7.27 x 10-4 | 7.34 x 10-3 |

Conclusion

Predicted concentrations of FREE LAND 10 EC in the environment from use in PT18 suggests no unacceptable risk of toxicity to birds and mammals from Cypermethrin from secondary poisoning via the food chain.

All PECoral,predator/PNECoral ratios determined indicate that there is no unacceptable risk of secondary poisoning following the appropriate use of the product.

#### 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** |
| Scenario 1 – TIER 1 - private use | 1.87 x 10-5 | 1.63 | 1.15 x 10-5 |
| Scenario 1 – TIER 1 - industrial use | 2.47 x 10-5 | 1.52 x 10-5 |
| Scenario 1 – TIER 2 - private use | 3.48 x 10-6 | 2.13 x 10-6 |
| Scenario 1 – TIER 2 - industrial use | 4.20 x 10-6 | 2.58 x 10-6 |
| Scenario 2 - private use | 2.49 x 10-6 | 1.53 x 10-6 |
| Scenario 2 –industrial use | 2.87 x 10-6 | 1.76 x 10-6 |
| Scenario 3 - private use | 1.09 x 10-5 | 6.69 x 10-6 |
| Scenario 3 - industrial use | 1.41 x 10-5 | 8.65 x 10-6 |
| Scenario 4 – Urban area –industrial use | 3.58 x 10-4 | 2.20 x 10-4 |
| Scenario 4 – Urban area - private use | 2.24 x 10-4 | 1.37 x 10-4 |
| Scenario 4 – Rural area - houses | not relevant | - |
| Scenario 4 – Rural area – large buildings | not relevant | - |
| Scenario 6 – Ant nest eradication | not relevant | - |

Scenario 3 is related to Intended Uses# 5 (Indoor barrier application in crack & crevice, professional use) and #6 (Indoor barrier application in crack & crevice, non-professional use), which were included in the original dossier but they were not further supported by the applicant. Scenario 3 is presented for completeness reasons.

**Conclusion:**

As a result of the risk assessment performed there is no risk for STP when the product FREE LAND 10 EC is used according the instructions of use.

***Aquatic compartment***

**Surface water**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECwater**  **[mg/l]** | **PNECwater [mg/l]** | **PEC/PNEC** |
| Scenario 1 – TIER 1 - private use | 1.00 x 10-6 | 4.00 x 10-6 | 2.50 x 10-1 |
| Scenario 1 – TIER 1 - industrial use | 1.33 x 10-6 | 3.33 x 10-1 |
| Scenario 1 – TIER 2 - private use | 1.87 x 10-7 | 4.68 x 10-2 |
| Scenario 1 – TIER 2 - industrial use | 2.25 x 10-7 | 5.63 x 10-2 |
| Scenario 2 - private use | 1.34 x 10-7 | 3.35 x 10-2 |
| Scenario 2 –industrial use | 1.54 x 10-7 | 3.85 x 10-2 |
| Scenario 3 - private use | 5.83 x 10-7 | 1.46 x 10-1 |
| Scenario 3 –industrial use | 7.59 x 10-7 | 1.90 x 10-1 |
| Scenario 4 – Urban area –industrial use | 1.92 x 10-5 | **4.80** |
| Scenario 4 – Urban area - private use | 1.20 x 10-5 | **3.00** |
| Scenario 4 – Rural area - houses | not relevant | - |
| Scenario 4 – Rural area – large buildings | not relevant | - |
| Scenario 6 – Ant nest eradication | not relevant | - |

**Sediment of surface water**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECsed**  **[mg/kgwwt]** | **PNECsed** [mg/kgwwt] | **PEC/PNEC x 10 (\*)** |
| Scenario 1 – TIER 1 - private use | 1.30 x 10-2 | 0.050 | **2.6** |
| Scenario 1 – TIER 1 - industrial use | 1.70 x 10-2 | **3.4** |
| Scenario 1 – TIER 2 - private use | 2.33 x 10-3 | 4.66 x 10-1 |
| Scenario 1 – TIER 2 - industrial use | 2.82 x 10-3 | 5.64 x 10-1 |
| Scenario 2 - private use | 1.67 x 10-3 | 3.34 x 10-1 |
| Scenario 2 –industrial use | 1.92 x 10-3 | 3.84 x 10-1 |
| Scenario 3 - private use | 7.29 x 10-3 | 1.46 |
| Scenario 3 – industrial use | 9.49 x 10-3 | 1.90 |
| Scenario 4 – Urban area – industrial use | 0.241 | **48.2** |
| Scenario 4 – Urban area - private use | 0.150 |  | **30.0** |
| Scenario 4 – Rural area - houses | not relevant |  | - |
| Scenario 4 – Rural area – large buildings | not relevant | - |
| Scenario 6 – Ant nest eradication | not relevant | - |

(\*) 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.

Scenario 3 is related to Intended Uses# 5 (Indoor barrier application in crack & crevice, professional use) and #6 (Indoor barrier application in crack & crevice, non-professional use), which were included in the original dossier but they were not further supported by the applicant. Scenario 3 is presented for completeness reasons.

