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)



HC6 EC

Product type 18

Cypermethrin and imidacloprid

Case Number in R4BP: BC-GV059252-20

Evaluating Competent Authority: France

Date: December 2022

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# CONCLUSION

HC6 EC is an emulsifiable concentrate (EC) containing imidacloprid and cypermethrin as active substances. The product is applied by spraying after dilution in water and is to be used as insecticide (PT18) by professional users for the control of crawling insects, indoors, in industrial, commercial and public premises and in private homes and in confined areas not object to wet cleaning.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

A classification according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product contains 2 non-active substances (so called “co-formulant(s)”) which are considered as substances of concern for human health.The non-active substances considered as substances of concern are Propylene carbonate and DPM. More detailed information on the substances of concern is provided in the confidential annex.

The biocidal product should be considered not to have endocrine-disrupting properties*.*

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains imidacloprid which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: very persistent (vP) and toxic (T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[[2]](#footnote-3). The assessment is presented under section 3.10 of the PAR. The competent authority concluded that no products have been identified as potential better alternatives for HC6 EC.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

**Conclusions of the assessment for each area**

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

**Conclusion on the physical, chemical and technical properties**

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR. The product should be stored at a temperature below 40°C and should be protected from light. The shelf life of the product is 30 months in HDPE and HDPE/PA packaging.

Conclusion on the physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Conclusion on the methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substances in the biocidal product are available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring of residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff. More information is available in section 3.4 of the PAR.

**Conclusion of the efficacy**

The elements submitted in the dossier demonstrated the efficacy of the product HC6 EC indoors, in confined areas not object to wet cleaning at the application rate of 50 mL /m² of 1% v/v diluted product for non-porous surface and 2% v/v for porous surface against crawling insects:

* Cockroaches (*B. germanica* and *B. orientalis*) adults and nymphs
* Black ants (*L. niger*) workers
* Silverfish (*Lepisma saccharina*) adults and nymphs
* Bed bugs (*C. lectularius*) stage adults and nymphs

The product has a residual efficacy up to 4 weeks against ants, cockroaches and silverfish.

**Conclusion on resistance**

Imidacloprid

Enhanced detoxification mediated by cytochrome-P450-dependent monooxygenases appears to be the major mechanism.

Resistance phenomena to imidacloprid have been reported in particular for cockroaches and bedbugs in studies available in scientific literature.

Cypermethrin

Cypermethrin belongs to the pyrethroid family. Resistance phenomena to cypermethrin have been reported in particular in cockroaches and bedbugs in studies available in the public literature.

Therefore the applicant should implement a monitoring of scientific literature related to the resistance of the target organisms (notably cockroaches and bedbugs) to the active substances imidacloprid and cypermethrin and provide an assessment of this monitoring at the renewal of the authorisation.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

**Conclusion on the risk for Human Health**

For the product HC6 EC, the risk is considered acceptable for professional users and the general public, considering a qualitative and quantitative risk assessment, with the application of risk mitigation measures (RMM) and the wearing of personal protective equipment (PPE) listed in the SPC.

**Conclusion on the dietary risk assessment**

Considering the uses, food or feed contamination is not expected. As a consequence the exposure via food, via livestock or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

**Conclusion on the environmental risk assessment**

* The use of product HC6 EC as a barrier treatment (i.e. a medium-sized area treatment) on surfaces leads to unacceptable risks for the surface water and sediment compartments, even if only emissions from the applicator cloths washing are taken into account.
* The use as a spot treatment (i.e. in restricted areas) in cracks and crevices leads also to unacceptable risks for the environment and emissions from washing of applicator cloths after use of the product at the dilution of 2% also leads to unacceptable risks.

Hence, the use of the product must be restricted to applications that leads to no emission to the environment. The following risk mitigation measures must be applied:

* The product is only for indoor use in restricted areas and to be strictly applied in non-wet-cleaned surfaces (cellars, ventilation vents or ducts, wall boxes of electrical system, in the thin cracks and crevices between furniture, or where insects may harbour).
* The applicator must wear disposable protective coverall to avoid emissions to the sewer system due to washing of contaminated clothes.

In this frame, the risk cannot be excluded for application in non-cleaned areas but for which product drift occurs, as for use behind skirting for example.

In the table below, the intended treated areas associated to the pests are presented. Applications that do not fit the restrictions mentioned above are **shaded**.

|  |  |  |  |
| --- | --- | --- | --- |
| **Use** | **Dilution** | **Targets** | **Initially claimed treated areas** |
| 1 | 1%-2% | Bed bugs, adults and nymphs | Under bed and night table structures, furniture, around picture, window and door frames, behind skirting boards and electrical sockets |
| Cockroaches and Silverfishes, adults and nymphs  Garden ants, adults | In damp or warm indoor areas, such us cellars, garages, ventilation vents or ducts, wall boxes of electrical system, behind the skirting boards, in the thin cracks and crevices between furnituree, or where insects may harbour |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| HC6 EC\* |  |
| TATHRIN HYDRO EC |  |
| TATHRIN EC |  |
| TETRACIP HYDRO EC |  |
| CMP INSECTICIDA CONCENTRADO |  |
| TATHRIN HYDRO-EC |  |
| BUKOR EC |  |
| INVICTO EC |  |
| IMIZA-PLUS EC |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Zapi S.p.A. |
| **Address** | Via Terza Strada 12  35026 Conselve (PD)  Padova  Italy |
| **Authorisation number** | **FR-2023-0005** | |
| **Date of the authorisation** | **12/02/2023** | |
| **Expiry date of the authorisation** | **11/02/2028** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Zapi S.p.A. |
| **Address of manufacturer** | Via Terza Strada 12  35026 Conselve (PD)  Padova  Italy |
| **Location of manufacturing sites** | Via Terza Strada 12  35026 Conselve (PD)  Padova  Italy |

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

|  |  |
| --- | --- |
| **Active substance** | Imidacloprid |
| **Name of manufacturer** | Ningbo Generic Chemical Co., Ltd. (Art. 95 List: ZAPI S.p.A.) |
| **Address of manufacturer** | Room 10-6, Shidal Square 8,  315010, Zhejiang,  China |
| **Location of manufacturing sites** | Shaanxi Hengtian Chemical Co., Ltd.,  Plant address: Dali Core Zone, Wei nan National Agricultural Science and Technology Park, Shanxi province, China |

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin |
| **Name of manufacturer** | Arysta Lifesciences Benelux Sprl. |
| **Address of manufacturer** | Rue de Rénory 26/1, BE-4102 Ougrée Belgium |
| **Location of manufacturing sites** | D, ½, MIDC, Lote Parshuram Tal. Khed Dist. Ratnagiri, 415 722 Maharashtra, India |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Cypermethrin cis/trans +/- 40/60 |
| **IUPAC or EC name** | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropane carboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 607-421-00-4 |
| **Minimum purity / content** | 92% |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Imidacloprid (ISO) |
| **IUPAC or EC name** | (2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine |
| **EC number** | 428-040-8 |
| **CAS number** | 138261-41-3 |
| **Index number in Annex VI of CLP** | 612-252-00-4 |
| **Minimum purity / content** | 98.1% |
| **Structural formula** | http://www.alanwood.net/pesticides/structures/imidacloprid.gif |

#### Candidate(s) for substitution

The active substance imidacloprid is considered as a candidate for substitution according to the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012.

Imidacloprid is considered as a candidate for substitution based on the following criteria: very persistent (P/vP) and toxic (T). Therefore, a comparative assessment has been performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[[3]](#footnote-4).

Please see section 2.2.11 for the overall conclusion of the comparative assessment.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin cis/trans +/- 40/60 technical (min 92% w/w) | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 5.43 |
|  |  |
| Imidacloprid technical (min 98.1% w/w) | (2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine | Active substance | 138261-41-3 | 428-040-8 | 2.04 |
|  |  |
| Propylene carbonate | 4-methyl-1,3-dioxolan-2-one | Non-active substance | 108-32-7 | 203-572-1 | 57.43 |
| Dipropopylene glycol monomethyl ether | 2-[(1-methoxypropan-2-yl)oxy]propan-1-ol | Non-active substance | 34590-94-8 | 252-104-2 | 17 |

Full product composition is provided in the confidential annex of this document.

#### Information on technical equivalence

Imidacolprid: According to the decision on technical equivalence under Art 54(4) of the BPR from the 11th of December 2018 (decision number TAP-D-1206592-18-00/F), the alternative source of imidacloprid is considered technically equivalent compared to the reference source in respect of which the initial risk assessment was carried out. Applicant is listed in art.95 list as substance and product supplier. Technical imidacloprid does not contain relevant impurity according to regulation 2011/69.

Cypermethrin: A letter of access to have access to active substance endpoints was granted to the applicant. The source of the active substance is identical as the one indicated in the CAR. Technical cypermethrin does not contain relevant impurity according to regulation 2018/1130.

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

Propylene carbonate and Dipropopylene glycol monomethyl ether have been identified as substances of concern in the biocidal product.

Please see the confidential annex for further details.

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

The biocidal product contains the active substance “Imidacloprid”, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

It also contains Cypermethrin which is not considered to have endocrine disrupting properties according to the interim criteria of Article 5(3).

None of the co-formulants contained in the HC6 EC product are regulatory identified as endocrine disruptors or have significant ED properties.

However, there are indications that one co-formulant has potential ED properties and they should be further assessed in the frame of REACH Regulation.

For further details, please refer to the Confidential Annex.

#### Type of formulation

|  |
| --- |
| EC (emulsifiable concentrate) |

### 

### Hazard and precautionary statements[[4]](#footnote-5)

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

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit. 2  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H319 Causes serious eye irritation.  H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319 Causes serious eye irritation.  H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P264: Wash hands thoroughly after handling.  P273: Avoid release to the environment.  P280: Wear protective gloves, protective clothing and eye protection.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337+P313 If eye irritation persists: Get medical advice/attention.  P391: Collect spillage.  P501: Dispose of contents/container in according to local regulation. |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Spray

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Crawling insects, including   * Cockroaches (*Blattella germanica*, *Blatta orientalis*), adults and nymphs * Garden ants (*Lasius niger*), workers * Silverfishes (*Lepisma saccharina*), adults and nymphs |
| **Field of use** | Indoor  Use indoor, only in confined areas not object of wet cleaning  Only for indoor use in restricted areas and to be strictly applied in non-wet-cleaned surfaces (cellars, ventilation vents or ducts, wall boxes of electrical system, in the thin cracks and crevices between furniture, or where insects may harbour). |
| **Application method(s)** | Spraying (low pressure) |
| **Application rate(s) and frequency** | * Non-porous surface: 50 mL/m² of 1% v/v diluted product (10 mL of product in 990 ml of water) * Porous surface: 50 mL/m² of 2% v/v diluted product (20 mL of product in 980 ml of water)   Delay of action is about a one week to 2 weeks  The product has a residual effect of 4 weeks  Application frequency: up to 11 applications per year |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | * HDPE bottle : 100 mL to 1000 mL * HDPE/PA bottle : 50 mL to 1000 mL * HDPE tank : 5 L to 25 L   The above-reported packaging can be made available on the market as single unit or packed in the following packaging:   * Bottles can be packed in boxes/cartons (carton) containing from 1 to 24 pieces. * Tanks (sizes from 5 to 10 L) can be packed in cartons (carton) containing from 1 to 4 pieces. |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

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| --- |
| * Application frequency: up to 11 applications per year. * Wash hands after applying the product, and before eating, drinking or smoking. * Inform the authorization holder if the treatment is ineffective. * Alternate products containing active substances with a different mode of action (to remove resistant individuals from the population). * Apply only on infested area. * Diluted product should never be stored: a fresh dilution should be prepared as necessary * Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. * Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc). * The applicator must ensure that information is provided to the person responsible for cleaning to avoid any wet-cleaning of treated areas. |

#### Risk mitigation measures

|  |
| --- |
| * 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. * The use of eye protection during handling of the product is mandatory. * Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). * Wear a protective coverall (at least category 3 type 4) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information). * The applicator must wear disposable protective coverall to avoid emissions to the sewer system due to washing of contaminated clothes. * The product must be used only in areas that are inaccessible to infants, children, companion animals and non-target animals. * The product is only for indoor use in restricted areas and to be strictly applied in non-wet-cleaned surfaces (cellars, ventilation vents or ducts, wall boxes of electrical system, in the thin cracks and crevices between furniture, or where insects may harbour). * Contain Cypermethrin. Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity. * Re­move or cover terraria, aquaria and animal cages before application. Turn off aquarium air-filter while spraying. |

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

|  |
| --- |
| IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.  IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.  Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. |

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

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste (disposable cloths), in accordance with local regulations. |

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

|  |
| --- |
| Shelf life: 30 months  Protect from light  Do not store at a temperature higher than 40°C |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 100 – 1000 mL | HDPE | HDPE | Professional | Yes |
| Bottle | 250 – 1000 mL | COEX HDPE/PA | HDPE | Professional | Yes |
| Bottle | 50 – 1000 mL | COEX HDPE/PA | PP | Professional | Yes |
| Tank | 5 – 25L | HDPE | HDPE | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

For the complete list of studies please refer to IUCLID files.

#### Access to documentation

A letter of access is submitted to grant access to dossier related to approval of active subtance imidacloprid. A letter of access is submitted to grant access to dossier related to approval of active subtance cypermethrin.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – Spraying

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use |  |
| Target organism (including development stage) | Scientific name: Crawling insects Common name: Crawling insects Development stage: Adults/Nymphs   Scientific name: *Cimex lectularius* Common name: Common bedbug Development stage: Adults and Nymphs   Scientific name: *Blattella germanica* Common name: German cockroach Development stage: Adults and Nymphs   Scientific name: *Blatta orientalis* Common name: Oriental cockroach Development stage: Adults and Nymphs   Scientific name: *Lepisma saccharina* Common name: Silverfishes Development stage: Adults and Nymphs   Scientific name: *Lasius niger* Common name: Garden ants Development stage: Adults |
| Field of use | Indoor Use indoors, only in confined areas not object of wet cleaning. |
| Application method(s) | Method: Spraying  Detailed description:  After dilution in water, spray only in confined areas not object of wet cleaning where insects hide and walk.  For common bedbug treatment: apply the obtained mixture in particular under bed and night table structures, furniture, around picture, window and door frames, behind skirtings, boards and electrical sockets (after switching-off the electricity).  For cockroach, silverfish and ant treatment: apply the obtained mixture in particular in damp or warm indoor areas, such us cellars, garages, ventilation vents or ducts, wall boxes of electrical system, behind the skirting boards, in the thin cracks and crevices between furniture, or where insects may harbor. |
| Application rate(s) and frequency | Application Rate: Product shall be diluted in water before use. Obtained mixture shall be applied at a rate of 50 ml/m2  Dilution (%): - at 1% (10 mL + 990 mL of water) for application on non-porous surfaces; - at 2% (20 mL + 980 mL of water) for application on porous surfaces. Apply the obtained mixture at a rate of 50 ml/m2. Before use, mixture shall be shaken to obtain a stable and uniform emulsion. It is advisable to use the mixture within the day of preparation.  Number and timing of application:  After product application, target insects are knocked-down within 10 minutes-few hours after contact with treated surfaces and die within 24 hours. HC6 EC residual efficacy, depending on target insects and treated surfaces, lasts up to 2/4 weeks.  Application frequency: up to 11 applications per year. |
| Category(ies) of user(s) | Trained professional Professional |
| Pack sizes and packaging material | * BOTTLE (HDPE; closure HDPE) FROM 100 TO 1000 ML * BOTTLE (COEX: internal layer PA; external layer HDPE; closure HDPE) FROM 250 TO 1000 ML * BOTTLE (COEX: internal layer PA; external layer HDPE; closure PP) FROM 50 TO 1000 ML * TANK (HDPE; closure HDPE) FROM 5 TO 25 LT   The above-reported packaging can be made available on the market as single unit or packed in the following packaging:   * BOTTLES: can be packed in boxes/cartons (carton) containing from 1 to 24 pcs. * TANKS (sizes from 5 to 10 lt) can be packed in cartons (carton) containing from 1 to 4 pcs. |

### Physical, chemical and technical properties

The product HC6 EC is an emulsifiable concentrate that contains 5.43% of technical cypermethrin and 2.04% of technical imidacloprid. The product is not the representative one assessed in the CAR of the active substances. Physico chemical properties on the claimed formulation were provided.

The product does not contain H304 co-formulants. The product does not contain PT6 conservative.

The product is for professional users.