**Conclusion:**

As a result of the risk assessment performed for aquatic compartment, there is an unacceptable risk for sediment drewlling organisms for Scenario 1, Tier 1 (with Fraction emitted to treated surfaces during application = 0.85 according to exposure assessment). Furthermore, there is an unacceptable risk for sediment drewlling organisms and aquatic organisms in Scenario 4 when the product is used in urban areas. Therefore, these uses are **NOT AUTHORISED.**

***Terrestrial compartment***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECsoil**  [mg/kgwwt] | **PNECsoil [mg/kgwwt]** | **PEC/PNEC** |
| Scenario 1 – TIER 1 private use | 4.30 x 10-4 | 0.0708 | 6.07 x 10-3 |
| Scenario 1 – TIER 1 industrial use | 5.68 x 10-4 | 8.02 x 10-3 |
| Scenario 1 – TIER 2 private use | 7.98 x 10-5 | 1.13 x 10-3 |
| Scenario 1 – TIER 2 industrial use | 9.64 x 10-5 | 1.36 x 10-3 |
| Scenario 2 - private use | 5.72 x 10-5 | 8.08 x 10-4 |
| Scenario 2 –industrial use | 6.58 x 10-5 | 9.29 x 10-4 |
| Scenario 3 - private use | 2.49x 10-4 | 3.52 x 10-3 |
| Scenario 3 –industrial use | 3.25 x 10-4 | 4.59 x 10-3 |
| Scenario 4 – Urban area –industrial use | 8.23 x 10-3 | 1.16 x 10-1 |
| Scenario 4 – Urban area - private use | 5.14 x 10-3 | 7.26 x 10-2 |
| Scenario 4 – Rural area - houses | 0.048 | 6.78 x 10-1 |
| Scenario 4 – Rural area – large buildings | 0.049 | 6.92 x 10-1 |
| Scenario 6 – Ant nest eradication | 0.056 | 7.91 x 10-1 |

Scenario 3 is related to Intended Uses# 5 (Indoor barrier application in crack & crevice, professional use) and #6 (Indoor barrier application in crack & crevice, non-professional use), which were included in the original dossier but they were not further supported by the applicant. Scenario 3 is presented for completeness reasons.

**Conclusion:**

As a result of the risk assessment performed for terrestrial compartment there are no risks when the product FREE LAND 10 EC is used according to instructions of use.

***Groundwater***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **PECGW**  **[mg/l]** | **EU trigger value (mg/L)** | **Acceptable** |
| Scenario 1 – TIER 1 private use | 1.01 x 10-8 | 0.0001 | yes |
| Scenario 1 – TIER 1 industrial use | 1.33 x 10-8 | yes |
| Scenario 1 – TIER 2 private use | 1.87 x 10-9 | yes |
| Scenario 1 – TIER 2 industrial use | 2.25 x 10-9 | yes |
| Scenario 2 - private use | 1.34 x 10-9 | yes |
| Scenario 2 –industrial use | 1.54 x 10-9 | yes |
| Scenario 3 - private use | 5.84 x 10-9 | yes |
| Scenario 3 –industrial use | 7.60 x 10-9 | yes |
| Scenario 4 – Urban area –industrial use | 1.93 x 10-7 | yes |
| Scenario 4 – Urban area - private use | 1.2 x 10-7 |  | yes |
|  |  |  |  |
| Scenario 4 – Rural area - houses | 4.68 x 10-6 | yes |
| Scenario 4 – Rural area – large buildings | 4.83 x 10-6 | yes |
| xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx  xxxxxxxxxx | Xxxxxxxxxxxxx  xxxxxx  Xxxxxxxxxxxxx  xxxxxx | xxx |
| xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx  xxxxxxxxxx | Xxxxxxxxxxxxx  xxxxxx  Xxxxxxxxxxxxx  xxxxxxxxxxx | xxx |
| Scenario 6 – Ant nest eradication | 5.48 x 10-6 | yes |

***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 FREE LAND 10 EC primary poisoning assessment for birds or mammals is not relevant.

Secondary poisoning

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Concentration** | **PECoral predator** | **PEC/PNEC**  **birds** | **PEC/PNEC**  **mammals** |
| **Scenario: Application, Aquatic**  **compartment** | **PECsurface water**  **(mg/L)** | **(mg/kg wet**  **fish)** |  |  |
| Cypermethrin | 1.92 x 10-5 | 8.01 x 10-2 | 2.40 x 10-3 | 2.43 x 10-2 |
| **Scenario: Application, Terrestrial**  **compartment** | **PECporewater**  **(mg/L)** | **(mg/kg wet**  **earthworm)** |  |  |
| Cypermethrin | 5.48 x 10-6 | 2.42 x 10-2 | 7.27 x 10-4 | 7.34 x 10-3 |

Conclusion

Predicted concentrations of FREE LAND 10 EC in the environment from use in PT18 suggests no unacceptable risk of toxicity to birds and mammals from Cypermethrin from secondary poisoning via the food chain.

All PECoral,predator/PNECoral ratios determined indicate that there is no unacceptable risk of secondary poisoning following the appropriate use of the product FREE LAND 10 EC.

Risk characterisation for metabolites

*Metabolites of Cypermethrin in surfacewater*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC aquatic (mg/l) | PNEC aquatic (mg/l) | PEC/PNEC |
| 3-PBA | 2.43 × 10-8 | > 0.010 | 2.43 × 10-6 |
| DCVC | 4.29 × 10-8 | 4.00 × 10-6 (\*) | 1.07 × 10-2 |

(\*) 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.