Use rates proposed: 1-2% v/v in water

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Evaluation FR** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830.6303  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | Liquid | Acceptable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Colour at 20 °C and 101.3 kPa | OPPTS 830.6302  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | Light yellow | Acceptable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Odour at 20 °C and 101.3 kPa | OPPTS 830.6304  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | Characteristic odour | Acceptable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Acidity / alkalinity | CIPAC MT 75.3  OECD No. 122  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | pH value of the neat test item without dilution at 20°C = 2.7 (rounded mean value of two measurements)  pH value of a 1 % w/v aqueous dispersion of the test item sample at 20°C = 4.7 (rounded mean value of two measurements)  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. | Acceptable for the 1% v/v dilution.  A measurement was reported for neat product using CIPAC MT 75.3. However, the result does not seem reliable. eCA considers that only pH at 1% w/v is acceptable. | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Relative density / bulk density | CIPAC MT 3.2  OECD No. 109  EC 440/2008 No. A.3, GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741 | Test item density is 1.0937 g/mL at 19.63°C  𝐷2020 = 1.0957  𝐷204= 1.0937 | Acceptable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Storage stability test – **accelerated storage** | 8 weeks storage stability at 40°C  GIFAP Monograph n°17  CIPAC MT 46  OPPTS 830.6302;  OPPTS 830.6303;  OPPTS 830.6304; CIPAC MT 75.3;  OECD No. 122; CIPAC MT 47.3 and MT 18; CIPAC MT 36.3 and MT 18  Internal methods CH0568/2019 and CH0569/2019  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  Tested in the following packs:   * 50 ml COEX HDPE/PA Bottle * 250 ml COEX HDPE/PA Bottle * 100 ml HDPE Bottle | **50ml COEX HDPE/PA bottle:**    **250ml COEX Bottle HDPE/PA:**    **100ml HDPE Bottle:**    Statement from test laboratory regarding testing at 40°C rather than 54°C:  *“Since the test item is an EC (Emulsifiable Concentrate) formulation, it was preferred to conduct the accelerated storage stability at 40°C for 8 weeks instead of 54°C for 14 days considering that, based on our experience, higher temperatures may lead to solvent evaporation.*  *Therefore, to avoid the decrease of active ingredient content, caused by test item weight variation, it was opted for conducting accelerated stability studies at a lower temperature.”* | The product is stable 8 weeks at 40°C in HDPE and HDPE/PA bottles.  Since the test is not performed at 54°C for 2 weeks, the risk mitigation measure “do not store the product at temperature higher than 40°C”.  Since the same batch is used for initial characterisation and storage tests, the initial content of a.s is identical in PE bottle and COEX bottles.  Technical properties at min and max use rates are acceptable before and after storage.  As the lowest packaging sizes (50mL for coex HDPE/PA and 100mL for HDPE) were tested, all higher sizes claimed are considered acceptable. | Nichetti S., Chemservice srl, 2019.  CH0675/2019  CH0677/2019  CH0679/2019  Statement 05/03/2021 |
| Storage stability test – **long term storage at ambient temperature** | GIFAP Monograph n°17  OPPTS 830.6302;  OPPTS 830.6303;  OPPTS 830.6304; CIPAC MT 75.3;  OECD No. 122; CIPAC MT 47.3 and MT 18  CIPAC MT 36.3 and MT 18 Internal methods CH0568/2019 and CH0569/2019  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  Tested in the following packs:   * 50 ml COEX HDPE/PA Bottle * 250 ml COEX HDPE/PA Bottle * 100 ml HDPE Bottle | The 3 years long term storage stability study at ambient temperature is still ongoing.  The main physico-chemical properties and the active ingredients content will be determined on the test item after 6, 12, 18, 24, 30 and 36 months of storage at ambient warehouse temperature and compared with the data obtained in the initial characterisation  Intermediate results (after 30 months of storage at ambient temperature):  **Initial results**    **50ml COEX Bottle (HDPE/PA):**    **250ml COEX Bottle (HDPE/PA):**    **100ml HDPE Bottle:** | Results demonstrate that the product is stable up to 30 months in HDPE and HDPE/PA packaging. Variations of active substance content remain below 10% and technical properties are still acceptable after storage.  The shelf life is still ongoing (results are available up to 30 months only). A shelf life of 30months is acceptable based on the available results.    Note that the current study has been launched for 3 years. If the applicant claims a longer shelf life than 30 months, a dossier for minor change application should be provided separately. | Nichetti S., Chemservice srl, 2019.  CH0676/2019  CH0678/2019  CH0680/2019 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  GLP  CIPAC MT 39.3  CIPAC MT 36.3  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle  HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 305627  COEX HDPE/PA bottle (500mL) | After 7 days at 0 ± 2°C and after 24 hours of thermal equilibrium at 23 ± 2°C and a single inversion: no visual separation of solid or liquid material, nor changes in its physical state.  After 7 days at 0 ± 2°C, emulsion characteristics remain acceptable.  before storage: complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (1% v/v and 2% v/v). No oil, no cream formed after 0.5h, 2h, 24h, 24.5h (after 10 inversion).  after storage 7 days at 0°C: complete initial emulsification (0h); complete re-emulsification (24h) for both application rates (1% v/v and 2% v/v). No oil, no cream formed after 0.5h, 2h, 24h, 24.5h (after 10 inversion). | Acceptable. The formulation is stable following 7 days at 0°C. | Nichetti S., Chemservice srl, 2019. CH0567/2019  Nichetti S, Chemsevice srr, 2021  CH0116/2021 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not applicable. Label claims "Protect from light". | Data is missing but in the SPC the applicant specifies that the product should be protected from light. As active substances are sensitive to light, this mitigation measure is relevant. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not applicable. Label claims “Store in a cool and well-ventilated place away from heat sources”. | eCA rather proposes the mitigation measure “do not store at a temperature higher than 40°C”.  See data on the accelerated storage study 8 weeks at 40°C. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | 8 weeks storage stability at 40°C  GIFAP Monograph n°17  CIPAC MT 46  OPPTS 830.6302;  OPPTS 830.6303;  OPPTS 830.6304; CIPAC MT 75.3;  OECD No. 122; CIPAC MT 47.3 and MT 18; CIPAC MT 36.3 and MT 18  Internal methods CH0568/2019 and CH0569/2019  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Tested in the following packs:   * 50 ml COEX HDPE/PA Bottle * 250 ml COEX HDPE/PA Bottle * 100 ml HDPE Bottle | The sample of HC6 EC formulation is stable in its commercial packaging under the tested accelerated storage conditions. | Acceptable  The product is compatible with HDPE/PA and HDPE bottles. | Nichetti S., Chemservice srl, 2019.  CH0675/2019  CH0677/2019  CH0679/2019 |
| Wettability |  |  | Since the biocidal product is a formulation not intended to be dispersed in water this test does not need to be performed. | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Since the biocidal product is not a SC formulation these tests do not need to be performed. | Not applicable |  |
| Wet sieve analysis and dry sieve test |  |  | Since the biocidal product is not a dispersable or suspension concentrate, these tests do not need to be performed. | Not applicable |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3  CIPAC MT 18  GLP  (Standard Water D  and Standard Water A) | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741 | A complete initial emulsification was noted after a single inversion and waiting for 30 seconds either for 1.0 % v/v and 2.0 % v/v suspensions in Standard Water D and A.  Moreover, a complete re-emulsification was noted after 24 h and 10 inversions and waiting for 30 seconds either for 1.0 % v/v and 2.0 % v/v suspensions in Standard Water D and A. | Acceptable, since the tests are performed at the lowest and highest concentrations recommended for use | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Disintegration time |  |  | Since the biocidal product is a liquid formulation this test does not need to be performed. | Not applicable |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Since the biocidal product is a liquid formulation this test does not need to be performed. | Not applicable |  |
| Persistent foaming | CIPAC MT 47.3  and MT 18  GLP  (Standard Water D) | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741 | After 1 minute (as mean of two determinations):  V = 45 mL for 1.0 % v/v suspension  V = 55 mL for 2.0 % v/v suspension | Acceptable  The test is performed at the lowest and highest concentrations recommended for use | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Flowability/Pourability/Dustability |  |  | Since the biocidal product is not a granular, suspension concentrate or a powder, this test does not need to be performed. | Not applicable |  |
| Burning rate — smoke generators |  |  | Since the biocidal product is not a smoke generator this test does not need to be performed. | Not applicable |  |
| Burning completeness — smoke generators |  |  | Since the biocidal product is not a smoke generator this test does not need to be performed. | Not applicable |  |
| Composition of smoke — smoke generators |  |  | Since the biocidal product is not a smoke generator this test does not need to be performed. | Not applicable |  |
| Spraying pattern — aerosols |  |  | Since the biocidal product is not an aerosol this test does not need to be performed. | Not applicable |  |
| Physical compatibility |  |  | The product is not applied in mixture with other products. For this reason, a derogation to perform these studies is requested. | Not applicable as the product is not intended to be mixed with other products. |  |
| Chemical compatibility |  |  | The product is not applied in mixture with other products. For this reason, a derogation to perform these studies is requested. | Not applicable as the product is not intended to be mixed with other products. |  |
| Degree of dissolution and dilution stability |  |  | Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation these tests do not need to be performed. | Not applicable as the product is not sold in WSB. |  |
| Surface tension | OECD No. 115,  EC 440/2008 No. A.5  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | Surface tension at 20°C of the undiluted test item = 24.7 mN/m  Surface tension at 20°C of 1.0 % v/v test item aqueous solutions = 32.1 mN/m  Surface tension at 20°C of 2.0 % v/v test item aqueous solutions = 32.4 mN/m | Acceptable  The product should be considered as surface-active material | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Viscosity | CIPAC MT 22.1  OECD No. 114  GLP (U tube viscometer) | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | Kinematic viscosity:  At 20°C  U viscometer size 100: 7.07 cSt (mm2/s) at 20°C  U viscometer size 75: 6.85 cSt (mm2/s) at 20°C  Mean value: 6.96 cSt (mm2/s) at 20°C  At 40°C  U viscometer size 100: 4.38 cSt (mm2/s) at 40°C  U viscometer size 75: 4.11 cSt (mm2/s) at 40°C  Mean value: 4.24 cSt (mm2/s) at 40°C  Dynamic viscosity:  At 20°C  U viscometer size 100: 7.73 cP (mPa.s) at 20°C  U viscometer size 75: 7.49 cP (mPa.s) at 20°C  Mean value: 7.61 cP (mPa\*s) at 20°C  At 40°C  U viscometer size 100: 4.79 cP (mPa.s) at 40°C  U viscometer size 75: 4.50 cP (mPa.s) at 40°C  Mean value: 4.64 cP (mPa\*s) at 40°C  Note from test laboratory: due to type of formulation (EC), the U-tube viscometers were used to determinate the viscosity.  For the test, two different U-tube viscometers (as two shear rates) for both temperatures (20°C and at 40°C) were used and, since the values obtained using viscometers with different size but at the same temperature were similar, it was demonstrated that the test item was a Newtonian liquid.  For this reason, the kinematic and dynamic viscosities at 20°C and 40°C were calculated as mean of the two obtained values using both viscometers.  The value of shear rate, using this method, is not available. Each u-tube viscometers have a calibration constant that changes depending on the size and it was used for the calculation of kinematic viscosity. | Acceptable. Due to the type of method (U-tube viscometer), shear rate is not available. However, results were similar with two different U-tube viscometers, meaning that the product can be regarded as a Newtonian fluid. | Nichetti S., Chemservice srl, 2019. CH0567/2019 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| HC6 EC is a clear light yellow liquid with characteristic odour emulsifiable concentrate.  All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  HC6 EC is not classified for the physico-chemical aspect. The product has a pH value of 4.7 at 1% dilution at 20°C, a density of 1.0937 g/mL at 20°C, a surface tension of 32.1 mN/m at 1%v/v.  There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C in HDPE and HDPE/PA packagings, neither the active ingredient content nor the technical properties were changed.  Long term storage stability study results up to 30 months are available and found acceptable. A shelf life of 30 months at ambient temperature in HDPE bottle and COEX HDPE/PA bottle (commercial packagings) can be granted.  A 36 months storage stability study is also on-going and the results could be submitted in a minor-change application to increase the shelf-life.  Its technical characteristics are acceptable for an emulsifiable concentrate formulation.  No data have been provided for the stability at light and some packaging are transparent. The product should be store away from light.  **Shelf life:** 30 months  **Risk mitigation measure to be added:**  Protect from light  Do not store the product at temperature higher than 40°C. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Evaluation FR** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Differential Scanning Calorimetry method (DSC)  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch L099120939 | In the temperature range used (from room temperature to 600°C), no exothermic reaction was observed.  This thermodynamic information allows knowing that the test item shall not be classified as explosive and the test on explosive properties with Un test series 1-3 should not be performed. | Acceptable  The product is not explosive | Halbwachs P., Defitraces. 2020. 19-926005-004 |
| Flammable gases | Not applicable. | - | The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | Acceptable, the product is not a gas |  |
| Flammable aerosols | Not applicable. | - | The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol this test does not need to be performed. | Acceptable, the product is not an aerosol |  |
| Oxidising gases | Not applicable. | - | The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | Acceptable, the product is not a gas |  |
| Gases under pressure | Not applicable. | - | The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | Acceptable, the product is not a gas |  |
| Flammable liquids | EC 440/2008 No. A.9  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | The flash point of the test item is 83°C (as mean of three measurements).  Since its flash point is higher than 60°C, it is classified as not flammable liquid. | Acceptable  The product is not flammable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Flammable solids | Not applicable. | - | Not relevant as the product is a liquid. | Acceptable, the product is not a solid |  |
| Self-reactive substances and mixtures | Not required. | - | Since the DSC analysis shows no exothermic reactions, the product is not classified as a self-reactive mixture. | Acceptable |  |
| Pyrophoric liquids | Not required. | - | The study does not need to be conducted as based on experience in handling and manufacture of the product, pyrophoric properties are not expected. | Acceptable |  |
| Pyrophoric solids | Not applicable. | - | Not relevant since the product is a liquid. | Acceptable, the product is not a solid |  |
| Self-heating substances and mixtures | Not required. | - | The study does not need to be conducted as the biocidal product is liquid. | Acceptable |  |
| Substances and mixtures which in contact with water emit flammable gases | Not required. | -- | Experience in production, handling and use of the biocidal product shows that the mixture does not react with water. | Acceptable | - |
| Oxidising liquids | O.2 method  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch L099120939 | No mean pressure rise time was obtained with the test item / cellulose mixture.  The test item was not classified as an oxidising liquid of Division 5.1 and thus was not assigned to any packing group, under the experimental conditions used.  According to EC No. 1272/2008 (CLP), the test item was not classified as an oxidizing liquid. | Acceptable  The product is not an oxidizing liquid | Halbwachs P., Defitraces. 2020. 19-926005-004 |
| Oxidising solids | Not applicable. | - | Not relevant since the product is a liquid. | Acceptable, the product is not a solid |  |
| Organic peroxides | Not applicable. | - | The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria | Acceptable, the product is not an organic peroxide |  |
| Corrosive to metals | UN test C.1 from UN-MTC, Section 37.4  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 091599  PEHD bottle | Volume of solution: 1.5L  Specimens of steel tested: steel S235JR+M was used instead of S235JR+CR. the two typologies of steel specimens characterized by the same chemical composition (S235JR) are equivalent for the purposes of the test to be performed  Specimens of aluminium tested: 7075 T6  Size of the specimens: 2mmX1000mmx2000mm  Metal sheets were polished with grinding paper. After removing the remaining grinding with alcohol in an ultrasound bath and degreasing with acetone, the metal were weighed.  The test was initiated the same day to prevent reformation of oxide layer. For each test, one metal specimen was dipped into the solution, another one only half way and a third one was hang in the gas phase.  The test temperature of 55 +/-1°C was maintained throughout the test and monitored. Sheets were exposed at these stable conditions for one week.  After finishing the test, the metal specimens were rinsed of and cleaned.  After final cleaning with alcohol and then acetone in an ultrasound bath, and once dry, the metal samples were weighed.  After 7 days at 55°C±1°C, the corrosion test proved to be negative for specimens (aluminium and steel type sheets) in the gas phase, partially dipped and completely dipped into the solution, since the weight loss showed to be less than 13.5%.  The same results were obtained with both types of metal.  Aluminium (max weight loss = 12,02% w/w with specimen dimensions 2000mmx1000mmx2mm, eq to -0,64 for initial sample weight of 5,34g)  Dipped: weight difference of 0,0001g (-0,0019 %w/w)  Half way: weight difference of 0,0003g (-0,0056 %w/w)  Gas phase: weight difference of 0,0002g (+0,0038 %w/w)  Steel (max weight loss = 12,02% w/w with specimen dimensions 2000mmx1000mmx2mm, eq to -1,77 for initial sample weight of 14,7g)  Dipped: weight difference of 0,0035g (-0,0237 %w/w)  Half way: weight difference of 0,0075g (-0,0509 %w/w)  Gas phase: weight difference of 0,0067g (-0,0454 %w/w)  No sign of localized corrosion occurs and according to UN-MTC Section 37.4, the intrusion depth wa not measured. | Acceptable, the product is not corrosive to metals.  The sizes of the specimens tested are different from the standard ones in the manual (50mm\*20mm\*2mm and diameter of the hole 3mm). eCA has calculated the adjusted maximum % weight loss based on these dimensions. For steel, the maximum loss to classify the product would be approx. 1,77g and for aluminium 0,64g. Results after 7d are always below these limits, meaning that no uniform corrosion is observed.  Pictures of the coupons (aluminium and steel) were provided for initial and tested samples (after 7 days, dipped, half way and in gas phase). No sign of localized corrosion occurs.  The product is not corrosive to metals in the sense of test C.1 from manual UN RTDG. | Fragomeni V., Eurofins Biolab srl. 2019. STULV19AA4472-1. |
| Auto-ignition temperatures of products (liquids and gases) | EC 440/2008 No. A.15  GLP | HC6 EC containing Imidacloprid 2% + Cypermethrin 5%  Batch 090741  PE bottle | The auto-ignition temperature of the test item formulation sample is 332°C. | Acceptable | Nichetti S., Chemservice srl, 2019. CH0567/2019 |
| Relative self-ignition temperature for solids | Not applicable. | - | The relative self-ignition temperature has to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed. | Acceptable, the product is not a solid |  |
| Dust explosion hazard | Not applicable. | - | The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is liquid this test does not need to be performed. | Acceptable, the product is not a powder |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product HC6 EC is not explosive and has no oxidizing properties. The product is not flammable and its auto-ignition temperature is 332°C. The product is not an oxidising liquid. It is not corrosive to metals. |

### Methods for detection and identification

**Analytical method for the determination of imidacloprid active substance in the biocidal product**

Report: HC6 EC: Validation of the Analytical Method for the Determination of the Imidacloprid Active Ingredient Content, S. Nichetti, 2019

Report no CH-0568/2019

Test facility: ChemService S.r.l. Controlli e Ricerche

GLP Studies Department

Via F.lli Beltrami, 15

20026 Novate Milanese - MI - (Italy)

Principle of the method:

Samples are extracted with methanol. The determination of Imidacloprid is performed by HPLC, using an internal standard (ethyl paraben) and UV detector.