*Metabolites of Cypermethrin in sediment*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC (mg/kg wwt) | PNEC (mg/kg wwt) | PEC/PNEC |
| 3-PBA | 4.21 × 10-4 | 0.009 | 4.68 × 10-2 |
| DCVC | 2.83 × 10-4 | 0.005 (\*) | 5.67 × 10-2 |

(\*) 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.

*Metabolites of Cypermethrin in soil*

|  |  |  |  |
| --- | --- | --- | --- |
|  | PEC soil (mg/kg ww soil) | PNEC soil (mg/kg ww soil) | PEC/PNEC |
| 3-PBA | 2.94 × 10-3 | 1.44 | 2.04 × 10-3 |
| DCVC | 4.92 × 10-3 | 0.0708 (\*) | 6.95 × 10-2 |

(\*) 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.

*Metabolites of Cypermethrin in groundwater*

Groundwater concentrations of Cypermethrin metabolites are above the EU trigger value of 0.1 µg/L. A refinement of PEClocalgrw.metabolite was perfomed using FOCUS PEARL as indicated in ENV 10.

As presented in the table below, groundwater concentrations of Cypermethrin metabolites are above 0.1 µg/L at Scenarios 4 and 6 where the relevant receiving compartments are soil and groundwater.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Groundwater** | | | | |
| **Scenario** | **3-PBA** | | **DCVC** | |
| **PECsoil [mg/kg]** | **PECgroundwater [μg/l]** | **PECsoil [mg/kg]** | **PECgroundwater [μg/l]** |
| Scenario 1-Industrial use- Tier 2 | 5.06E-06 | 1.28E-03 | 8.47E-06 | 7.23E-03 |
| Scenario 1-Private use- Tier 2 | 4.19E-06 | 1.06E-03 | 7.01E-06 | 6.01E-03 |
| Scenario 2-Industrial use | 3.45E-06 | 8.72E-04 | 5.78E-06 | 4.96E-03 |
| Scenario 2-Private use | 3.00E-06 | 7.58E-04 | 5.03E-06 | 4.31E-03 |
| Scenario 4-rural area-houses | 2.52E-03 | **0.64** | 4.22E-03 | **3.6** |
| Scenario 4-rural area-large buildings | 2.57E-03 | **0.65** | 4.31E-03 | **3.7** |
| Scenario 6 | 2.94E-03 | **0.74** | 4.92E-03 | **4.2** |

FOCUS PEARL calculations

Emission to groundwater has been assessed using the latest version of FOCUS PEARL (version 5.5.5.) by applying the metabolite’s physical-chemical parameters as presented in the table below.

The application rate (kg/ha) of the active substance was calculated for both scenarios 4 and 6 considering application from professional users as worst-case (domestic premises and large buildings). Then the application rate (kg/ha) of each metabolite was calculated from the app.rate of the a.s. multiplied by the ratio of molecular weights.

For scenario 6, application of the product to one nest and 16 domestic premises per hectare (ENV 98) and 3 large buildings per hectare (area of a large building is 3280 m2 according to the ESD) were considered. For scenario 4, application of the product around building with a band of 1m height and 2 applications per year to 16 domestic premises and 3 large buildings per hectare were considered.

As presented in the table below, higher application rates occur with scenario 4 and therefore were used as worst-case inputs for grounwater modelling.

|  |  |  |  |
| --- | --- | --- | --- |
| **Application rate (kg/ha)** | | | |
| **Scenario** | **Cypermethrin** | **3-PBA** | **DCVC** |
| Scenario 4-rural area-large buildings | 0.033\* | 0.01698 | 0.01658 |
| Scenario 6 | 0.00025 | 0.000129 | 0.000126 |

\*It should be highlighted that this is considered an unrealistic worst-case since it is aggregated application dose.

Since scenario 4 concerns outdoor application to rural areas (direct emission to soil), the selection of application schemes (timelines and crops) was based on ENV 157-groundwater assessment for outdoor applications. FOCUS PEARL was perfomed for all nine FOCUS scenarios for grass/alfalfa crop considering ten applications evenly distributed over the year. Crop interception was set to zero. Input parameters are presented in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters for groundwater modelling** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 214.22 | g/mol | 3-PBA |
| 209.07 | g/mol | DCVC |
| Water solubility (at 25°C) | 16.91 | mg/l | 3-PBA |
| 127.6 | mg/l | DCVC |
| Molar enthalpy of dissolution | 27 | kJ/mol | Default |
| Vapour pressure (at 25°C) | 0.000421 | Pa | 3-PBA |
| 0.26 | Pa | DCVC |
| Molar enthalpy of vaporisation | 95 | kJ/mol | Default |
| Diffusion coefficient in water | 4.3E-05 | m2/d | Default |
| Gas diffusion coefficient | 0.43 | m2/d | Default |
| Reference temperature to degradation, vaporization and dissolution | 20 | °C | Default |
| Exponent for the effect of liquid (degradation moisture relationship) | 0.7 | - | Default |
| Koc | 217.8 | l/kg | 3-PBA |
| 59.47 | l/kg | DCVC |
| DT50 for degradation in soil\* | 15.8 | days (at 20ºC) | 3-PBA |
| 30.9 | days (at 20ºC) | DCVC |
| Arrhenius activation energy | 65.4 | kJ/mol | Default |
| Freundlich exponent (1/n) | 0.9 | - |  |
| Application type | To the soil surface | - |  |
| Crop type | Grass/alfalfa | - |  |
| Application time | 10.01  15.02  24.03  29.04  05.06  11.07  17.08  22.09  29.10  04.12 | - |  |
| Application rate | 0.01698 | Kg/ha | 3-PBA |
|  | 0.01658 | Kg/ha | DCVC |
| \* The degradation rate value is required at 20ºC for modelling purposes (the model applies temperature correction as part of its internal routines). DT50 values reported at BCP-35 Harmonised list of endpoints for RA were used. | | | |