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| HPLC column | Sigma-Aldrich or equivalent  Ascentis Phenyl, 5 µm, 250 x 4.6 mm i.d |
| Detector | UV/Vis operating: from 0 to 7 min. at 270 nm ; from 7 to 15 min. at 260 nm |
| Column temperature | Room temperature |
| Eluent A | Water |
| Eluent B | Acetonitrile |
| Eluent D | H3PO4 1 % v/v solution |
| Eluent (gradient) | A:B:D = 50:40:10 for 11 minutes  from A:B:D = 50:40:10 to B:D = 90:10 in 5 minutes  B:D = 90:10 for 4 minutes f  rom B:D = 90:10 to A:B:D = 50:40:10 in 5 minutes  A:B:D = 50:40:10 for 5 minutes |
| Eluent flow | 1.0 mL/min |
| Volume of injection | 10 µL |
| Imidacloprid ret. time | about 5.9 minutes |
| Ethyl paraben ret. time | about 8.7 minutes |
| Total analysis time | 30 minutes |

The validation of this method was considered in compliance with SANCO/3030/99 rev.5.

test item: HC6 EC, batch 090741, imidacloprid 2% w/w, cypermethrin 5.02% w/w placebo HC6 EC batch 240619/1

Test substances:

* imidacloprid technical, 98,2% w/w, batch 182864
* cypermethrin technical (40:60), 93.3% w/w, batch BCMT18K184

Reference substances

* imidacloprid pestanal, 100% w/w, batch BCBT2267
* ethyl paraben (internal standard), 99.9% w/w, batch STBB6758V

Validation data:

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| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (methanol) * Ethyl paraben internal standard * Imidacloprid reference material * Placebo * Test item of the product   No interference was found: no peak appears in the solvent blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available.  The analytical method was shown to be specific for Imidacloprid active ingredient in the HC6 EC formulation samples | |
| Linearity | Calibration appropriate to the nominal concentration.  range ± 20% in relevant analytical solutions.  - single determinations at 5 concentrations. | |
| 31.20 to 72.80 µg/mL (eq to 1,20 – 2,81 % w/w) Y = 0.9383 X + 0.0183 R>0.99  n = 5 | |
| Precision | Repeatability was evaluated by analyzing five test item solutions once  Horrat value < 1 : acceptable | |
| Compound | Repeatability (RSD) |
| Imidacloprid (2.03% w/w) | Mean = 2,03 % w/w (n=5)  RSD = 0.64%  Horwitz RSDr = 2.41 %  Horrat value = 0.26 |
| Accuracy | 2 independent recovery determination spiked twice (two weights). Placebo was fortified with technical imidacloprid at 2% w/w. Total recovery calculation was used.  Each recovery value in the range 90 to 110 % for active ingredient content between 1.0 % w/w and 10 % w/w  Recovery spike A = 100.10% (n=1)  Recovery spike B = 99.38% (n=1) | |

The analytical method is fully validated for the determination of the active substance imidacloprid in the product.

**Analytical method for the determination of cypermethrin active substance in the biocidal product**

Report: HC6 EC: Validation of the Analytical Method for the Determination of the Cypermethrin Active Ingredient Content, S. Nichetti, 2019

Report no CH-0569/2019

Test facility: ChemService S.r.l. Controlli e Ricerche

GLP Studies Department

Via F.lli Beltrami, 15

20026 Novate Milanese - MI - (Italy)

Principle of the method:

Samples are diluted with 2-propanol and place in an ultrasonic bath for 3 minutes then diluted with eluent. The determination of cypermethrin is performed by HPLC, using an internal standard and UV detector.

|  |  |
| --- | --- |
| HPLC column | Zorbax RX-SIL, 150 x 4.60 mm i.d., 5.0 µm |
| Detector | UV/Vis operating at 278 nm |
| Column temperature | 35.0°C |
| Eluent A | iso octane/ethyl acetate at 99.5/0.5 % v/v |
| Eluent (gradient) isocratic | 100% of Eluent |
| Eluent flow | 2.0 mL/min |
| Volume of injection | 10 µL |
| R. T. Cypermethrin Cis I | about 8.2 minutes |
| R. T. Cypermethrin Cis II | about 9.4 minutes |
| R. T. Cypermethrin Trans I | about 11.5 minutes |
| R. T. Cypermethrin Trans II | about 13.2 minutes |
| Total Analysis Time | 35 minutes |

test item: HC6 EC, batch 090741, imidacloprid 2% w/w, cypermethrin 5.02% w/w

placebo HC6 EC batch 240619/1

tests substances:

* imidacloprid technical, 98.2% w/w, batch 182864
* cypermethrin technical (40:60), 93.3% w/w, batch BCMT18K184

reference substances

* cypermethrin pestanal, 95.2% cypermethrin, 48.9% cis isomer, 46.3% trans isomer, batch BCBT2496

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Blank (eluent with 10 % v/v of 2-propanol) * Cypermethrin reference material * Placebo * Test item of the product   Cypermethrin active ingredient peaks were well separated and interferences with the Placebo peak were not evidenced.  Therefore, by using the conditions stated in the method, interferences can be avoided and the active ingredient can be reliably determined in test item formulation samples. The analytical method was shown to be specific for Cypermethrin active ingredient in the HC6 EC formulation samples | |
| Linearity | Calibration appropriate to the nominal concentration.  range ± 20% in relevant analytical solutions.  - single determinations at 5 concentrations. | |
| Compound | Linearity % |
| Cypermethrin | 57.12 to 342.72 µg/mL (eq to 1.43 – 8.57 %w/w) Y = 16503 X - 86540 R> 0.99  n = 5 |
| Cypermethrin Cis isomer | 29.34 to 176.04 µg/mL (eq to 0,73- 4.40% w/w) Y = 16453 X - 39290 R>0.99  n = 5 |
| Cypermethrin Trans isomer | 27.78 to 166.68 µg/mL (eq to 0,69-4.17 %w/w) Y = 16557 X - 47251 R>0.99  n = 5 |
| Precision | Repeatability was evaluated by analyzing five test item solutions. Horrat value < 1 | |
| Compound | Repeatability (RSD) |
| Cypermethrin (4.75% w/w) | Mean = 4.75%w/w (n=5)  RSD = 0.52%  Horwitz RSDr = 2.12 %  Horrat = 0.25 |
| Cypermethrin Cis isomer (1.93% w/w) | Mean = 1.93%w/w (n=5)  RSD = 0.52%  Horwitz RSDr = 2.43 %  Horrat =0.21 |
| Cypermethrin Trans isomer (2.81% w/w) | Mean = 2.81%w/w (n=5)  RSD = 0.54%  Horwitz RSDr = 2.29 %  Horrat =0.24 |
| Accuracy | At least 2 independent recovery determination (two weights).  Placebo was fortified with technical cypermethrin at 5.35% w/w. Total recovery calculation was used.  Each recovery value in the range 90 to 110 % for active ingredient content between 1.0 % w/w and 10 % w/w  Recovery spike A = 94.72% (n=1)  Recovery spike B = 94.93% (n=1) | |
| Isomer ratio | Cis/trans : 40.6/59.2 (based on mean contents for precision, obtained with biocidal product containing technical active ingredients) | |

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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** |
| Imidacloprid | HPLC-UV | Two samples were used as fortification range.  Each sample was measured twice. | Five concentration levels over the range 31.20 to 72.80 µg/mL (eq to 1,20 – 2,81 % w/w) were measured.  Each concentration was measured once.  Correlation coefficient: 0.99997 | Placebo was analysed  No interference was found: no peak appears in the solvent blank, one peak is observed at the same retention time for the reference item and test item | Mean Recovery = 99.74 % (n=2, fortification level =2%w/w)  Precision:  Mean = 2,03 % w/w (n=5)  RSD = 0.64%  Horwitz RSDr = 2.41 %  Horrat value = 0.26 | - | S. Nichetti, 2019  Report no CH-0568/2019 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
| Cypermethrin | HPLC-UV | Two samples were used as fortification range.  Each sample was measured twice. | Five concentration levels over the range 57.12 – 342.72 µg/mL (eq to 1.43 – 8.57 %w/w) were measured.  Each concentration was measured once. Correlation coefficient: 0.99993 | Cypermethrin active ingredient peaks were well separated and interferences with the Placebo peak were not evidenced | Mean Recovery = 94.8 % (n=2, fortification level=5.35% w/w)  Precision  cypermethrin  Mean = 4.75%w/w (n=5)  RSD = 0.52%  Horwitz RSDr = 2.12 %  Horrat = 0.25  Cis isomer  Mean = 1.93%w/w (n=5)  RSD = 0.52%  Horwitz RSDr = 2.43 %  Horrat =0.21  Trans isomer  Mean = 2.81%w/w (n=5)  RSD = 0.54%  Horwitz RSDr = 2.29 %  Horrat =0.24 | - | Content, S. Nichetti, 2019  Report no CH-0569/2019 |
| Cypermethrin Cis isomer | Five concentration levels over the range 29.34 – 176.04 µg/mL (eq to 0,73- 4.40% w/w) were measured.  Each concentration was measured one. Correlation coefficient: 0.99991 |
| Cypermethrin Trans isomer | Five concentration levels over the range 27.78 – 166.68 µg/mL (eq to 0,69-4.17 %w/w) were measured.  Each concentration was measured once. Correlation coefficient: 0.99994 |

**Analytical method for the determination of imidacloprid residues**

Analytical methods for the determination of imidacloprid residues in soil, water and air have previously been evaluated at EU level and accepted at active substance approval.

Soil

Liquid Chromatography, using Mass Spectrometry for the determination of Imidacloprid

Limit of quantification (LOQ): 0.005 mg/kg

Air

Liquid Chromatography, using UV detection for the determination of Imidacloprid

Limit of quantification (LOQ): 5 µg/m3

Drinking and Surface Water

Liquid Chromatography, using UV detection for the determination of Imidacloprid

Limit of quantification (LOQ): 0.03 µg/L

**Analytical method for the determination of cypermethrin residues**

Analytical methods for the determination of cypermethrin residues in animal and human body tissues, soil, water and air have previously been evaluated at EU level and accepted at active substance approval.

Food or feedstuffs

Gas Chromatography with Electron Capture Detection (GC-ECD) for the determination of cypermethrin

Limit of quantification (LOQ):

- 0.05 mg/kg for oilseed rape

- 0.025 mg/kg for wheat

Animal and human body tissues

Gaz Chromatography, using Mass Spectrometry (GC-MSD) for the determination of cypermethrin

Limit of quantification (LOQ):

- 0.05 mg/kg for bovine edible tissues (muscle, liver, kidney, fat)

- 0.005 mg/kg for bovine milk

- 0.01 mg/kg for hen eggs

Soil

Gaz Chromatography, using Mass Spectrometry (GC-MSD) for the determination of cypermethrin

Limit of quantification (LOQ): 0.05 mg/kg

Air

Gaz Chromatography, using Mass Spectrometry (GC-MSD) for the determination of cypermethrin

Limit of quantification (LOQ): 0.375 µg/m3

Drinking and Surface Water

Gas Chromatography with Electron Capture Detection (GC-ECD), with confirmatory analysis by Gas Chromatography with Mass Spectrometric Detection (GC-MS with negative chemical ionisation) for the determination of cypermethrin

Limit of quantification (LOQ): 0.01 µg/L

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Analytical methods for the determination of imidacloprid and cypermethrin in the formulation are available and validated. The applicant has access to the CAR of the active substances with LoAs and analytical methods for the determination of residues in air are available and validated.  Analytical methods were provided at EU level for the determination of cypermethrin residue in soil, water and air with respectively LOQ = 0.05mg/kg, 0.01µg/L, 0.375µg/m3. Analytical methods were provided at EU level for the determination of imidacloprid residue in soil, water and air with respectively LOQ = 0.005 – 0.01 mg/kg, 0.03 µg/L (surface/drinking water), 0.005 mg/m3.  As the product HC6 EC is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of imidacloprid and cypermethrin residues in food/feed of plant and animal origin is unnecessary.  Imidacloprid and cypermethrin are not toxic (T) or very toxic (T+) active substances. Therefore, an analytical method in biological matrices is not required. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

The biocidal product HC6 EC is an emulsion concentrate (EC), applied by spraying after proper dilution in water. It is intended to be used against crawling insects, indoors, in industrial, commercial and public premises and in private homes, in confined areas not object of wet cleaning up, with a residual efficacy up to 4 weeks.

Application is intended by professional users.

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

The product HC6 EC is intended to be used against crawling insects in order to control their infestation and protect human and their goods.

HC6 EC is used to control the following insects:

Crawling insects including:

* Bed bugs (*Cimex lectularius*), adults and nymphs;
* Cockroaches (*Blattella germanica*, *Blatta orientalis*), adults and nymphs;
* Silverfishes (*Lepisma saccharina*), adults and nymphs;
* Garden ants (*Lasius niger*), workers.

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

Cypermethrin is a synthetic pyrethroid insecticide which act by contact and ingestion.

Pyrethroids should be expected to exert a rapid knockdown efficacy against target species, following by a killing effect. This effect is expected to be shown a few minutes after contact, although may take longer with larger fewer sensitive species.

Imidacloprid is a neonicotinoid which acts on the central nervous system of insects by blockage of the nicotinergic neuronal pathway. This disturbance of the transmission of stimuli leads to paralysis and subsequent death of the target organisms. Imidacloprid acts as a contact insecticide as well as upon ingestion.

#### Mode of action, including time delay

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon.

Imidacloprid is a neonicotinoid which acts on the central nervous system of insects by blockage of the nicotinergic neuronal pathway. This disturbance of the transmission of stimuli leads to paralysis and subsequent death of the target organisms. Imidacloprid acts as a contact insecticide as well as upon ingestion.

#### Efficacy data

The following table summarises the efficacy studies submitted with the product HC6 EC by the applicant.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Spraying application | HC6 EC | *L. niger* | Laboratory trial (no choice test)  According to:  - C.E.B. method No. 135 / 159 | The trial was carried out in a closed room measuring 60 m3  Four types of material (panel of 15 cm x 15 cm) were tested:  synthetic carpet, unpainted wood,  porous side of ceramic tile and  ceramic tiles (non porous side).  The typical surfaces were treated flat and the total surface actually treated was 1 m² to adhere as closely as possible to practical conditions.  The day of treatment (2 hours after in order for the surfaces to be dry), an efficacy test was performed. It consisted of installing the pests on the treated surfaces for a period of one hour.  The residual effect was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels.  The control surfaces did not receive insecticide but the same amount of water.  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  5 replicates  5 replicates of 25 ants per each material type  Temperature:21.4 °C to 21.9 °C  Hygrometry :62 % to 71% RH  Light 700 lux,  Smooth ventilation 1 m3/h | KT100 at D0 and %mortality after 24h   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 30 | 100 | 0 | | wood | 60 | 100 | 0 | | porous tile | 60 | 100 | 0 | | Ceramic tile | 20 | 100 | 0 |   Residual effect after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (h)\* | Mortality (%) | control | | carpet | 4 | 100 | 0 | | wood | 4 | 100 | 0 | | porous tile | 4 | 100 | 0 | | Ceramic tile | 1 | 100 | 0 |   \*KT 100 = time from the beginning of the experiment - including the 1 hour exposure time of the insects onto the treated surfaces  The product showed 100% KD and mortality at D0 and up to 4 weeks after treatment against black ants, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Serrano B. 2018. Study No. 2332-LAB/0518  RI= 1 |
| Spraying application | HC6 EC | *L. niger*  (5 replicates of 25 ants) | Simulated use test | * Direct spray:   The product was applied using a professional sprayer, indoors in cracks and crevices, unreacheable to humans and pets, directly where the presence of ant workers was noticed, under the fridge, the kitchen sinks and behind kitchen skirtings, under the oven and the water-heater, in all cracks and crevices, voids or cavities that can be harbourage of ants.  KD was recorded after treatment every 5 minutes and mortality 24 hours after treatment.   * Residual efficacy:   Tiles of two materials (porous: concrete; non-porous: ceramic tile), treated 4 weeks before and stored inside in controlled climatic conditions, are set on the tracks of wild ants to record the knockdown and mortality. The tiles were placed indoors under the fridge, under the kitchen sinks and behind kitchen skirtings, under the oven and the water-heater, and in other confined places like voids or cavities that can be harbourage of ants  One tile of each material was set on the tracks (one per tile) and this was done in 5 replicates, so the trial was conducted of 1 tile x 5 replicates x 2 materials = 10 tiles.  Knockdown of insects was recorded at regular time until 5 hours. After observation of knockdown, insects were put in glass jars with food and water in order to check mortality 24 hours after treatment  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  The climatic conditions in the laboratory (residual effect) were:  Temperature:22°C +/- 2°C  Relative humidity: 70 +/- 5%,  Photoperiod: 16 hours light (1200 lux) and 8 hours darkness  Smooth ventilation: 1 m3/h  5 replicates (5 nests)  The treatment was not repeated along the trial (only 1 application).  No untreated control was designed in the field but 5 batches of 25 insects were set into the same jars with water and food and monitored until 24 hours to know the possible natural mortality during the trial. | Direct spray:   |  |  |  | | --- | --- | --- | | Treatment | KT100 (min) | Mortality (%) | | HC6 EC | < 5 | 100 | | Control | - | 2 |   Residual efficacy after 4 weeks of treatment   |  |  |  |  | | --- | --- | --- | --- | | surface | KT100 (h)\* | Mortality (%) | Control (%) | | porous | 1 | 100 | 0 | | Non-porous | 5 | 100 | 2 |   \*Time to see 50 knowkdown-ed insects in the 1 m² grid  The product showed 100% mortality after 24 h of direct spray in field and up to 4 weeks after treatment in laboratory against black ants, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Serrano B. 2018. Study No. 2332-FIELD /0518  RI = 2 |
| Spraying application | HC6 EC | *Lasius niger* | Field trial | The product was applied indoors, in confined areas not object of wet cleaning where ant presence was noticed, like: holes/crevices at the base of walls and floor from where the ants are entering the house (but not wet cleane, cracks between pipes and wall, on all cracks and crevices that can be an harbourage for ants but not-wet cleaned areas (i.e., skirtings, behind electrical sockets, etc).  The sites are chosen according to the following requirements: - Indoors, in confined areas not object of wet cleaning Significant activity of the ants (> 20 ants during the pre-count)  - Availability of the access along the trial (no other treatment)  5 sites were monitored per factor = 5 sites treated by the product and 5 untreated sites to be used as controls  The application was done using a professional sprayer at 50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  The assessment was the measure of the frequency of ant’s passage on their tracks BEFORE and AFTER the treatment.  The criteria was the FCS = Frequency of Crossing in Surface. The FCS was measured by counting the number of ants moving in a defined place and always in the same place along the trial. The observation was done in a grid of 0.5 m² set on the tracks and paths of the ants in the house.  The number of ants was recorded always in the same area at each assessment date in the morning (more activity) and always at the same hour of the day (10 am). The duration of this assessment was 5 minutes, and the count was done only one time (this was not a dynamic count along time, this was a kind of “photo shoot” of the number of ants walking around at each date). 6 assessments were done: 7 and 1 day before treatment: it gives the mean of the activity BEFORE treatment And 1, 2, 3 and 4 weeks AFTER treatment. | Percentages of reductions of ant population after treatment in comparison with pre-count   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site (pre-count\*) | W1 | W2 | W3 | W4 | | 1 (54) | 88.9 | 100 | 100 | 100 | | 2 (37) | 100 | 100 | 100 | 100 | | 3 (31) | 100 | 100 | 100 | 100 | | 4 (95) | 100 | 100 | 100 | 100 | | 5 (34) | 94.1 | 100 | 100 | 100 | | Control (44.8)\*\* | 5.6 | 2.5 | -7.8 | -9.9 |   W: week  \*pre-count = mean of Day -5 and Day – 3  \*\*: mean of 5 untreated sites  The product showed 90% reduction population of ants after 1 weeks and up to 100% within 2/4 weeks after treatment, on all sites at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Serrano B. 2021. Study No. 2644-ANT/0221  RI = 1 |
| Spraying application | HC6 EC | *B. germanica* (20 adults: 10 males + 10 females);  *B. orientalis* (20 adults : 10 males + 10 females);  *C. lectularius* (20 adults: 10 males + 10 females of susceptible- and resistant-pyrethroid strains) | Laboratory trial (no choice test)  According to:  - C.E.B. method No. 135 / 159 | The trial was carried out in a closed room measuring 60 m3  Four types of material (panel of 15 cm x 15 cm) were tested:  synthetic carpet, unpainted wood,  porous side of ceramic tile and  ceramic tiles (non porous side).  The typical surfaces were treated flat and the total surface actually treated was 1 m² to adhere as closely as possible to practical conditions.  The day of treatment (2 hours after in order for the surfaces to be dry), an efficacy test was performed. It consisted of installing the pests on the treated surfaces for a period of one hour.  The residual effect was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels.  The control surfaces did not receive insecticide but the same amount of water.  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  5 replicates  Temperature:21.6 °C to 22 °C  Hygrometry :61 % to 72% RH  Light 700 lux,  Smooth ventilation 1 m3/h | German cockroaches:  KT100 at D0 and %mortality after 24h   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 10 | 100 | 0 | | wood | 10 | 100 | 0 | | porous tile | 10 | 100 | 0 | | Ceramic tile | 10 | 100 | 0 |   Residual effect after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 30 | 100 | 0 | | wood | 30 | 100 | 0 | | porous tile | 30 | 100 | 0 | | Ceramic tile | 30 | 100 | 0 |   \*KT 100 = time from the beginning of the experiment - including the 1 hour exposure time of the insects onto the treated surfaces  Oriental cockroaches:  KT100 at D0 and %mortality after 24h   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min) | Mortality (%) | control | | carpet | 10 | 100 | 0 | | wood | 10 | 100 | 0 | | porous tile | 10 | 100 | 0 | | Ceramic tile | 10 | 100 | 0 |   Residual effect after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 30 | 100 | 0 | | wood | 30 | 100 | 0 | | porous tile | 30 | 100 | 0 | | Ceramic tile | 30 | 100 | 0 |   The product showed 100% KD and mortality at D0 and up to 4 weeks after treatment against German and oriental cockroaches, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface.  Bed bugs pyrethroid-susceptible strain  KT100 at D0 and %mortality after 24h   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 10 | 100 | 0 | | wood | 10 | 100 | 0 | | porous tile | 10 | 100 | 0 | | Ceramic tile | 10 | 100 | 0 |   \*KT 100 = time from the beginning of the experiment - including the 1 hour exposure time of the insects onto the treated surfaces  Residual effect after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 30 | 100 | 0 | | wood | 30 | 100 | 0 | | porous tile | 30 | 100 | 0 | | Ceramic tile | 30 | 100 | 0 |   \*KT 100 = time from the beginning of the experiment - including the 1 hour exposure time of the insects onto the treated surfaces  Bed bugs pyrethroid-resistant strain  KT100 at D0 and %mortality after 24h   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 10 | 100 | 0 | | wood | 10 | 100 | 0 | | porous tile | 10 | 100 | 0 | | Ceramic tile | 10 | 100 | 0 |   Residual effect after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | Surface | KT100 (min)\* | Mortality (%) | control | | carpet | 30 | 100 | 0 | | wood | 30 | 100 | 0 | | porous tile | 30 | 100 | 0 | | Ceramic tile | 30 | 100 | 0 |   \*KT 100 = time from the beginning of the experiment - including the 1 hour exposure time of the insects onto the treated surfaces  The product showed 100% KD and mortality at D0 and up to 4 weeks after treatment against pyrethroid-susceptible and resistant bed bugs, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Serrano B. 2019. Study No. 2450-LAB/0419  RI = 1 |
| Spraying application | HC6 EC | *Cimex lectularius*  *Adults and nymphs*  (5 replicates) | Field trial | The test was conducted in hotel rooms infested by bed bugs (15 bedbugs trapped overnight is a minimum to consider a site as a testable unit).  Two precounts were made with sticky traps, at Day - 5 and Day - 3: the mean of these values give the pre-treatment infestation level (10 trap settled by site).  The product was applied using a professional sprayer in the preferred insect’s locations (and unreachable to humans and pets) as: on the bed base, under the bed, under the night tables and on all cracks and crevices that can be a harborage for bedbugs around the bed (i.e. skirtings, behind electrical sockets, etc).  The product was applied in 5 different sites to control natural infestations of bed bugs in hotel rooms.  The efficacy was monitored with sticky traps until 4 weeks after treatment (traps were distributed always in the same places and retrieved one night later at the same hour of the day).  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  The inside climatic conditions recorded (by a data logger) were:  - from 22 to 26 °C  - from 63 to 72% RH  Untreated sites: 50 mL/m² of water  The treatment was not repeated along the trial (only 1 application). | % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (31) | 93.5 | 96.8 | 100 | 100 | | 2 (20) | 100 | 100 | 100 | 100 | | 3 (17) | 100 | 100 | 100 | 100 | | 4 (18) | 94.4 | 94.4 | 94.4 | 100 | | 5 (21) | 100 | 100 | 100 | 100 | | Control (18)\*\* | 6 | -1.7 | 6.1 | 6.7 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed reduction population of bed bugs more than 90% after 1 week and up to 100% within 2/4 weeks after treatment, on all sites at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface.  No residual effect was proven in this field test as 100% of population reduction, required in ECHA guidance Vol II parts B+C (2018), has been achieved after only 4 weeks for site 4. | Serrano B. 2019. Study No. 2450-FTBB/0419  RI = 1 |
| Spraying application | HC6 EC | *B. germanica;*  *B. orientalis* | Field trial | German cockroaches:  The test was conducted in occupied apartments with enough infestation (> 10 insects trapped overnight with sticky traps)  Oriental cockroaches:  The test was conducted in bakeries/bars/restaurants/food storage premises with enough infestation (> 10 insects trapped overnight with sticky traps).  For the two cockroaches species, two pre-counts were made with sticky traps at Day-3 and Day-1: the mean of these values gave the pre-treatment infestation level (5 traps settled by site)  For german cockroaches, only the kitchen was treated (12 m² for all apartments) and for oriental cockroaches only the preferred locations for the cockroaches were treated, usually the room or the part of the site with a water source and/or a heat source (oven, fridges etc).  The quantities of product were previously prepared for each site in relation with its treated area.  The product was applied using a professional sprayer in the preferred insect’s locations (and unreachable to humans and pets) as: under the fridge, under the kitchen sinks and behind kitchen skirtings, under the oven and the water-heater, and in all cracks and crevices, voids or cavities that can be harborage for cockroaches  The efficacy was monitored with sticky traps until 4 weeks after treatment (traps were distributed always in the same places and retrieved one night later at the same hour of the day).  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  5 untreated sites were monitored as controls (natural evolution of the insects' populations)  Untreated : 50 mL/m² of water  The treatment was not repeated along the trial (only 1 application). | German cockroaches:  % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (263) | 93.9 | 97.7 | 98.1 | 99.2 | | 2 (187) | 92.5 | 98.9 | 97.9 | 99.5 | | 3 (302) | 90.1 | 96.4 | 97.4 | 96.7 | | 4 (150) | 85.3 | 98 | 98.7 | 98.7 | | 5 (176) | 95.5 | 100 | 99.4 | 100 | | Control (109)\*\* | 3.6 | -2.8 | -8.4 | -15.1 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed reduction population of german cockroaches more than 90% after 1 to 2 weeks and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface.  Oriental cockroaches  % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (26) | 84.6 | 92.3 | 96.2 | 100 | | 2 (71) | 88.7 | 93 | 91.5 | 87.3 | | 3 (44) | 95.5 | 97.7 | 93.2 | 97.7 | | 4 (35) | 100 | 100 | 100 | 100 | | 5 (39) | 97.4 | 97.4 | 100 | 100 | | Control (32)\*\* | 3.1 | -0.9 | -0.6 | -7.5 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed reduction population of oriental cockroaches more than 90% after 1 to 2 weeks and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Serrano B. 2019. Study No. 2450-FTCO/0419  Supportive data |
| Spraying application | HC6 EC | *B. germanica;*  *B. orientalis* | Field trial | German cockroaches:  The test was conducted in occupied apartments with enough infestation (> 10 insects trapped overnight) with sticky traps  Oriental cockroaches:  The test was conducted in bakeries/bars/restaurants/food storage premises with enough infestation (> 10 insects trapped overnight with sticky traps).  The product was applied using a professional sprayer in confined areas not object of wet cleaning where cockroach presence was noticed, like: - wall boxes of electrical system - behind the skirting boards - in the thin cracks and crevices between furniture - ventilation vents or ducts - in cracks or holes near the water-heater and/or the oven (where wet cleaning is not possible)  The efficacy was monitored with sticky traps until 4 weeks after treatment (traps were distributed always in the same places and retrieved one night later at the same hour of the day).  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces  5 untreated sites were monitored as controls (natural evolution of the insects' populations) | German cockroaches:  % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (169) | 82.8 | 96.4 | 98.8 | 100 | | 2 (301) | 94.7 | 97.7 | 95.3 | 92.4 | | 3 (151) | 95.4 | 98 | 100 | 100 | | 4 (108) | 91.7 | 96.3 | 99.1 | 100 | | 5 (89) | 87.6 | 92.1 | 97.8 | 98.9 | | Control (67)\*\* | 4.1 | -3.3 | -9.4 | -10.4 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed 90%reduction population of german cockroaches after 1/2 weeks and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface.  Oriental cockroaches  % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (28) | 92.9 | 100 | 100 | 100 | | 2 (32) | 100 | 100 | 100 | 100 | | 3 (46) | 97.8 | 91.3 | 100 | 100 | | 4 (53) | 100 | 100 | 100 | 100 | | 5 (31) | 100 | 96.8 | 96.8 | 96.8 | | Control (20)\*\* | -4.4 | -7.7 | -8 | -9.9 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed reduction population of oriental cockroaches more than 90% after 1 week and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface | Serrano B. 2021. Study No. 2644-CO/0221  RI = 1 |
| Spraying application | HC6 EC | *Lepisma saccharina*  (30 silverfishes) | Laboratory trial (no choice test) | The trial was conducted, on two types of material porous and non-porous (wood and ceramic). For each material, 5 trays of 30 silverfishes were treated vs 5 non-treated trays of 30 silverfishes (controls).  The efficacy was proved by counting dead silverfishes at 1, 6, 12, 24 and 48h after their introduction on the treated surface following by a daily monitoring during 7 days with a comparison between treated and non-treated tray.  All specific surfaces were treated on one-side of each material in devices by spraying with a spray bottle containing HC6 EC at 1% and HC6 EC at 2% at the dosage of:  - 1% dilution in crack & crevices on non-porous surface (1L of diluted product to treat 20m2)  - 2% dilution in crack & crevices on porous surface (1L of diluted product to treat 20m2) and left with a drying time of 24h.  The residual effect was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels  Climatic conditions: 26°C ± 1°C and 55% HR ± 10  5 replicates | Mortality at D0 and after 4 weeks   |  |  |  |  | | --- | --- | --- | --- | | surface | Mortality\* (%) at D0 | Mortality (%) at D28 | control | | porous | 100 after 24h | 100 after 48h | 0-6 | | Non-porous | 100 after 24 | 100 after 48h | 0-1 |   The product showed 100% mortality at D0 and up to 28 days after treatment against silverfish, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Guichard A. 2019. Study No. 19ZAPLsLab001  RI = 1 |
| Spraying application | HC6 EC | *Lepisma saccharina* | Field trial | The trials were carried out at 3 test sites, infested with silverfishes causing annoyances to the owners in Lyon (Rhone-Alpes, South West of France).  Two-population monitoring were done using sticky traps, 14 and 7 days before the start of the treatment.  The product was sprayed in cracks and crevices behind skirting, under the kitchen skirting, behind or under the fridge, inside electrical sockets (after having switched-off the voltage), inside of voids, cavities or service vents which should also be closed/sealed after application.  Five series of population monitoring events at separate test sites were performed after treatment under the same conditions as in the pre-test period (similar times, same locations, etc.) by counting silverfishes at the infested areas. The different observation times were at D1, D7, D15, D22 and D30  Dosage:  - 1% dilution in crack & crevices on non-porous surface: 1L of diluted product to treat 20m2  - 2% dilution in crack & crevices on porous surface: 1L of diluted product to treat 20m2  Climatic conditions:  - from 20 to 25 °C  - from 65 to 79% RH | % difference of the 2 monitoring population   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | D1 | D7 | D15 | D22 | D30 | | 1 (11.5) | 65.2 | 82.6 | 100 | 100 | 100 | | 2 (13) | 84.6 | 100 | 100 | 100 | 100 | | 3 (14) | 35.7 | 92.9 | 100 | 100 | 100 |   The product showed more than 90% efficacy after 1 to 2 weeks and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface. | Guichard A. 2019. Study No. 19ZAPLsF001  RI = 1 |
| Spraying application | HC6 EC | *Lepisma saccharina* (adults and nymphs) | Field trial | The test was conducted in sites naturally infested by silverfishes.  Sticky raps were used as a monitoring device.  A site was considered as a testable unit with a minimum pre-count of 15 silverfishes trapped overnight  The product was applied using a professional sprayer in confined areas not object of wet cleaning where silverfish presence was noticed, like:  holes in the wall in warehouses (not containing food), cracks between pipes and wall, on all cracks and crevices that can be an harbourage for silverfishes (i.e. skirtings, behind electrical sockets, etc,).  The efficacy was monitored with sticky traps until 4 weeks after treatment (traps were placed overnight in each site and collected the next morning and returned to the laboratory for processing.)  5 sites were treated with the test product and 5 were monitored as untreated controls.  Dosage:  50 mL/m² of 1% dilution on non-porous surfaces and 2% dilution on porous surfaces | % reduction in comparison with pre-trapping   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Site\* (pre-trapping) | W1 | W2 | W3 | W4 | | 1 (26) | 100 | 100 | 100 | 100 | | 2 (44) | 100 | 100 | 100 | 100 | | 3 (21) | 100 | 100 | 100 | 100 | | 4 (35) | 100 | 100 | 100 | 100 | | 5 (52.5) | 100 | 100 | 100 | 100 | | Control (23.3)\*\* | 8.6 | 13.2 | 3 | -2.1 |   W: week  \*: mean of precounts at D-5 & D-3  \*\*: mean of 5 untreated sites  The product showed 100% reduction population of silverfish after 1 week and up to 4 weeks after treatment, at the application rate of 50 mL/m² of 1% diluted product on non-porous surface and 2 % on porous surface | Serrano B. 2021. Study No. 2644-SF/0221  RI = 1 |

Regarding the efficacy claims against crawling insects including ants, bed bugs and silverfish, laboratory and field tests have been conducted with the product HC6 EC.

* For crawling insects:
* Cockroaches (at the application rate of 50 mL/m² of 1% v/v diluted product on non-porous surface and 2% v/v on porous surface):
* In laboratory test (no choice test), the product HC6 EC showed KT100 in 10 min at D0 and 30 min after 4 weeks, and 100% mortality within 24 hours after the treatment and up to 4 weeks on porous and non-porous surface against *B. germanica* and *B. orientalis* (adults).
* In field test (crack and crevices), the product HC6 EC showed more than 90% mortality against cockroaches (*B. germanica*, *B. orientalis*, stage adults and nymphs), within 1 to 2 weeks and up to 4 weeks after the treatment.