The predicted 80th percentile concentration for Cypermethrin metabolites for each scenario calculated considering application at 04.12 (worst-case values) are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **PECgroundwater - Output (FOCUS PEARL [vs 5.5.5]) in µg/L** | | |
|  | Application time: 04.12 | |
| **Location** | 3-PBA | DCVC |
| **Chateaudun** | 0 | 0.012366 |
| **Hamburg** | 0 | 0.032926 |
| **Jokioinen** | 0 | 0.008115 |
| **Kremsmunster** | 0 | 0.012255 |
| **Okehampton** | 0 | 0.042777 |
| **Piacenza** | 0 | 0.025530 |
| **Porto** | 0 | 0.030864 |
| **Sevilla** | 0 | 0.001050 |
| **Thiva** | 0 | 0.002189 |

The results of the higher tier modelling indicate negligible groundwater concentrations in all FOCUS scenarios. All groundwater concentrations of Cypermethrin metabolites are below the EU trigger value of 0.1 µg/L.

***Mixture toxicity***

Mixture toxicity is not relevant for FREE LAND 10 EC.

***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, or it is deemed unlikely, 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.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| As a result of the environmental risk assessment for all relevant environmental compartments (STP, terrestrial, aquatic), Scenario 4 – Targeted residual treatment around the building against mosquitoes when the product is used in urban areas, posed an unacceptable risk to aquatic and sediment drewlling organisms. Thus, this use is **NOT AUTHORISED.**  The risk of the remaining uses is acceptable when FREE LAND 10 EC is used according to indication of use.  [Note: Risk for the environment has been identified for sediment drewlling organisms for Scenario 1 – TIER 1 (private / industrial use)]  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 FREE LAND 10 EC.  xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx |

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

Open and handle containers with care, avoid contact with skin and eyes. Ensure the work area is well ventilated. Do not eat, drink or smoke or apply cosmetics in work area. Always wash after handling product.

Avoid contamination of drains or bodies of water.

Store upright in the original tightly closed container. Store in a cool, well ventilated, bunded area, away from heat and ignition sources such as smoking and open flames. Keep away from direct sunlight and protect against frost. Store away from strong oxidizing agents.

Store away from food and animal feed.

UN number

|  |  |
| --- | --- |
| ADR / RID, IMDG,  IATA: | 3082 |
| ADR / RID: | In accordance with Special Provision 375, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to ADR provisions. |
| IMDG: | In accordance with Section  2.10.2.7 of IMDG Code, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to IMDG Code  provisions. |
| IATA: | In accordance with SP A197, this product, when is packed in receptacles of a capacity ≤ 5Kg or 5L, is not submitted to IATA dangerous goods  regulations. |

UN proper shipping name

|  |  |
| --- | --- |
| ADR / RID: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Cypermethrin) |
| IMDG: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Cypermethrin) |
| IATA: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Cypermethrin) |

Transport hazard class(es)

|  |  |  |  |
| --- | --- | --- | --- |
| ADR / RID: | Class: 9 | Label: 9 |  |
| IMDG: | Class: 9 | Label: 9 |  |
| IATA: | Class: 9 | Label: 9 |  |

Packing group

|  |  |
| --- | --- |
| ADR / RID, IMDG, IATA: | III |

Environmental hazards

|  |  |  |
| --- | --- | --- |
| ADR / RID: | Environmentally Hazardous |  |
| IMDG: | Marine Pollutant |  |
| IATA: | Environmentally Hazardous |  |

Special precautions for user

|  |  |  |  |
| --- | --- | --- | --- |
| ADR / RID: | HIN - Kemler: 90 | Limited  Quantities: 5 L | Tunnel  restriction code: (-) |
|  | Special Provision: - |  |  |
| IMDG: | EMS: F-A, S-F | Limited  Quantities: 5 L |  |
| IATA: | Cargo: | Maximum  quantity: 450 L | Packaging  instructions: 964 |
|  | Pass.: | Maximum  quantity: 450 L | Packaging  instructions: 964 |
|  | Special Instructions: | A97, A158,  A197 |  |

Suitable Extinguishing Media

DO NOT use water stream. : Use class B extinguishing devices: CO2, foam, chemical powder, sand, earth, nebulized water

**In case of fire, nature of reaction products, combustion gases, etc.**

*Specific Hazards*

Carbon monoxide might be formed in fire

*Fire fighting advice*

Individual protection devices equipped with oxygen respirator. Use water stream only to cool surfaces of containers exposed to fire.

Use water spray or fog, dry chemical carbon dioxide.

Do not use water jets.

Use appropriate containment equipment to avoid environmental contaminations especially watercourses and drainage systems.

Smoke from fires is toxic, take precautions to protect personnel from exposure. Wear positive breathing apparatus.

**Emergency measures in case of an accident**

Direct or indirect effects: Pyrethroids, like Cypermethrin, may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

First aid instructions are detailed below.

*If inhaled:*

Remove affected person to fresh air and apply artificial respiration if required. Seek medical advice is specific symptomatic reactions are observed.

*If swallowed:*

Immediately call a poison control centre or doctor for treatment advice. Do not give any liquid to the person. Do not induce vomiting. If vomiting occurs spontaneously, keep head below hips to prevent aspiration. Do not give anything by mouth to an unconscious person.

*If on skin or hair:*

Remove contaminated clothing and wash with soap and running water. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice if irritation persists.

*If in eyes:*

Remove contact lenses, if present. Hold eyelids apart and flush eye continuously with running water for 15 – 20 minutes. Call a poison control centre or doctor for treatment advice or if irritation persists.

In the event of a leak or spillage:

* Shut off the source of the leak if it is safe to do so

Immediate actions:

* Contain the product to avoid environmental contamination.
* Recover product where possible.

Clean up-actions:

* Absorb spillage in earth, sand or sawdust or other inert material.
* Place in appropriate metal or plastic containers.
* Seal the containers and label them.
* Remove the contaminated material to a safe location for subsequent disposal.

If contamination of drainage systems or watercourses is unavoidable, immediately inform the appropriate authorities.

**Possibility of destruction or decontamination following release in or on the following: air, water, including drinking water and soil**

Contamination of water may occur in the case of leakage at the manufacturing plant.

Should any contamination of water occur outside the plant, the contaminated water should be collected or contained with clean-up via suction and filtering.

If surface waters are contaminated, Cypermethrin will be durably bound to the sediment where it is susceptible to biotic and abiotic degradation. The buffer capacity of sediment can be enhanced by addition of organic matter. Sediments can also be dredged and removed to an approved dumping site.

If the product is spilled in soil, Cypermethrin will be durably bound to the soil where it is susceptible to biotic and abiotic degradation. Soil could also be collected and removed to an incineration plant or approved landfill site.

Prevent the product from flowing into sewers or contaminating surface waterways. Soak up spills with inert absorbent material. Contaminated waters should be isolated where possible to limit the extent of contamination. Expert advice should be sought to establish the degree of contamination and the feasibility of available treatment techniques such as flocculation, carbon adsorption, etc. Where relevant the appropriate authorities should be notified. Wear appropriate personal protective equipment during any cleanup operations.

**Procedures for waste management of the active substance for industry or professional users**

For industrial users waste and contaminated materials are hazardous waste and can be disposed of by incineration.

The product is supplied to professional and non-professional users in a range of packaging sizes. Empty containers must not be used for any other purpose. They should be punctured and disposed of according to national waste disposal requirements.

Ventilate area. Collect leaking and spilled liquid in sealable containers (heavy duty plastic drums). Absorb remaining liquid in sand or inert absorbent and transfer to sealable containers for disposal. Wash area thoroughly with water and detergent, preventing runoff from entering drains. Wear chemical resistant goggles, gloves and boots, light protective clothing and self-contained breathing apparatus if contaminated area is not well ventilated. If material enters drains advise emergency services.

Solid absorbent material collected from spillage incidents should be disposed of at approved landfill sites. Triple- (or preferably) pressure-rinse containers before disposal. Do not dispose of undiluted chemicals on-site. Do not wash product or spillages into waterways, drains or sewers.

**Possibility of re-use or recycling**

None.

**Conditions for controlled discharge including leachate qualities on disposal**

Under Hazardous Waste Directive (91/689/EEC) surplus Cypermethrin and contaminated materials (including sawdust) must be classified a “Special Waste”.

Disposal must be in accordance with these regulations and requirements set out in the Integrated Pollution Prevention and Control Directive.

The active substance can be disposed to an approved landfill site as specified by the local or county authorities. Due to the high binding capacity of Cypermethrin to soil any release from an approved landfill site would not leach significantly into surrounding soil.

**Observations on undesirable or unintended side-effects e.g. on beneficial and other non-target organisms**

The products containing Cypermethrin are likely to be extremely dangerous to fish and other aquatic life.

**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances**

Cypermethrin falls within the scope of List I of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substance.

### Assessment of a combination of biocidal products

FREE LAND 10 EC is not intended to be authorised for the use with other biocidal products.

# Annexes[[4]](#footnote-3)

## List of studies for the biocidal product

In relation to product application, the following data have been submitted:

* 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
* Storage stability test – long term storage at ambient temperature (in progress)
* Emulsion characteristics and re-emulsification properties
* Persistent foam
* Surface tension
* Viscosity
* Explosives: BAM FALLHAMMER and KOENEN TUBE
* Closed Cup Flash Point
* Oxidising liquids
* Corrosive to metals
* Auto-ignition temperature
* Methods for detection and identification
* Efficacy studies.