In field test in in confined areas not object of wet cleaning and crack and crevices, the product HC6 EC showed more than 90% mortality against cockroaches (B. germanica, B. orientalis, stage adults and nymphs), within 1/2 weeks and up to 4 weeks after the treatment.

According to the efficacy guidance, for professional users, simulated-use test should be normally provided for claims against cockroaches. Considering the robustness of field tests and demonstration of residual effect both in laboratory (no choice tests) and in field tests, e-CA agree with the applicant to waive it.

* Black ants (at the application rate of 50 mL/m² of 1% v/v diluted product on non-porous surface and 2% v/v on porous surface):
* In laboratory test (no choice test), the product HC6 EC showed KT100 in no more than 1 hour at D0 and 1-4 hours after 4 weeks, depending on the treated surface, and 100% mortality within 24 hours after the treatment and up to 4 weeks on porous and non-porous surface against *L. niger*.
* In simulated use test, the product HC6 EC showed 100% mortality against black ants (*L. niger*), after 24 hours. Residual efficacy of 4 weeks (100% mortality) is demonstrated with 4 week-aged porous and non porous surfaces, inserted in the test.
* In field test in in confined areas not object of wet cleaning and crack and crevices, the product HC6 EC showed more than 90% mortality against black ants (*L. niger*), after 1 to 2 weeks and up to 4 weeks after the treatment.
* Bed bugs (at the application rate of 50 mL/m² of 1% v/v diluted product on non-porous surface and 2% v/v on porous surface):
* In laboratory test (no choice test), the product HC6 EC showed KT100 in 10 min at D0 and 30 min after 4 weeks, 100% mortality within 24 hours after the treatment and up to 4 weeks on porous and non-porous surface against *C. lectularius*.
* In field test (crack and crevices and in confined areas not object of wet cleaning), the product HC6 EC showed more than 90% mortality against bed bugs (*C. lectularius*, stage adults and nymphs), within 1 week and 100% within 2 to 4 weeks after the treatment.
* Silverfish (at the application rate of 50 mL/m² of 1% v/v diluted product on non-porous surface and 2% v/v on porous surface):
* In laboratory test (no choice test), the product HC6 EC showed 100% mortality within 24 and 48 hours respectively after the treatment and up to 28 days on porous and non-porous surface against *Lepisma saccharina*
* In field test (crack and crevices), the product HC6 EC showed more than 90% mortality against silverfish (*Lepisma saccharina*, stage adults and immature), within 1 week and up to 4 weeks after the treatment.
* In field test in in confined areas not object of wet cleaning and crack and crevices, the product HC6 EC showed more than 90% mortality against silverfish (*Lepisma saccharina*, stage adults and immature), within 1 week and up to 4 weeks after the treatment.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities consider that the elements submitted in the dossier demonstrated the efficacy of the product HC6 EC indoors, in confined areas not object of wet cleaning.at the application rate of 50 mL /m² of 1% v/v diluted product for non-porous surface and 2 % v/v for porous surface against crawling insects :   * Cockroaches (*B. germanica* and *B. orientalis*) adults and nymphs * Black ants (*L. niger*) * Silverfish (*Lepisma saccharina*) adults and nymphs * Bed bugs (*C. lectularius*) stage adults and nymphs   The product has a residual efficacy up to 4 weeks against ants, cockroaches and silverfish. |

#### Occurrence of resistance and resistance management

Imidacloprid

Enhanced detoxification mediated by cytochrome-P450-dependent monooxygenases appears to be the major mechanism.

Resistance phenomena to imidacloprid have been reported in particular for cockroaches[[5]](#footnote-6) and bedbugs[[6]](#footnote-7) in studies available in scientific literature.

Cypermethrin

Cypermethrin belongs to the pyrethroid family. Resistance phenomena to cypermethrin have been reported in particular in cockroaches[[7]](#footnote-8) and bedbugs[[8]](#footnote-9) in studies available in scientific literature.

Therefore the applicant should implement a monitoring of scientific literature related to the resistance of the target organisms (notably cockroaches and bedbugs) to the active substances imidacloprid and cypermethrin and provide an assessment of this monitoring at the renewal of the authorisation.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

#### None

#### Evaluation of the label claims

#### See Efficacy conclusion

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

#### The product is not intended to be used with other biocidal products

### Risk assessment for human health

No toxicological studies have been submitted for the product HC6 EC.

The classification of the product has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Causes eye irritation |
| Justification for the value/conclusion | The concentration of one of the co-formulants, propylene carbonate is above the threshold value of 10% for classification as Category 2 Eye Irritant. |
| Classification of the product according to CLP | The product HC6 EC is classified as Eye Irrit. 2; H319, according to the CLP criteria. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value / Conclusion | Not irritating for the respiratory tract. |
| Justification for the conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Skin sensitization***

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising for the respiratory tract |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by dermal route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via dermal route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Information on dermal absorption***

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Imidacloprid | Cypermethrin |
| Value(s) | 70% | 25% (concentrate)  70% (in-use dilutions) |
| Justification for the selected value(s) | Default dermal absorption value for emulsifiable concentrate with a concentration in active substance below 5%, based on the EFSA guidance on dermal absorption (2017) | Default dermal absorption value for emulsifiable concentrate with a concentration in active substance above 5% for the concentrated product and below 5% for the in-use dilutions, based on the EFSA guidance on dermal absorption (2017) |

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

According to the definition of Substance of Concern (SoC) laid down in the *Guidance on the BPR for Human Health Assessment & Evaluation, volume III Part B+C (2017)*, the product HC6 EC contains two SoCs.

Indeed, propylene carbonate is considered a SoC, as it is present in the product in sufficient concentration to trigger the classification of the product as Eye Irritant Cat. 2 (H319) by itself. Taking into account the classification of the product, a Band A is assigned to the substance, leading to the application of P-statements normally associated with the concerned H-statements.

(2-methoxymethylethoxy)propanol (DPM) is a substance for which a Community and international workplace exposure limit is associated. Since the product is used by professional users and inhalation exposure is expected, this substance is considered as SoC, a Band C is assigned, and a quantitative inhalation risk assessment against the IOELV (Indicative Occupational Exposure Limit Values) is performed.

Please refer to the Confidential Annex for further information.

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

Not relevant.

***Other***

Not relevant.

#### Exposure assessment and risk characterisation

The product HC6 EC is used by professionals. It is applied by spraying indoor in confined areas not object of wet cleaning where insects hide and walk.

For common bedbugs treatment, the product is applied in particular under bed and night table structures, furniture, around pictures, window and door frames, behind skirtings, boards and electrical sockets (after switching off the electricity).

For cockroach, silverfish and ant treatment, the product is applied in particular in damp and warm indoor areas, such as cellars, garages, ventilation vents and ducts, wall boxes of electrical system and behind the skirting boards.The product is to be diluted manually in water before use at 1% for application on non-porous surfaces and at 2% for application on porous surfaces. The 2% dilution rate is considered the worst-case scenario and the only one taken into account in the risk assessment.

Secondary exposure may occur from the toddler crawling into the room after the application.

The product contains two active substances: Imidacloprid and Cypermethrin.

According to the Assessment Report of Imidacloprid and Cypermethrin (respectively Germany, 2011, and Belgium, 2017), both active substances are characterised by systemic effects observed in toxicity studies. Consequently, a quantitative risk assessment for systemic effects is performed for the biocidal product for dermal, inhalation and oral routes when relevant.

A combined risk assessment is also provided for Imidacloprid and Cypermethrin contained in the product.

For the substance of concern DPM, a quantitative inhalation risk assessment against the IOELV (Indicative Occupational Exposure Limit Values) of 308 mg/m3 is performed.

As the product is classified as Eye irritant Cat 2 (H319), a qualitative assessment for local effects is also performed, only for the mixing and loading task. Indeed, after dilution, the product is no longer classified, therefore a qualitative assessment for local effects during the application, the post-application and the secondary exposure is no longer necessary.

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

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

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Mixing and loading | Primary exposure  The professional user dilutes the product into water. | Professionals |
| 2. | Application by spraying | Primary exposure  The professional user applies the diluted product by spraying. | Professionals |
| 3. | Post-application | Primary exposure  After the application, the professional user cleans the spray equipment. | Professionals |
| 4. | Crawling on the floor and hand-to-mouth transfer | Secondary exposure  Toddlers (worst-case) can be exposed to the diluted product after the application by crawling onto the treated floor and by hand-to-mouth transfer. | General public (infants) |

Reference values to be used in Risk Characterisation – Imidacloprid

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute neurotoxicity, supported by dog, 28-d (acute effects) | 100 | / | 0.4 mg/kg/d |
| AELmedium-term | Rat, 2-gen., supported by dog, 90-d and rabbit, developmental | 100 | / | 0.2 mg/kg/d |
| AELlong-term | Rat, 2-years | 100 | / | 0.06 mg/kg/d |
| ARfD | Not relevant | | | |
| ADI | Not relevant | | | |

Reference values to be used in Risk Characterisation – Cypermethrin

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute delayed neurotoxicity, oral behavioural effects | 100 | 44% | 0.088 mg/kg/d |
| AELmedium-term | Dog, 90-d, oral | 100 | 44% | 0.055 mg/kg/d |
| AELlong-term | Rat, 2-years, oral | 100 | 44% | 0.022 mg/kg/d |
| ARfD | Not relevant | | | |
| ADI | Not relevant | | | |

***Industrial exposure***

Not relevant

***Professional exposure***

*Scenario [1] – Mixing and loading*

| **Description of Scenario [1] – Mixing and loading** | | | |
| --- | --- | --- | --- |
| Before use, the product is to be diluted manually in water at 1% for application on non-porous surfaces and at 2% for application on porous surfaces.  According to HEEG Opinion 1, the *EUROPOEM II* model is the most relevant to assess the mixing and loading of product up to 20 L.  The exposure value from the model is as follow:   * 8 mg/kg as (hand); * 1.95 mg/kg as (body); * 0.003 mg/kg as (inhalation).   The 2% dilution rate is considered the worst-case scenario, meaning that 400 mL of product is handled for a maximum volume of diluted product of 20L (2% x 20L).  Exposure via dermal and inhalation route are expected. For dermal route, a qualitative local risk assessment is performed as the product is classified. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of active substance (imidacloprid) | 2.04% w/w | Applicant’s data |
| Concentration of active substance (cypermethrin) | 5.43% w/w | Applicant’s data |
| Concentration of SoC (DPM) | 17% w/w | Applicant’s data |
| Body weight | 60 kg | Ad Hoc Recommendation 14 |
| Density of product | 1.0937 | Applicant’s data |
| Volume of product handled | 400 ml | See calculation above |
| **Dermal exposure** | | | |
| Tier 1 | Dermal exposure value (hands) | 8 mg/kg as | HEEG Opinion 1 (EUROPOEM II database) |
| Dermal exposure value (body) | 1.95 mg/kg as | HEEG Opinion 1 (EUROPOEM II database) |
| Dermal absorption (imidacloprid) | 70% | Default value according to EFSA Guidance 2017 |
|  | Dermal absorption (cypermethrin) | 25% | Default value according to EFSA Guidance 2017 |
| **Inhalation exposure** | | | |
| Tier 1 | Inhalation exposure value | 0.0003 mg/kg as | HEEG Opinion 1 (EUROPOEM II database) |
| Exposure duration | 10 min | BHHEM |
| Inhalation rate | 1.25 m3/h | Ad Hoc Recommendation 14 |
| Inhalation absorption | 100% | Default value |

**Calculations for Scenario [1]**

Imidacloprid

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [1] | 1/ No PPE | 4.46x10-7 | 1.04x10-3 | nr | 1.04x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [1] | 1/ No PPE | 1.19x10-6 | 9.85x10-4 | nr | 9.86x10-4 |

DPM

| **Summary table: estimated exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [1] | 1A/ No PPE | 1.07x10-3 |

*Scenario [2] – Application by spraying*

| **Description of Scenario [2] – Application by spraying** | | | |
| --- | --- | --- | --- |
| After the dilution in water, the product is sprayed by the professional user indoor in confined areas where insects hide and walk.  To assess the exposure during the application, RISKOFDERM and ART models are used. Indeed, according to the Recommendation 3 of the Ad Hoc Working Group (Spraying models for assessing exposure to insecticides for low pressure downward uses), the use of the *Spraying model 1* would be an overestimation for this type of application and a combination of values from RISKOFDERM and ART models are considered more appropriate for the dermal and inhalation exposure.  For dermal exposure, the 75th percentile from RISKOFDERM seems to be reasonable for exposure estimates, with different values depending on the application rate (between 0.35 and 3 L/min):   * For an application rate of 0.35 L/min:   + 25.6 mg bp/min (hands)   + 89.4 mg bp/min (body) * For an application rate of maximum 3 L/min:   + 56.2 mg bp/min (hands)   + 354 mg bp/min (body)   In TIER A, the assessment is performed with the highest dilution of the product (2%). An application rate of 3 L/min is first assumed as a worst-case and the calculations are made with the corresponding values from the models.  A second refinement (TIER B) is proposed, which involves a restriction in the spray application rate. Indeed, calculations are made using the exposure values from the models for an application rate of 0.35 L/min.  In TIER A and B, a duration of exposure of 120 min is used for the exposure assessment, which is the default value set for this type of use.  In a TIER C, a reverse scenario is performed to calculate the maximum application duration so as not to exceed the long-term AEL, with the highest flow rate (3 L/min).  In Tier 1, it is assumed that the professional user does not wear PPE. In Tier 2, suitable PPE are taken in account (gloves and impermeable coverall).  For inhalation exposure, a default value of 12 mg bp/m3 from ART model is proposed, independent from the spraying application rate and the dilutions.  The concentrations of active substances and SoC in the 2% dilution (worst-case) are:   * Imidacloprid: 0.0446% (2% x 2.04% x 1.0937) * Cypermethrin: 0.1188% (2% x 5.43% x 1.0937) * DPM: 0.37% (2% x 17% x 1.0937) | | | |
|  | Parameters | Value | Justification |
| **Tier 1**  Without PPE |  | | |
|  | Concentration of active substance (imidacloprid) | 0.0446% w/w | Applicant’s data |
| Concentration of active substance (cypermethrin) | 0.1188% w/w | Applicant’s data |
| Concentration of SoC (DPM) | 0.37% w/w | Applicant’s data |
| Density of the product | 1.0937 | Applicant’s data |
| Inhalation exposure value | 12 mg/m3 | Ad hoc Recommendation 3 |
| Inhalation rate | 1.25 m3/h | Ad Hoc Recommendation 14 |
| Body weight | 60 kg | Ad Hoc Recommendation 14 |
| Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| Inhalation absorption | 100% | Default value |
| TIER A – max 3 L/min spraying application rate | Dermal exposure value (hands) | 56.2 mg/min bp | Ad hoc Recommendation 3 |
| Dermal exposure value (body) | 354 mg/min bp | Ad hoc Recommendation 3 |
| TIER B – 0.35 L/min spraying application rate | Dermal exposure value (hands) | 25.6 mg/min bp | Ad hoc Recommendation 3 |
| Dermal exposure value (body) | 89.4 mg/min bp | Ad hoc Recommendation 3 |
| TIER A and B | Duration of exposure | 120 min | Default value from BHHEM (p.79) |
| TIER C | Duration of exposure | 50 min | Reverse scenario |
| **Tier 2**  Gloves and impermeable coverall | Protection factor for gloves | 90% | HEEG Opinion 9 |
| Protection factor for impermeable coverall | 95% | HEEG Opinion 9 |

**Calculations for Scenario [2]**

Imidacloprid

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **TIER A – Spraying max 3 L/min** | | | | | |
| Scenario [2] | 1A/ No PPE | 2.23x10-4 | 2.56x10-1 | nr | 2.56x10-1 |
| 2A/ Gloves + impermeable coverall | 2.23x10-4 | 1.46x10-2 | nr | 1.48x10-2 |
| **TIER B – Spraying 0.35 L/min** | | | | | |
| Scenario [2] | 1B/ No PPE | 2.23x10-4 | 7.18x10-2 | nr | 7.21x10-2 |
| 2B/ Gloves + impermeable coverall | 2.23x10-4 | 4.39x10-3 | nr | 4.61x10-3 |
| **TIER C –Spraying 3 L/min – 50 min** | | | | | |
| Scenario [2] | 1C/ No PPE | 9.30x10-5 | 1.07x10-1 | nr | 1.07x10-1 |
|  | 2C/ Gloves + impermeable coverall | 9.30x10-5 | 6.07x10-3 | nr | 6.16x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **TIER A – Spraying max 3 L/min** | | | | | |
| Scenario [2] | 1A/ No PPE | 5.94x10-4 | 6.82x10-1 | nr | 6.83x10-1 |
| 2A/ Gloves + impermeable coverall | 5.94x10-4 | 3.88x10-2 | nr | 3.94x10-2 |
| **TIER B – Spraying max 0.35 L/min** | | | | | |
| Scenario [2] | 1B/ No PPE | 5.94x10-4 | 1.91x10-1 | nr | 1.92x10-1 |
| 2B/ Gloves + impermeable coverall | 5.94x10-4 | 1.17x10-2 | nr | 1.23x10-2 |
| **TIER C – Spraying 3 L/min – 50 min** | | | | | |
| Scenario [2] | 1C/ No PPE | 2.47x10-4 | 2.84x10-1 | nr | 2.84x10-1 |
|  | 2C/ Gloves + impermeable coverall | 2.47x10-4 | 1.62x10-2 | nr | 1.64x10-2 |

DPM

| **Summary table: estimated exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure (mg/m3)** |
| Scenario [2] | 1/ No PPE | 4.46x10-2 |