## Output tables from exposure assessment tools

### Human Health exposure assessment

****

### Environment

#### Scenario 1 - Indoor spot treatment - TIER 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT1", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 2 | [-] | O |
| Local emission to air | ?? | 2,31E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 5,92E-04 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[PRIVATE USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | No applicable A-table, B4.5 (specific uses) | No applicable A-table, B4.5 (specific uses) |  | S |
| Emission scenario |  |  |  | D |
| 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 |
| Fraction of tonnage released to air | 0 | 0 | [-] | O |
| Fraction of tonnage released to wastewater | 0 | 0 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 0 | 0 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 0 | 0 | [-] | O |
| Number of emission days per year | 365 | 2 | [-] | O |
| Local emission to air | ?? | 1,72E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 4,48E-04 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | D |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S1-FL10EC-SPOTT1", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 2,96E-04 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 2,47E-05 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,665916 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 2,47E-05 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S1-FL10EC-SPOTT1", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 2,24E-04 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 1,87E-05 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,503561 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 1,87E-05 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT1", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 6,43E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 3,52E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 1,33E-06 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 7,28E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,33E-06 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 7,28E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 0,016603 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 1,59E-06 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 8,71E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,59E-06 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 8,71E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 0,019868 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 5,68E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,35E-04 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 5,40E-05 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,33E-08 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT1", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 4,77E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 2,61E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 1,00E-06 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 5,50E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,00E-06 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 5,50E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 0,012555 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 1,20E-06 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 6,59E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,20E-06 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 6,59E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 0,015024 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 4,30E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,02E-04 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 4,08E-05 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,01E-08 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 1 - Indoor spot treatment - TIER 2

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT2", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 2 | [-] | O |
| Local emission to air | ?? | 2,31E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 1,00E-04 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[PRIVATE USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | No applicable A-table, B4.5 (specific uses) | No applicable A-table, B4.5 (specific uses) |  | S |
| Emission scenario |  |  |  | D |
| 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 |
| Fraction of tonnage released to air | 0 | 0 | [-] | O |
| Fraction of tonnage released to wastewater | 0 | 0 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 0 | 0 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 0 | 0 | [-] | O |
| Number of emission days per year | 365 | 2 | [-] | O |
| Local emission to air | ?? | 1,72E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 8,32E-05 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | D |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S1-FL10EC-SPOTT2", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 5,02E-05 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 4,20E-06 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,112946 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 4,20E-06 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S1-FL10EC-SPOTT2", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 4,16E-05 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 3,48E-06 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,093574 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 3,48E-06 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT2", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 6,43E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 3,52E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 2,25E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 1,23E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 2,25E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 1,23E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 2,82E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 2,70E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 1,48E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 2,70E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,48E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 3,37E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 9,64E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 2,29E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 9,15E-06 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 2,25E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S1-FL10EC-SPOTT2", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 4,77E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 2,61E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 1,87E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 1,02E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,87E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 1,02E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 2,33E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 2,23E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 1,22E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 2,23E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,22E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 2,79E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 7,98E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,90E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 7,58E-06 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,87E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 2 - Indoor spot crack and crevice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S2-FL10EC-CC", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 2 | [-] | O |
| Local emission to air | ?? | 2,31E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 6,86E-05 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[PRIVATE USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | No applicable A-table, B4.5 (specific uses) | No applicable A-table, B4.5 (specific uses) |  | S |
| Emission scenario |  |  |  | D |
| 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 |
| Fraction of tonnage released to air | 0 | 0 | [-] | O |
| Fraction of tonnage released to wastewater | 0 | 0 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 0 | 0 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 0 | 0 | [-] | O |
| Number of emission days per year | 365 | 2 | [-] | O |
| Local emission to air | ?? | 1,72E-05 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 5,96E-05 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | D |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S2-FL10EC-CC", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 3,43E-05 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 2,87E-06 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,077165 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 2,87E-06 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S2-FL10EC-CC", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 2,98E-05 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 2,49E-06 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,067045 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 2,49E-06 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S2-FL10EC-CC", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 6,43E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 3,52E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 1,54E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 8,43E-10 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,54E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 8,43E-10 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 1,92E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 1,84E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 1,01E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,84E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 1,01E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 2,30E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 6,58E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,56E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 6,25E-06 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,54E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S2-FL10EC-CC", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 4,77E-09 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 2,61E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 1,34E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 7,33E-10 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 1,34E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 7,33E-10 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 1,67E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 1,60E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 8,77E-10 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 1,60E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 8,77E-10 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 2,00E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 5,72E-05 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 1,36E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 5,43E-06 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 1,34E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 3 – Indoor barrier application in crack & crevice

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S3-FL10EC-BARRIERCC", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 2 | [-] | O |
| Local emission to air | ?? | 2,31E-04 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 3,38E-04 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[PRIVATE USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | No applicable A-table, B4.5 (specific uses) | No applicable A-table, B4.5 (specific uses) |  | S |
| Emission scenario |  |  |  | D |
| 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 |
| Fraction of tonnage released to air | 0 | 0 | [-] | O |
| Fraction of tonnage released to wastewater | 0 | 0 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 0 | 0 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 0 | 0 | [-] | O |
| Number of emission days per year | 365 | 2 | [-] | O |
| Local emission to air | ?? | 1,72E-04 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 2,60E-04 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | S |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S3-FL10EC-BARRIERCC", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 1,69E-04 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 1,41E-05 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,380703 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 1,41E-05 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S3-FL10EC-BARRIERCC", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | ?? | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | ?? | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | ?? | 0 | [%] | O |
| Concentration in untreated wastewater | ?? | 1,30E-04 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 1,09E-05 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | ?? | 0,292417 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 1,09E-05 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S3-FL10EC-BARRIERCC", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 6,43E-08 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 3,52E-10 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 7,59E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 4,16E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 7,59E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 4,16E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 9,49E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 9,09E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 4,98E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 9,09E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 4,98E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 0,011359 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 3,25E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 7,71E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 3,08E-05 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 7,60E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S3-FL10EC-BARRIERCC", IC=15/UC=39][PRIVATE USE]** |  |  |  |  |
| Concentration in air during emission episode | ?? | 4,77E-08 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | ?? | 2,61E-10 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | ?? | 5,83E-07 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | ?? | 3,20E-09 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | ?? | 5,83E-07 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | ?? | 3,20E-09 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | ?? | 7,29E-03 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | ?? | 6,98E-07 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | ?? | 3,82E-09 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | ?? | 6,98E-07 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | ?? | 3,82E-09 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | ?? | 8,72E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | ?? | 2,49E-04 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | ?? | 5,92E-05 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | ?? | 2,37E-05 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | ?? | 5,84E-09 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | ?? | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | ?? | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | ?? | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | ?? | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 4 - Targeted residual treatment around the building against mosquitoes – Urban area