*Scenario [3] – Post-application – Cleaning of spray equipment*

| **Description of Scenario [3] – Post-application – Cleaning of spray equipment** | | | |
| --- | --- | --- | --- |
| After the application, the professional user can be exposed to the diluted product during the cleaning of the spray equipment.  Dermal exposure during this task is assessed using the *BEAT scenario Cleaning of the spray equipment*.  The exposure values from the model are as follow:   * 35.87 µl/min bp (hand) * 19.28 µl/min (body)   The concentrations of active substances in the dilution are:   * Imidacloprid: 0.0446% (2% x 2.04% x 1.0937) * Cypermethrin: 0.1188% (2% x 5.43% x 1.0937)   As exposure by inhalation is not expected during this task, the exposure assessment of the SoC (DPM) is not performed. | | | |
|  | Parameters | Value | Justification |
| **Tier 1**  Without PPE |  | | |
| Concentration of active substance (imidacloprid) | 0.0408% | Applicant’s data |
| Concentration of active substance (cypermethrin) | 0.1086% | Applicant’s data |
| Density of the product | 1.0937 | Applicant’s data |
| Duration | 10 min | Default value |
| Dermal exposure value (hands) | 35.87 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal exposure value (body) | 19.28 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| Body weight | 60 kg | Ad Hoc Recommendation 14 |
| **Tier 2** | Protection factor for impermeable coverall | 95% | HEEG Opinion 9 |
| Protective factor for gloves | 90% | HEEG Opinion 9 |

**Calculations for Scenario [3]**

Imidacloprid

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [3] | 1/ No PPE | nr | 2.87x10-3 | nr | 2.87x10-3 |
|  | 2/ Gloves + impermeable coverall | nr | 2.37x10-4 | nr | 2.37x10-4 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [3] | 1/ No PPE | nr | 7.64x10-3 | nr | 7.64x10-3 |
|  | 2/ Gloves + impermeable coverall | nr | 6.31x10-4 | nr | 6.31x10-4 |

Outcome of systemic exposure and risk characterisation

**Summary table: estimated systemic exposure and risk characterisation for professional users**

* Imidacloprid

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.06 mg/kg bw/d |
| Scenario [1] | 1/ no PPE | nr | 1.04x10-3 | 4.46x10-7 | 1.04x10-3 | 2% |
| Scenario [2] | **TIER A – Spraying max 3L/min** | | | | | |
| 1A/ no PPE | nr | 2.56x10-1 | 2.23x10-4 | 2.56x10-1 | **427%** |
| 2A/ gloves + impermeable coverall | nr | 1.46x10-2 | 2.23x10-4 | 1.48x10-2 | 25% |
| **TIER B – Spraying max 0.35L/min** | | | | | |
| 1B/ no PPE | nr | 7.18x10-2 | 2.23x10-4 | 7.21x10-2 | **120%** |
| 2B/ gloves + impermeable coverall | nr | 4.39x10-3 | 2.23x10-4 | 4.61x10-3 | 8% |
| **TIER C – Spraying 3L/min – 50 min** | | | | | |
| 1C/ no PPE | nr | 1.07x10-1 | 9.30x10-5 | 1.07x10-1 | **178%** |
| 2C/ gloves + impermeable coverall | nr | 6.07x10-3 | 9.30x10-5 | 6.16x10-3 | 10% |
| Scenario [3] | 1/ no PPE | nr | 2.87x10-3 | nr | 2.87x10-3 | 5% |
|  | 2/ gloves + impermeable coverall | nr | 2.37x10-4 | nr | 2.37x10-4 | 0.4% |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022 mg/kg bw/d |
| Scenario [1] | 1/ no PPE | nr | 9.85x10-4 | 1.19x10-6 | 9.86x10-4 | 4% |
| Scenario [2] | **TIER A – Spraying max 3L/min** | | | | | |
| 1A/ no PPE | nr | 6.82x10-1 | 5.94x10-4 | 6.83x10-1 | **3103%** |
| 2A/ gloves + impermeable coverall | nr | 3.88x10-2 | 5.94x10-4 | 3.94x10-2 | **179%** |
| **TIER B – Spraying max 0.35L/min** | | | | | |
| 1B/ no PPE | nr | 1.91x10-1 | 5.94x10-4 | 1.92x10-1 | **872%** |
| 2B/ gloves + impermeable coverall | nr | 1.17x10-2 | 5.94x10-4 | 1.23x10-2 | 56% |
| **TIER C – Spraying 3L/min – 50 min** | | | | | |
| 1C/ no PPE | nr | 2.84x10-1 | 2.47x10-4 | 2.84x10-1 | **1293%** |
| 2C/ gloves + impermeable coverall | nr | 1.62x10-2 | 2.47x10-4 | 1.64x10-2 | 75% |
| Scenario [3] | 1/ no PPE | nr | 7.64x10-3 | nr | 7.64x10-3 | 35% |
|  | 2/ gloves + impermeable coverall | nr | 6.31x10-4 | nr | 6.31x10-4 | 3% |

**Combined scenarios**

Outcome of combined systemic exposure and risk characterisation for primary exposure

**Summary table: combined local exposure and risk characterisation for professional users**

* Imidacloprid

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.06 mg/kg bw/d | **Acceptable (Yes/No)** |
| **TIER A – Spraying max 3L/min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1A/ no PPE | nr | 2.60x10-1 | 2.24x10-4 | 2.60x10-1 | **434%** | **No** |
|  | 2A/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 1.58x10-2 | 2.24x10-4 | 1.61x10-2 | 27% | Yes |
| **TIER B – Spraying max 0.35L/min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1B/ no PPE | nr | 7.58x10-2 | 2.24x10-4 | 7.60x10-2 | **127%** | **No** |
|  | 2B/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 5.66x10-3 | 2.24x10-4 | 5.89x10-3 | 10% | Yes |
| **TIER C – Spraying 3L/min – 50 min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1C/ no PPE | nr | 1.11x10-1 | 9.34x10-5 | 1.11x10-1 | **185%** | **No** |
|  | 2C/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 7.34x10-3 | 9.34x10-5 | 7.44x10-3 | 12% | Yes |

* Cypermethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022 mg/kg bw/d | **Acceptable (Yes/No)** |
| **TIER A – Spraying max 3L/min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1A/ no PPE | nr | 6.91x10-1 | 5.95x10-4 | 6.91x10-1 | **3142%** | **No** |
|  | 2A/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 4.04x10-2 | 5.95x10-4 | 4.10x10-2 | **186%** | **No** |
| **TIER B – Spraying max 0.35L/min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1B/ no PPE | nr | 2.00x10-1 | 5.95x10-4 | 2.00x10-1 | **911%** | **No** |
|  | 2B/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 1.33x10-2 | 5.95x10-4 | 1.39x10-2 | 63% | Yes |
| **TIER C – Spraying 3L/min – 50 min** | | | | | | | |
| Scenarios [1 + 2 + 3] | 1C/ no PPE | nr | 2.93x10-1 | 2.49x10-4 | 2.93x10-1 | **1332%** | **No** |
|  | 2C/ gloves + impermeable coverall (scenarios 2 + 3) | nr | 1.78x10-2 | 2.49x10-4 | 1.80x10-2 | 82% | Yes |

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

The product HC6 EC contains two active substances: Imidacloprid and Cypermethrin.

For both substances, systemic effects have been observed, therefore a combined exposure to both substances is performed according the *Guidance for Human Health Risk Assessment and Evaluation, Volume III, Part B & C (2017)*, as follow:

* Tier 1: risk assessment of substance by substance;
* Tier 2: assessment of combined exposure by concentration addition;
* Tier 3: confirmation of concentration addition, considering common target organs.

The first step (Tier 1) of this approach is to verify acceptability for each substance used in the product. This step corresponds to the comparison of the exposure values to the AEL of each substance and leading to the calculation of Hazard Quotients (HQ).

**HQ= Internal Exposure / AEL**

**If HQ <1**: the risk from the individual components is considered acceptable and the default additivity must be assessed (as outline in Tier 2 below).

**If HQ >1**: the risk from the individual components is not considered acceptable.

In a second step (tier 2), additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index). This assessment is presented only for scenario for which HQ < 1.

**HI=Σ HQa.s.**

**If HI ≤ 1** the risk related to use of the mixture will be considered acceptable;

**If HI > 1** the risk related to use of the mixture will be considered unacceptable and a refinement considering common target organs (Tier 3) could be performed.

If a risk is considered acceptable in Tier 2, Tier 3 is not necessary.

**Tier 1 and Tier 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Primary exposure** | **Imidacoprid** | **Cypermethrin** | **Conclusions** |
| **TIER A - Spraying max 3L/min - Scenarios 1 + 2 + 3** | | | |
| **Without PPE** | |  |  |
| Tier 1 | 434% AEL | 3142% AEL | **Not acceptable** |
| HQ = 4.34 > 1 | HQ = 31.42 > 1 |
| **With gloves and impermeable coverall during the application and the post-application** | | | |
| Tier 1 | 27% AEL | 186% AEL | **Not acceptable** |
| HQ = 0.27 < 1 | HQ = 1.86 > 1 |
| **TIER B - Spraying max 0.35L/min - Scenarios 1 + 2 + 3** | | | |
| **Without PPE** | | | |
| Tier 1 | 127% AEL | 911% AEL | **Not acceptable** |
| HQ = 1.27 > 1 | HQ = 9.11 > 1 |
| **With gloves and impermeable coverall during the application and the post-application** | | | |
| Tier 1 | 10% AEL | 63% AEL | Acceptable |
| HQ = 0.1 < 1 | HQ = 0.63 < 1 |
| Tier 2 | 0.10 | 0.63 | Acceptable |
| HI = 0.73 < 1 | |
| **TIER C - Spraying 3L/min – 50 min - Scenarios 1 + 2 + 3** | | | |
| **Without PPE** | | | |
| Tier 1 | 185% AEL | 1332% AEL | **Not acceptable** |
| HQ = 1.85 > 1 | HQ = 13.32 > 1 |
| **With gloves and impermeable coverall during the application and the post-application** | | | |
| Tier 1 | 12% AEL | 82% AEL | Acceptable |
| HQ = 0.12 < 1 | HQ = 0.82 < 1 |
| Tier 2 | 0.12 | 0.82 | Acceptable |
| HI = 0.94 < 1 | |

Outcome of quantitative local exposure and risk characterisation

**Summary table: estimated local exposure and risk characterisation for professional users**

* DPM

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: estimated local exposure and risk characterisation for professional users** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure**  **[mg/m3]** | **Estimated total exposure [mg/m3]** | **Estimated exposure / AEC**  **(%)**    LTEL = 308 mg/m3 |
| Scenario [1] | 1/ no PPE | 1.07x10-3 | 1.07x10-3 | 0.0003% |
| Scenario [2] | 1/ no PPE | 4.46x10-2 | 4.46x10-2 | 0.01% |

**Outcome of qualitative local risk assessment for professional users:** The product is classifiedEye irritant category 2 H319 for the mixing and loading task. Considering that, a qualitative risk assessment is performed.

After the dilution (2% or 1%), the product is no longer classified and no qualitative local risk assessment is necessary for the application and the post-application tasks.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** |  | **Exposure information** | | |  |  |  | **Risk** |  |
| **Hazard category** | **Effects in**  **terms of C&L** | **PT** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential**  **degree of**  **exposure** | **Relevant**  **RMMs & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)** |
| LOW | Eye Irrit. Cat 2  (H319) | 18 | Mixing & loading | Eye | Frequency: 11 applications per year  Duration: 10 min | Eye exposure through potential splashes or hand to eye transfer | PPE:  - Chemical goggles  Labelling:  - Labelling according to CLP  Professionals:  - Professional workers  - Instructions for use minimising exposure for professionals | Acceptable | (**↓**) Professionals following instructions for use and RMM on the label  (**↓**) Professionals using PPE  (**↓**) Low exposure duration (few minutes per day)  (**↑**) Moderate frequency |

**Conclusion on the risk assessment for human health from systemic and local exposure to both active substances for primary exposure**

For the product HC6 EC, used by professionals by spraying application, the risk is considered acceptable taking into account the active substances (Imidacloprid and Cypermethrin) and the substance of concern (DPM), and a refinement of the spray application duration to 50 min.

With a maximum flow rate application of 3 L/min from the device and the application rate of 50 ml/m² claimed by the applicant, a maximum treated surface of 3000 m² can be calculated as follows:

With:

S = maximum surface that can be treated (m²)

T = duration of exposure (min)

D = application rate from the spraying device, 3 L/min as a worst-case scenario

A = application rate of the product (50 ml/m²)

According to the information presented for the environmental risk assessment, the product can only be applied in “restricted area” due to the high toxicity of cypermethrin for the environment. In this context, as a maximum treated surface of 3000 m2 has been calculated for the human health risk assessment, the risk is deemed acceptable without any additional risk mitigation measure (RMM) on application duration and with the wearing of the following personal protective equipment (PPE):

During handling of the product:

* Chemical goggles
* Gloves and impermeable coverall

***Non-professional exposure***

Not relevant.

***Secondary exposure – Exposure of the general public***

*Scenario [4] – Toddler crawling on the floor and hand-to-mouth transfer*

| **Description of Scenario [4] – Toddler crawling on the floor and hand-to-mouth transfer** | | | |
| --- | --- | --- | --- |
| General public may secondarily be exposed to the diluted product when re-entering the room after the application. Toddlers (considered as the worst-case population) can crawl into the treated premise and be dermally exposed to the treated floor. They also can be orally exposed to the active substance after hand-to-mouth transfer.  The systemic exposure by dermal and oral route is determined using the parameters established in the HEEG Opinion 7 on Choice of secondary exposure parameters for PTs 2, 3 and 4, which can also be used for PT18.  It is indicated that the external dose is calculated as follow:  External dose = Sarea x Fdislod x Wf  Sarea: the total area rubbed during exposure (m²), calculated as the product of the transfer coefficient and exposure duration.  According to the Ad hoc Recommendation 12 “New default values for indoor transfer coefficient”, a transfer coefficient of 2000 cm²/h for infant is proposed.  Fdislog: the amount of product applied on a surface area that may potentially be wiped off per unit of surface area (mg/m²). This factor is dependent on the application rate (50 ml/m² according to the applicant) and the dislodgeable fraction of residues from the surface.  Wf: the weight fraction of active substance in the product.  According to the ConsExpo Pest Control Products Fact Sheet, 10% of the dermal exposure is taken in orally due to hand-to-mouth transfer.  Secondary exposure may also occur by inhalation route with aerosol particles settling during the acute phase of the secondary exposure. However, the active substance CARs already conclude that inhalation exposure (secondary) as a result of use of Imidacloprid and Cypermethrin in the biocidal product is low since vapour pressure of the two active substances is low (according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure >0.01 kPa at 20ºC). Thus, secondary exposure through inhalation is considered negligible.  The concentrations of active substances in the dilution are as follows:   * Imidacloprid: 0.0446% (2% x 2.04% x 1.0937) * Cypermethrin: 0.1188% (2% x 5.43% x 1.0937) | | | |
|  | Parameters | Value | Reference and justification |
| Tier 1 |  | | |
|  | Concentration of active substance (imidacloprid) | 0.0446% w/w | Applicant’s data |
| Concentration of active substance (cypermethrin) | 0.1188% w/w | Applicant’s data |
|  | Density of the product | 1.0937 | Applicant’s data |
|  | Transfert coefficient | 2000 cm²/h | Ad Hoc Recommendation 12 |
| Exposure duration | 1h | Default value. It is supposed that an infant crawls on the floor on hour per day |
| Application rate | 50 mL/m² | Applicant’s data |
| Dislodgeable fraction | 30% | Consexpo Pest Control Product Fact Sheet |
| Dermal absorption | 70% | Default value according to EFSA Guidance 2017 |
| Oral absorption of Imidacloprid | 100% | Default value |
| Oral absorption of Cypermethrin | 57% | Assessment Report of Cypermethrin (2017) |
| Body weight | 10 kg | Ad Hoc Recommendation 14 |

**Calculations for Scenario [4]**

Imidacloprid

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [4] | 1/ No PPE | nr | 9.37x10-2 | 1.34x10-2 | 1.07x10-1 |

Cypermethrin

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/d)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake (mg/kg bw/d)** | **Estimated total uptake (mg/kg bw/d)** |
| Scenario [4] | 1/ No PPE | nr | 2.49x10-1 | 2.03x10-2 | 2.70x10-1 |

**Summary table: estimated systemic exposure and risk characterisation for general public**

* Imidacloprid

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for the general public** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.4 mg/kg bw/d |
| Scenario [4] | 1/ no PPE | 1.34x10-2 | 9.37x10-2 | nr | 1.07x10-1 | 27% |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for the general public** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.088 mg/kg bw/d |
| Scenario [4] | 1/ no PPE | 2.03x10-2 | 2.49x10-1 | nr | 2.70x10-1 | **307%** |

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

A cumulative exposure and risk assessment of both active substances is not required since the assessment of each substance already results in an unacceptable risk.

**Overall conclusion**

For the product HC6 EC, used by professionals by spraying application, the risk is considered acceptable taking into account the active substances (Imidacloprid and Cypermethrin) and the substance of concern (DPM), and a refinement of the spray application duration to 50 min.

With a maximum flow rate application of 3 L/min from the device and the application rate of 50 ml/m² claimed by the applicant, a maximum treated surface of 3000 m² can be calculated as follows:

With:

S = maximum surface that can be treated (m²)

T = duration of exposure (min)

D = application rate from the spraying device, 3 L/min as a worst-case scenario

A = application rate of the product (50 ml/m²)

According to the information presented for the environmental risk assessment, the product can only be applied in “restricted area” due to the high toxicity of cypermethrin for the environment. In this context, as a maximum treated surface of 3000 m2 has been calculated for the human health risk assessment, the risk is deemed acceptable without any additional risk mitigation measure (RMM) on application duration and with the wearing of the following personal protective equipment (PPE):

During handling of the product:

* Chemical goggles
* Gloves and impermeable coverall

Secondary exposure for infants crawling on the treated floor is not considered acceptable considering the quantitative risk assessment for the Cypermethrin.