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S4-FL10EC-ABURBAN", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 300 | [-] | O |
| Local emission to air | 0 | 0 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 8,58E-03 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | S |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S4-FL10EC-ABURBAN", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | 0 | 5,44E-04 | [%] | O |
| Fraction of emission directed to water by STP | 100 | 8,356459 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | 0 | 0 | [%] | O |
| Concentration in untreated wastewater | 0 | 4,29E-03 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 3,58E-04 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | 0 | 9,64807 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 3,58E-04 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S4-FL10EC-ABURBAN", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | 0 | 1,30E-11 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | 0 | 1,07E-11 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | 0 | 1,92E-05 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | 0 | 1,58E-05 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | 0 | 1,92E-05 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | 0 | 1,58E-05 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | 0 | 0,240545 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | 0 | 2,30E-05 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 0 | 1,89E-05 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 0 | 2,30E-05 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | 0 | 1,89E-05 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 0 | 0,287856 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | 0 | 8,23E-03 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | 0 | 1,95E-03 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | 0 | 7,82E-04 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | 0 | 1,93E-07 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 4 - Targeted residual treatment around the building against mosquitoes – Rural areas

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S4-FL10EC-ABRURAL-LARGEB-HOUSE", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 300 | 300 | [-] | O |
| Local emission to air | 0 | 0 | [kg.d-1] | O |
| Local emission to wastewater | ?? | 0 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | S |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S4-FL10EC-ABRURAL-LARGEB-HOUSE", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | 0 | 0 | [%] | O |
| Fraction of emission directed to water by STP | 100 | 100 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | 0 | 0 | [%] | O |
| Concentration in untreated wastewater | 0 | 0 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | 2,07E-04 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | 0 | 0 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | 2,07E-04 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S4-FL10EC-ABRURAL-LARGEB-HOUSE", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | 0 | 0 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | 0 | 0 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | 0 | 1,11E-05 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | 0 | 9,13E-06 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | 0 | 1,11E-05 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | 0 | 9,13E-06 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | 0 | 0,138796 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | 0 | 0 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

#### Scenario 6 – Ant nest eradication

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section/parameter** | **Reference value** | **Actual value** | **Unit** | **Stat** |
|  |  |  |  |  |
| **IDENTIFICATION OF THE SUBSTANCE** |  |  |  |  |
| General name | Cypermethrin | Cypermethrin |  | S |
| CAS-No | 52315-07-8 | 52315-07-8 |  | S |
| EC-notification no. |  |  |  | D |
| EINECS no. | 257-842-9 | 257-842-9 |  | S |
| Molecular weight | 416 | 416 | [g.mol-1] | S |
|  |  |  |  |  |
| **PHYSICO-CHEMICAL PROPERTIES** |  |  |  |  |
| Melting point | 47 | 47 | [oC] | S |
| Boiling point | ?? | ?? | [oC] | D |
| Vapour pressure at 20 [oC] | 4,25E-07 | 4,25E-07 | [Pa] | S |
| Vapour pressure at 25 [oC] | 6,00E-07 | 6,00E-07 | [Pa] | O |
| 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 |
| Henry's law constant at 25 [oC] | 0,058203 | 0,031604 | [Pa.m3.mol-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| Tonnage of substance in Europe | 0 | 0 | [tonnes.yr-1] | O |
| Regional production volume of substance | 0 | 0 | [tonnes.yr-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[1 "S6-FL10EC-ANT", IC=15/UC=39]** |  |  |  |  |
| Industry category | 15/0 Others | 15/0 Others |  | D |
| Use category | 39 Biocides, non-agricultural | 39 Biocides, non-agricultural |  | D |
| Fraction of tonnage for application | 1 | 1 | [-] | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **[INDUSTRIAL USE]** |  |  |  |  |
| Use specific emission scenario | Yes | Yes |  | D |
| Emission tables | A3.16 (general table), B3.14 (general table) | A3.16 (general table), B3.14 (general table) |  | S |
| Emission scenario |  |  |  | D |
| Main category industrial use | II Inclusion into or onto a matrix | II Inclusion into or onto a matrix |  | D |
| 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 | (18.3.4) Outdoor, spot application | (18.3.4) Outdoor, spot application |  | S |
| Fraction of tonnage released to air | 1,00E-04 | 1,00E-04 | [-] | O |
| Fraction of tonnage released to wastewater | 1,00E-02 | 1,00E-02 | [-] | O |
| Fraction of tonnage released to surface water | 0 | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 5,00E-03 | 5,00E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | 0 | [-] | O |
| Fraction of the main local source | 1 | 1 | [-] | O |
| Number of emission days per year | 1 | 1 | [-] | O |
| Local emission to air | 0 | 0 | [kg.d-1] | O |
| Local emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Intermittent release | No | No |  | D |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **RELEASE ESTIMATION** |  |  |  |  |
| **TOTAL REGIONAL EMISSIONS TO COMPARTMENTS** |  |  |  |  |
| Total regional emission to air | 0 | 0 | [kg.d-1] | O |
| Total regional emission to wastewater | 0 | 0 | [kg.d-1] | O |
| Total regional emission to surface water | 0 | 0 | [kg.d-1] | O |
| Total regional emission to industrial soil | 0 | 0 | [kg.d-1] | O |
| Total regional emission to agricultural soil | 0 | 0 | [kg.d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **PARTITION COEFFICIENTS** |  |  |  |  |
|  |  |  |  |  |
| Organic carbon-water partition coefficient | 7,14E+03 | 5,75E+05 | [l.kg-1] | S |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DEGRADATION AND TRANSFORMATION** |  |  |  |  |
| Characterization of biodegradability | Not biodegradable | Not biodegradable |  | S |
| Degradation calculation method in STP | First order, standard OECD/EU tests | First order, standard OECD/EU tests |  | D |
| Rate constant for biodegradation in STP | 0 | 0 | [d-1] | O |
| Rate constant for biodegradation in surface water | 1,00E+06 | 0,948 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in bulk soil | 1,00E+06 | 17,2 | [d] (DT50,12[oC]) | S |
| Rate constant for biodegradation in aerated sediment | 1,00E+06 | 27 | [d] (DT50,12[oC]) | S |
| Rate constant for hydrolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] (12[oC]) | O |
| Rate constant for photolysis in surface water | 6,93E-07 | 6,93E-07 | [d-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **SEWAGE TREATMENT** |  |  |  |  |
| **LOCAL STP [1 "S6-FL10EC-ANT", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| **OUTPUT** |  |  |  |  |
| Fraction of emission directed to air by STP | 0 | 0 | [%] | O |
| Fraction of emission directed to water by STP | 100 | 100 | [%] | O |
| FstpSludge | FstpSludge | FstpSludge | FstpSludge | E |
| Fraction of the emission degraded in STP | 0 | 0 | [%] | O |
| Concentration in untreated wastewater | 0 | 0 | [mg.l-1] | O |
| - Total concentration in the STP-effluent | ?? | ?? | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | No |  | O |
| - Total concentration of chemical in combined sludge | 0 | 0 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | ?? | ?? | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **LOCAL SCALE** |  |  |  |  |
| **[1 "S6-FL10EC-ANT", IC=15/UC=39][INDUSTRIAL USE]** |  |  |  |  |
| Concentration in air during emission episode | 0 | 0 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | 0 | 0 | [mg.m-3] | O |
| Concentration in surface water during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average concentration in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in surface water during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average local PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in freshwater sediment during emission episode | 0 | 0 | [mg.kgwwt-1] | O |
| Concentration in seawater during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 0 | 0 | [mg.l-1] | O |
| Annual average local PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 30 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | 0 | 0 | [mg.kgwwt-1] | O |
| Local PEC in groundwater under agricultural soil | 0 | 0 | [mg.l-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **CONTINENTAL** |  |  |  |  |
| Continental PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Continental PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Continental PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Continental PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Continental PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **DISTRIBUTION** |  |  |  |  |
| **REGIONAL AND CONTINENTAL SCALE** |  |  |  |  |
| **REGIONAL** |  |  |  |  |
| Regional PEC in surface water (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in seawater (dissolved) | 0 | 0 | [mg.l-1] | O |
| Regional PEC in air (total) | 0 | 0 | [mg.m-3] | O |
| Regional PEC in agricultural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in pore water of agricultural soils | 0 | 0 | [mg.l-1] | O |
| Regional PEC in natural soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in industrial soil (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
| Regional PEC in seawater sediment (total) | 0 | 0 | [mg.kgwwt-1] | O |
|  |  |  |  |  |
| **ENVIRONMENT-EXPOSURE** |  |  |  |  |
| **BIOCONCENTRATION** |  |  |  |  |
| Bioconcentration factor for earthworms | 3,38E+03 | 3,38E+03 | [l.kgwwt-1] | O |
| Bioconcentration factor for fish | 8,56E+03 | 8,56E+03 | [l.kgwwt-1] | O |

## New information on the active substance

New information on the active substance is not available.

## Residue behaviour

No residues of FREE LAND 10 EC in food or feed occur.

## Summaries of the efficacy studies (B.5.10.1-xx)

Please, see section 2.2.5.5

## Confidential annex

Please refer to seperate file.

1. https://echa.europa.eu/documents/10162/1ccde4fc-e72e-da16-812c-8007f8f36aea [↑](#footnote-ref-1)
2. https://echa.europa.eu/documents/10162/716f554b-b973-1a61-5bf2-eff87b36a237 [↑](#footnote-ref-2)
3. . ECHA. Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment & Evaluation (Parts B+C). Version 2.0. October 2017. [↑](#endnote-ref-1)
4. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-3)