However, since the product is supposed to be applied on specific areas difficult to access for infants (under furniture and near frames), the risk is considered acceptable taking into account the following risk mitigations measures (RMM):

* For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.

***Monitoring data***

Not relevant

***Dietary exposure***

The product must be kept away from food, drink and animal feedstuffs. The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions.

The product does not come into contact with animals when application follows the label instructions. Therefore, exposure to residues in food is not considered relevant. Taking into account authorized uses and additional RMMs (see section Risk for consumers via residues in food) residues in food are not considered relevant. Therefore, no further assessment is considered necessary.

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

The product must be kept away from food, drink and animal feedstuffs. The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions.

The product does not come into contact with animals when application follows the label instructions. Therefore, exposure to residues in food is not considered relevant. Taking into account authorized uses and additional RMMs (see section Risk for consumers via residues in food) residues in food are not considered relevant. Therefore, no further assessment is considered necessary.

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

The product is not intended for non-professional use.

**Maximum residue limits or equivalent**

The active substance cypermethrin is approved for use in plant protection products while imidacloprid is not approved under regulation (EC) No 1107/2009. The EU pesticide database lists 378 MRL product/commodity values for imidacloprid and cypermethrin; these MRL values range from 0.05 to 5 mg/kg. In considering the proposed PT18 biocidal use of the active substances imidacloprid and cypermethrin, it is not considered appropriate to individually list the 378 product MRLs relating to the plant protection uses of the active substance.

|  |
| --- |
| **Information of non-biocidal use of the active substance** |
| **Summary table of other (non-biocidal) uses** |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1 | Plant protection  products | Insecticide (authorised under Reg.  1107/2009) | MRL range of 0.01 -2  mg/kg imidacloprid ([Reg. (EU) No 2021-1881](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1410352403329&uri=CELEX:32014R0491)) |
| 1 | Plant protection  products | Insecticide (authorised under Reg.  1107/2009) | MRL range of 0.05 - 2  mg/kg cypermethrin ([Reg. (EU) 2017/626](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0626)) |

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

The product does not come into direct or indirect contact with food and feedstuff when used according to label instructions. The product does not come into contact with animals when application follows the label instructions. Therefore, risk for consumers via residues in food is not considered relevant.

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

Not relevant

### Risk assessment for animal health

In the risk assessment for human health, the risk is considered acceptable for infant crawling into the treated floor and being orally exposed to the product by hand-to-mouth transfer, as the product is not supposed to be applied on areas easily accessible to them. RMM has been added in order to protect the general public. The same RMM is therefore required to avoid animal exposure:

* For use only in areas that are inaccessible to infants, children, companion animals and non-target animals.

### Risk assessment for the environment

The product HC6 EC is a PT18 emulsifiable concentrate containing Imidacloprid (CAS No. 138261-41-3, 2.04% w/w technical value) and Cypermethrin (CAS No. 52315-07-8, 5.43% w/w technical value) and used by professionals for the control of various crawling insects. According to the intended use, the product is applied indoor after dilution (1 or 2%) by spray in confined areas not object of wet cleaning in households and public and industrial buildings.

*Substances of Concern*

No substance of concern is identified in this product (see Confidential Annex). The following risk assessment is therefore carried out for the two active substances only.

#### Effects assessment on the environment

No new environmental studies have been carried out with the product HC6 EC. All data pertaining to the active substances are therefore derived from the CAR of Imidacloprid (2015) and Cypermethrin (2019).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **PNECSTP** | **PNECwater** | **PNECsediment**  **EPM** | **PNECsoil** | **PNECoral,birds** | **PNECoral, mammals** |
|  | [mg/L] | [mg/L] | [mg/kgww] | [mg/kgww] | [mg/kg] | [mg/kg] |
| **Imidacloprid** | 6.13E+01 | 4.80E-06 | 2.60E-05 | 1.58E-02 | 4.20E+00 | 8.33E+00 |
| **Cypermethrin** | 1.63E+00 | 4.00E-06 | 5.00E-03\* | 7.00E-02 | 3.33E+01 | 3.30E+00 |

\*This value already considers the additional factor of 10 needed in case of high Koc value

*Atmosphere:*

No PNEC value can be derived for the air compartment. Moreover, according to the information from the CAR of Imidacloprid and Cypermethrin:

* Imidacloprid: Its vapour pressure is 4.00E-10 Pa at 20°C and the Henry’s law constant is 1.70E-10 Pa m3/mol (calculated value).
* Cypermethrin: Its vapour pressure is 6.00E-07 Pa at 25°C and the Henry's law constant of 2.40E-02 Pa.m3/mol at 20°C.

Therefore, for both substances, direct evaporation is not expected and a low volatility from water is foreseen. Therefore, exposure to air is expected to be insignificant and no PEC value is presented for this compartment.

***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***

According to the currently applied harmonized classification (ATP01):

* Cypermethrin (5.43%) is classified H400 and H410,
* Imidacloprid (2.04%) is classified H400 and H410.

However, this harmonized classification is modified as follows in ATP17, applicable on 17/12/2022:

* Cypermethrin (5.43%) is classified H400 and H410, with acute and chronic M-factors of 100 000.
* Imidacloprid (2.04%) is classified H400 and H410, with respective M-factors of 100 and 1000.

Considering the absence of substance of concern, the product HC6 EC is classified H411 according to the current classification and H400/H410 according to the new classification.

***Further Ecotoxicological studies***

No new ecotoxicological studies have been carried out with the product HC6 EC.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |
| Justification | Available ecotoxicity data on the active substances and the co-formulant are considered sufficient to assess the toxicity of the product.  In addition, as explained in section 2.2.8 of the PAR, there is no direct exposure of the environment as the product is only used indoor.  Based on this assessment, no additional ecotoxicological study with the product was conducted to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product HC6 EC used as indoor spray.  Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. It is not relevant for the product HC6 EC used as indoor spray.  Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on secondary ecological effect. |
| Justification | As the product is for indoor use only, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the product HC6 EC and it can be concluded that no secondary ecological effect is expected when using the product HC6 EC according to the label recommendations.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

According to the intended use, the active substances can be released into the environment *via* the sewage treatment plant. The final environmental receiving compartments are surface waters including sediments (through STP effluent), soil and groundwater (from sludge application).

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in soil. |
| Justification | The soil is not expected to be directly contaminated as the product is only used indoor.  Moreover, several environmental data are available on both actives substances. These data are considered sufficient to assess the product behaviour.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in water and sediment. |
| Justification | The aquatic compartment (water and sediment) is not expected to be directly contaminated as the product is only used indoor.  Moreover, several environmental data are available on both active substances. These data are considered sufficient to assess the product behaviour.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in air. |
| Justification | Based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to local scale.   * + - * + Therefore, no additional study is deemed necessary to address this point. |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product HC6 EC is intended to be used indoor. This product is not used close to or on surface water. Thus no further data is needed.   * + - * + Based on this assessment, no additional study with the product was conducted to address this point. |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product HC6 EC is intended to be used indoor by professionals for direct surface treatment.  The product is not intended to be sprayed in the outdoor environment and it has no potential for large scale formation of dust. Therefore there is no risk of exposure of honeybees and non-target arthropods.   * + - * + Based on this assessment, no additional study with the product was conducted to address this point. |

#### Exposure assessment

The Product HC6 EC is an emulsifiable concentrate containing Imidacloprid (2.04% w/w technical value) and Cypermethrin (5.43% w/w technical value) as active substances, intended for indoors use by professionals for the control of various crawling insects.

The product is intended to be applied after dilution (1 or 2%) by spray in confined areas not object of wet cleaning in households and public and industrial buildings, up to 11 times a year.

Nevertheless, according to the detailed intended uses of the applicant (summarised in the table below), the intended treated areas are not restricted to not wet cleaned surfaces, especially for bedbugs treatment. The applicant proposed to take into account no emission to the environment. To our point of view, considering the intended uses, environmental exposure must be assessed (**Scenario 1 – Barrier treatment on indoor areas**). Possible refinements of the scenario 1 are presented and discussed in a second scenario. In fact, some treated zones can be considered as localised areas (spot) in cracks and crevices; therefore the **Scenario 2** covers restricted (spot) applications in cracks and crevices.

Both scenarios consider emissions via applicator clothes when they are washed. It should be noticed that such emission are possible even if the product is applied on not wet cleaned surfaces and should also be considered.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Use** | **Targets** | **Treated areas** | **Dilution** | **Application rate (diluted product)** | **Covered by** |
| 1 | Bed bugs, adults and nymphs | Under bed and night table structures, furniture, around picture, window and door frames, behind skirtings, boards and electrical sockets | 1-2% | 50 mL/m² | Scenario 1  and  Scenario 2 (refinements) |
| Cockroaches and Silverfishes, adults and nymphs  Garden ants, adults | In damp or warm indoor areas, such us cellars, garages, ventilation vents or ducts, wall boxes of electrical system, behind the skirting boards, in the thin cracks and crevices between furniture, or where insects may harbor |

General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Barrier treatment on indoor areas  Scenario 2: Restricted (spot) treatment on indoor crack and crevices |
| ESD(s) used | ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses’ ENV/JM/MONO(2008)14 (ESD 2008)  Technical Agreements for Biocides Environment (ENV), July 2021 |
| Approach | Scenario 1: Average consumption |
| Distribution in the environment | Calculated based the Volume IV Part B+C (2017) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1/2:  Production: No  Formulation No  Use: Yes  Service life: No |

##### **Emission estimation**

###### **Scenario 1: Barrier treatment on indoor areas**

The exposure assessment was conducted as described in Emission Scenario Document OECD “ESD for insecticides, acaricides and products to control other arthropods (PT18) for household and professional uses” ENV/JM/MONO(2008)14 (ESD 2008), considering the latest available updates of the TAB and the following:

*Emission to air and solid waste:*

As the emission to air and to solid waste are not further used in the risk assessment, they are not presented below.

*AREAtreated:*

Considering all the areas intended to be treated and the targets (especially bedbugs), the barrier scenario is used and treated areas of 20 m² in houses and 93 m² in large buildings are representative of the claimed use.

*Qprod,prep:*

According to the claimed instructions for use, 10 mL (dilution 1%) or 20 mL (dilution 2%) of undiluted product are necessary to prepare 1L of diluted product.

Considering an application rate of 50 mL/m² of diluted product:

* 1L of diluted product is sufficient to treat areas of 20 m² in houses,
* 5L of diluted product is sufficient to treat areas of 93 m² in large buildings.

Therefore, 10 to 20 mL of undiluted product are used for the treatment of houses and 50 to 100 mL of undiluted product are used for the treatment of large buildings.

The emission calculations are presented in the tables below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario 1 - Input parameters for calculating the local emission** | | | | | |
| **Input** | **Symbol** | **Value** | | **Unit** | **S/O/D - Remarks** |
|  |  | **Imidacloprid** | **Cypermethrin** |  |  |
| **MIXING AND LOADING** | | | | | |
| Quantity of undiluted product used for the mixing loading step | Qprod,prep (dilution 1 %) | House: 10.937  LB: 54.685 | | g | S – Considering a density of the undiluted product of 1.0937 g/mL (see explanations above) |
| Qprod,prep (dilution 2 %) | House: 21.874  LB: 109.37 | | g |
| Fraction of a.s. in the concentrate product (w/w) | FAIconc | 2.04E-02 | 5.43E-02 | - | S |
| Number of preparation per day | Nprep,building | 1 | | - | S - One preparation sufficient to treat an entire building or house |
| Fraction of b.p directed to the applicator | Fprep,applicator | 0.0012 | | - | D - Liquids  (Table 3.2-2, ESDPT 18) |
| Fraction of b.p directed to the floor | Fprep,floor | 2.50E-04 | | - | D - 20L container with unspecific design, for professionals (Table 3.2-3, ESDPT 18) |
| Cleaning efficiency for the floor and applicator during mixing loading | FCEprep,floor  / FCEprep, applicator | 1 | | **-** | D |
| Fraction directed to wastewater | FWW | 1 | | *-* | D |
| **APPLICATION** | | | | | |
| Quantity of diluted product applied | Qprod,appli | 5.00E-02 | | kg/m² | S – Claimed dose, considering a density of the diluted product of 1 (~water) |
| Fraction of a.s in the diluted product (w/w) | FAIdil (dilution 1%) | 2.23E-04 | 5.94E-04 | - | S – Claimed dilutions, considering a density of undiluted product of 1.0937 g/mL |
| FAIdil (dilution 2%) | 4.46E-04 | 1.19E-03 | - |
| Number of application per day | Nappli,building | 1 | | - | D - (ESDTP18, 2008) |
| Area treated with the product | AREAtreated | House: 20  LB: 93 | | m² | D – Barrier treatment (TAB, ENV 142, see explanations above) |
| Area treated and wet cleaned | AREAwetcleaned | House: 5.9  LB: 27 | | m² | D – Barrier treatment (TAB,ENV 142, see explanations above) |
| Fraction of b.p directed to the applicator | F,application,applicator | 0.02 | | - | D – Unspecified mode of spraying (Table 3.3-5, ESDPT 18) |
| Fraction of b.p directed to the adjacent floor | F,application,floor | 0.11 | | - | D – Unspecified mode of spraying (Table 3.3-5, ESDPT 18) |
| Fraction of b.p directed to the treated area | F,application,treated area | 0.85 | | - | D – Unspecified mode of spraying (Table 3.3-5, ESDPT 18) |
| Cleaning efficiency factor for floor and treated areas during application | FCE,application,floor/treated | 0.5 | | **-** | D - Spraying on surfaces |
| Cleaning efficiency factor for the applicator during application | FCE,application,applicator | 1 | | **-** | D |
| Fraction directed to wastewater | FWW | 1 | | *-* | D |
| **TOTAL, Emissions to one STP** | | | | | |
| Simultaneity factor | Fsim | 0.008151 | | *-* | 3-11 applications / year |
| Number of households/building feeding one STP | Nhouse/building | House: 4000  LB: 300 | | **-** | D |

LB: Large Building

The equation from the ESD for PT18 (2008) used to calculate the different Elocal values are simplified and presented below:

**MIXING AND LOADING, after cleaning of one building**

Eprep.applicator = (Qprod,prep x FAIconc x Nprep,building x Fprep,applicator x 1E-03) x Fww x FCEprep,applicator

Eprep.floor = (Qprod,prep x FAIconc x Nprep,building x Fprep,floor x 1E-03) x Fww x FCEprep,floor

**APPLICATION, after cleaning of one building**

Eapplication,applicator = (Qprod,appli x FAIdil x Nappli,building x F,application,applicator x AREAtreated) x Fww x FCE,application,applicator

Eapplication,floor = (Qprod,appli x FAIdil x Nappli,building x F,application,floor x AREAtreated,wet) x Fww x FCE,application,floor/treated

Eapplication,treated area = (Qprod,appli x FAIdil x Nappli,building x F,application,treated area x AREAtreated,wet) x Fww x FCE,application,floor/treated

**TOTAL, Emissions to one STP**

Elocalww,use Total = (Eprep.applicator + Eprep.floor + Eapplication,applicator + Eapplication,floor + Eapplication,treated area) x Fsim x Nhouse/building

Elocalww,applicator Total = (Eprep.applicator + Eapplication,applicator) x Fsim x Nhouse/building

Elocalww mixing/loading Total = (Eprep.floor)x Fsim x Nhouse/building

The detailed local emissions are presented in the table below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario 1 (Barrier, surface) - Local emission output** | | | | | | | |
| **Output** | **Symbol** | **Location** | **Value** | | | | **Unit** |
|  |  |  | **Dilution 1%** | | **Dilution 2%** | |  |
|  |  |  | **Imidacloprid** | **Cypermethrin** | **Imidacloprid** | **Cypermethrin** |  |
| **MIXING AND LOADING, after cleaning of one building** | | | | | | | |
| Emission to the applicator | Eprep,applicator | HOUSE | 2.68E-07 | 7.13E-07 | 5.35E-07 | 1.43E-06 | kg/d |
| LARGE BUILDING | 1.34E-06 | 3.56E-06 | 2.68E-06 | 7.13E-06 | kg/d |
| Emission to the floor | Eprep,floor | HOUSE | 5.58E-08 | 1.48E-07 | 1.12E-07 | 2.97E-07 | kg/d |
| LARGE BUILDING | 2.79E-07 | 7.42E-07 | 5.58E-07 | 1.48E-06 | kg/d |
| **APPLICATION, after cleaning of one building** | | | | | | | |
| Emission to the applicator | Eapplication,applicator | HOUSE | 4.46E-06 | 1.19E-05 | 8.92E-06 | 2.38E-05 | kg/d |
| LARGE BUILDING | 2.07E-05 | 5.52E-05 | 4.15E-05 | 1.10E-04 | kg/d |
| Emission to the floor | Eapplication,floor | HOUSE | 3.62E-06 | 9.64E-06 | 7.24E-06 | 1.93E-05 | kg/d |
| LARGE BUILDING | 1.66E-05 | 4.41E-05 | 3.31E-05 | 8.82E-05 | kg/d |
| Emission to the treated area | Eapplication,treated area | HOUSE | 2.80E-05 | 7.45E-05 | 5.59E-05 | 1.49E-04 | kg/d |
| LARGE BUILDING | 1.28E-04 | 3.41E-04 | 2.56E-04 | 6.81E-04 | kg/d |
| **TOTAL, Emissions to one STP** | | | | | | | |
| Total emission to wastewater from the use | Elocalww,use Total (House+LB) | HOUSE + LARGE BUILDING | 1.59E-03 | 4.24E-03 | 3.19E-03 | 8.49E-03 | kg/d |
| Total emission to wastewater from the applicator only | Elocalww,applicator Total (House+LB) | HOUSE + LARGE BUILDING | 2.08E-04 | 5.54E-04 | 4.16E-04 | 1.11E-03 | kg/d |
| Total emission to wastewater from floor after mixing loading only | Elocalww mixing/loading Total (House+LB) | HOUSE + LARGE BUILDING | 2.50E-06 | 6.66E-06 | 5.00E-06 | 1.33E-05 | kg/d |

###### **Scenario 2: Restricted (Spot) treatment in cracks and crevices**

Emissions from Scenario 1 leads to unacceptable risks for the environment (see risk assessment section), therefore, possible refinements are explored in this Scenario 2. As the efficacy section assessed and validated a use “spot treatment in cracks and crevices”, the corresponding scenario is conducted. The table below indicates only which inputs are modified compared to the Scenario 1.

*Qprod,prep*

According to the claimed instructions for use, 10 mL (dilution 1%) or 20 mL (dilution 2%) of undiluted product are necessary to prepare 1L of diluted product.

Considering an application rate of 50 mL/m², 1L of diluted product is sufficient to treat areas of 20 m². Thus, 1L of diluted product is sufficient to treat an entire house (2 m²) or a large building (9.3 m²).

Therefore, 10 to 20 mL of undiluted product are used for the treatment of houses and large buildings.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario 2 - Input parameters (different in Scenario 1) for calculating the local emission** | | | | |
| **MIXING AND LOADING** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **S/O/D - Remarks** |
| Quantity of undiluted product used for the mixing loading step | Qprod,prep (dilution 1 %) | 10.937 | g | S – Same volumes prepared for houses and large buildings - Considering a density of the undiluted product of 1.0937 g/mL (see explanations above) |
| Qprod,prep (dilution 2 %) | 21.874 | g |
| **APPLICATION** | | | | |
| Area treated with the product | AREAtreated | House: 2  LB: 9.3 | m² | D – Spot treatment (TAB, ENV 142) |
| Area treated and wet cleaned | AREAwetcleaned | House: 2  LB: 9.3 | m² | D – Spot treatment (TAB, ENV 142) |
| Cleaning efficiency factor for floor and treated areas | FCE | 0.25 | **-** | Spraying in cracks and crevices |

The detailed updated Elocal are not presented to ease the reading of the Emission estimations section but the associated PEC and RCR values are presented in the appropriate sections.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario 2 (Restricted area (spot), cracks and crevices ) - Local emission output** | | | | | | | | |
| **Output** | **Symbol** | **Location** | **Value** | | | | **Unit** |
|  |  |  | **Dilution 1%** | | **Dilution 2%** | |  |
|  |  |  | **Imidacloprid** | **Cypermethrin** | **Imidacloprid** | **Cypermethrin** |  |
| **TOTAL, Emissions to one STP** | | | | | | | | |
| Total emission to wastewater from the use | Elocalww,use Total | HOUSE + LARGE BUILDING | 2.66E-04 | 7.09E-04 | 5.33E-04 | 1.42E-03 | kg/d |
| Total emission to wastewater from the applicator only | Elocalww,applicator Total | HOUSE + LARGE BUILDING | 2.90E-05 | 7.72E-05 | 5.80E-05 | 1.54E-04 | kg/d |
| Total emission to wastewater from the floor after mixing loading only | Elocalww mixing/loading Total | HOUSE + LARGE BUILDING | 1.96E-06 | 5.20E-06 | 3.91E-06 | 1.04E-05 | kg/d |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Freshwater | Freshwater sediment | STP | Soil | Groundwater | Secondary poisoning |
| Scenario 1 – Barrier treatment on indoor areas | + | + | ++ | + | + | + |
| Scenario 2 – Restricted (Spot) treatment in cracks and crevices | + | + | ++ | + | + | + |

*++: direct exposure +: indirect exposure*

Input parameters for calculating the fate and distribution of the active substances in the environment are selected from the Imidacloprid (2015) and Cypermethrin assessment reports (2019) and gathered in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | | |
| Input | Values | | Unit | Remarks |
|  | Imidacloprid | Cypermethrin |  |  |
| Molecular weight | 255.70 | 416.30 | g/mol |  |
| Vapour pressure | 4.00E-10  (20°C) | 6.00E-07 (25°C) | Pa |  |
| Water solubility (at 20°C) | 6.13E+02 | 4.00E-03 | mg/L |  |
| Log Octanol/water partition coefficient | 5.70E-01 | 5.45E+00 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 2.30E+02 | 5.75E+05 | L/kg |  |
| Henry’s Law Constant | 1.70E-10  (calculated) | 2.40E-02  (at 20°C) | Pa/m3/mol |  |
| Biodegradability | Not readily biodegradable | Not readily biodegradable | - |  |
| DT50 for degradation in soil | 135.1 | 17.20 | d (at 12ºC) |  |
| k biosoil | 5.13E-03 | 4.03E-02 | d-1 |  |
| k volat (arable land) | 2.84E-12 | 3.10E-07 | d-1 |  |
| k leach (arable land) | 3.38E-04 | 1.39E-07 | d-1 |  |
| k total (arable land) | 5.47E-03 | 4.03E-02 | d-1 |  |

In the STP, the fractioning of the active substances between air, water, sludge and degradation has been calculated with Simple Treat 4.0 and is indicated in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | Remarks |
| Imidacloprid | Cypermethrin |
| Air | 2.38E-09 | 6.74E-04 | Simple Treat v4.0, considering a concentration suspended solids effluents (Css) of 30 mg/L or 0.03 kg/m3 (TAB 07/2021, ENV9) |
| Water | 97.11 | 8.36 |
| Sludge | 2.89 | 91.65 |
| Degraded in STP | 0 | 0 |

##### **Calculated PEC values**

A summary of the calculated PEC values for each environmental compartment after emission to the STP is indicated in the following table.

For each scenario, three sets of PECs are calculated, based:

* **a.** On the total emission to wastewater, (Elocalwwuse Total (House+LB)) to estimate the risk for the use.
* **b.** On the emission from the applicator only (Eprep,applicator andEapplication,applicator for houses and large buildings) to check whether RMMs or instructions potentially used to reduce emissions to the floor or the treated areas would be sufficient to ensure a safe use.
* **c.** On the emission from floor after the mixing and loading step only.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated Elocal and associated PEC values for Scenario 1** | | | | |
|  | Dilution 1% | | Dilution 2% | |
|  | Imidacloprid | Cypermethrin | Imidacloprid | Cypermethrin |
|  | Scenario 1 – Barrier treatment on indoor areas, (**a.**) | | | |
| **Elocalww,use Total (House+LB) [kg/d]** | 1.59E-03 | 4.24E-03 | 3.19E-03 | 8.49E-03 |
|  | | | | |
| **PECSTP** [mg/L] | 7.74E-04 | 1.77E-04 | 1.55E-03 | 3.55E-04 |
| **PECwater** [mg/L] | 7.74E-05 | 9.52E-06 | 1.55E-04 | 1.90E-05 |
| **PECsediment** [mg/kgww] | 4.47E-04 | 1.19E-01 | 8.95E-04 | 2.38E-01 |
| **PECsoil** [mg/kgww] twa 30d | 9.15E-05 | 4.20E-03 | 1.83E-04 | 8.40E-03 |
| **PECGW** [μg/L] | 1.51E-02 | 9.83E-05 | 3.02E-02 | 1.97E-04 |
|  | Scenario 1 – Barrier treatment on indoor areas, (**b.**), considering emissions from the applicator only | | | |
| **Elocalww,applicator Total (House+LB) [kg/d]** | 2.08E-04 | 5.54E-04 | 4.16E-04 | 1.11E-03 |
|  | | | | |
| **PECSTP** [mg/L] | 1.01E-04 | 2.32E-05 | 2.02E-04 | 4.63E-05 |
| **PECwater** [mg/L] | 1.01E-05 | 1.24E-06 | 2.02E-05 | 2.49E-06 |
| **PECsediment** [mg/kgww] | 5.84E-05 | 1.56E-02 | 1.17E-04 | 3.11E-02 |
| **PECsoil** [mg/kgww] | 1.20E-05 | 5.49E-04 | 2.39E-05 | 1.10E-03 |
| **PECGW** [μg/L] | 1.97E-03 | 1.28E-05 | 3.95E-03 | 2.57E-05 |
|  | Scenario 1 – Barrier treatment on indoor areas, (**c.**), considering emissions from floor after mixing and loading only | | | |
| **Elocalww mixing/loading Total (House+LB)**  **[kg/d]** | 2.50E-06 | 6.66E-06 | 5.00E-06 | 1.33E-05 |
|  |  |  |  |  |
| **PECSTP** [mg/L] | 1.21E-06 | 2.78E-07 | 2.43E-06 | 5.56E-07 |
| **PECwater** [mg/L] | 1.21E-07 | 1.49E-08 | 2.43E-07 | 2.99E-08 |
| **PECsediment** [mg/kgww] | 7.02E-07 | 1.87E-04 | 1.40E-06 | 3.73E-04 |
| **PECsoil** [mg/kgww] | 1.44E-07 | 6.59E-06 | 2.87E-07 | 1.32E-05 |
| **PECGW** [μg/L] | 2.37E-05 | 1.54E-07 | 4.74E-05 | 3.08E-07 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated Elocal and associated PEC values for Scenario 2** | | | | |
|  | Dilution 1% | | Dilution 2% | |
|  | Imidacloprid | Cypermethrin | Imidacloprid | Cypermethrin |
|  | Scenario 2 – Restricted (Spot) treatment on indoor cracks and crevices, (**a.**) | | | |
| **Elocalwwuse Total (House+LB) [kg/d]** | 2.66E-04 | 7.09E-04 | 5.33E-04 | 1.42E-03 |
|  | | | | |
| **PECSTP** [mg/L] | 1.29E-04 | 2.96E-05 | 2.59E-04 | 5.93E-05 |
| **PECwater** [mg/L] | 1.29E-05 | 1.59E-06 | 2.59E-05 | 3.18E-06 |
| **PECsediment** [mg/kgww] | 7.48E-05 | 1.99E-02 | 1.50E-04 | 3.98E-02 |
| **PECsoil** [mg/kgww] | 1.53E-05 | 7.02E-04 | 3.06E-05 | 1.40E-03 |
| **PECGW** [μg/L] | 2.53E-03 | 1.64E-05 | 5.05E-03 | 3.29E-05 |
|  | Scenario 2 - Restricted (Spot) treatment on indoor cracks and crevices, (**b.**), considering emissions from the applicator only | | | |
| **Elocalww,applicator Total (House+LB) [kg/d]** | 2.90E-05 | 7.72E-05 | 5.80E-05 | 1.54E-04 |
|  | | | | |
| **PECSTP** [mg/L] | 1.41E-05 | 3.23E-06 | 2.82E-05 | 6.45E-06 |
| **PECwater** [mg/L] | 1.41E-06 | 1.73E-07 | 2.82E-06 | 3.47E-07 |
| **PECsediment** [mg/kgww] | 8.14E-06 | 2.17E-03 | 1.63E-05 | 4.33E-03 |
| **PECsoil** [mg/kgww] | 1.67E-06 | 7.64E-05 | 3.33E-06 | 1.53E-04 |
| **PECGW** [μg/L] | 2.75E-04 | 1.79E-06 | 5.50E-04 | 3.58E-06 |
|  | Scenario 2 – Restricted (Spot) treatment on indoor cracks and crevices, (**c.**), considering emissions from floor after mixing and loading only | | | |
| **Elocalww mixing/loading Total (House+LB) [kg/d]** | 1.96E-06 | 5.20E-06 | 3.91E-06 | 1.04E-05 |
|  | | | | |
| **PECSTP** [mg/L] | 9.49E-07 | 2.18E-07 | 1.90E-06 | 4.35E-07 |
| **PECwater** [mg/L] | 9.49E-08 | 1.17E-08 | 1.90E-07 | 2.34E-08 |
| **PECsediment** [mg/kgww] | 5.49E-07 | 1.46E-04 | 1.10E-06 | 2.92E-04 |
| **PECsoil** [mg/kgww] | 1.12E-07 | 5.15E-06 | 2.24E-07 | 1.03E-05 |
| **PECGW** [μg/L] | 1.85E-05 | 1.21E-07 | 2.15E-04 | 1.40E-06 |

***Primary and secondary poisoning***

Primary poisoning

No calculation needed for primary poisoning, see the section Primary and secondary poisoning in the risk characterisation section (2.2.8.3).

Secondary poisoning

*Imidacloprid:*

Considering the low BCF values for Imidacloprid (0.61 for fish and 0.88 for earthworms), a risk characterisation of secondary poisoning is deemed not relevant as there is no concern for bioaccumulation.

*Cypermethrin:*

Due to its Log Pow value of 5.45, Cypermethrin may bioaccumulate in the food chain. A BCFfish of 417 L/kgww was derived with QSAR simulation and leads to less concern for the food chain but the substance still presents a bioaccumulation potential. Therefore, the risk for secondary poisoning is conducted below for Cypermethrin according to equations from the Volume IV Part B+C (2017). As mammals are more sensitive than birds, secondary poisoning assessment is only conducted for mammals and covers the risk for birds. The values of the Scenario 1 (2% dilution) represent the worst-case emission. They are used in the risk assessment and covers the risk for the Scenario 1 (dilution 1%) and Scenario 2.

The following table present input values and resulting PECoral for the secondary poisoning risk assessment.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input and PEC calculations for secondary poisoning - Cypermethrin** | | | |
| Scenario 1 – Barrier treatment on indoor areas (2% dilution) | | | |
| Input | Values | Unit | Remark |
| **Secondary poisoning in water** | | | |
| PECwater | 1.90E-05 | mg/L | See section Calculated PEC values |
| BCFfish | 417 | L/kgww | Cypermethrin AR (2019) |
| BMF | 1 | - | D value for substance with Log Kow between 5 and 8 – Vol IV Part B+C (2017) |
| **PECoral,water predator organisms** | **3.97E-03** | mg/kgfood | O - Vol IV Part B+C (2017) - Equation 107 |
|  | | |  |
| **Secondary poisoning in soil** | | | |
| PECsoil 180d | 1.99E-03 | mg/kgww | - |
| PECporewater 180d | 1.96E-07 | mg/L |  |
| BCFearthworm calculated | 3383 | L/kgww | Cypermethrin AR (2019) |
| CONVsoil | 1.13 | - | O - Vol IV Part B+C (2017) - Equation 102b |
| Fgut | 0.1 | - | D - Vol IV Part B+C (2017) |
| **PECoral,soil predator organisms** | **4.00E-04** | mg/kgfood | O - Vol IV Part B+C (2017) - Equation 103c |

#### Risk characterisation

A summary of the calculated RCR values for the relevant environmental compartments after emission to the STP is presented in the following table.

For each scenario, three sets of RCRs are calculated, based:

- **a.** On the total emission to wastewater, (Elocalwwuse Total (House+LB)) to estimate the risk for the use,

- **b.** On the emission due to the applicator only (Eprep,applicator andEapplication,applicator for houses and large buildings) to check whether RMMs or instructions potentially used to reduce emissions to the floor or the treated areas would be sufficient to ensure a safe use.  
- **c.** On the emission due to floor after mixing and loading step only

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated RCR values for Scenario 1** | | | | | | |
|  | Scenario 1 – Barrier treatment on indoor areas, (**a.**) | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 1.26E-05 | 1.09E-04 | 1.21E-04 | 2.53E-05 | 2.18E-04 | 2.43E-04 |
| **RCRwater** | **1.61E+01** | **2.38E+00** | **1.85E+01** | **3.22E+01** | **4.76E+00** | **3.70E+01** |
| **RCRsediment** | **1.72E+01** | **2.38E+01** | **4.10E+01** | **3.44E+01** | **4.76E+01** | **8.20E+01** |
| **RCRsoil** | 5.81E-03 | 6.00E-02 | 6.58E-02 | 1.16E-02 | 1.20E-01 | 1.32E-01 |
| **RCRoral,mammal,water** | - | - | - | - | 1.20E-03 | - |
| **RCRoral,mammal,soil** | - | - | - | - | 1.21E-04 | - |
| **PECGW** [μg/l] | 1.51E-02 | 9.83E-05 | 1.52E-02 | 3.02E-02 | 1.97E-04 | 3.04E-02 |
|  | Scenario 1 – Barrier treatment on indoor areas, (**b.**), considering emissions from the applicator only | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 1.65E-06 | 1.42E-05 | 1.59E-05 | 3.30E-06 | 2.84E-05 | 3.17E-05 |
| **RCRwater** | **2.11E+00** | 3.11E-01 | **2.42E+00** | **4.21E+00** | 6.22E-01 | **4.83E+00** |
| **RCRsediment** | **2.25E+00** | **3.11E+00** | **5.36E+00** | **4.50E+00** | **6.22E+00** | **1.07E+01** |
| **RCRsoil** | 7.59E-04 | 7.84E-03 | 8.60E-03 | 1.52E-03 | 1.57E-02 | 1.72E-02 |
| **RCRoral,mammal,water** | - | n.c | - | - | n.c | - |
| **RCRoral,mammal,soil** | - | n.c | - | - | n.c | - |
| **PECGW** [μg/l] | 1.97E-03 | 1.28E-05 | 1.99E-03 | 3.95E-03 | 2.57E-05 | 3.98E-03 |
|  | Scenario 1 – Barrier treatment on indoor areas, (**c.**), considering emissions from the mixing and loading only | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 1.98E-08 | 1.71E-07 | 1.90E-07 | 3.96E-08 | 3.41E-07 | 3.81E-07 |
| **RCRwater** | 2.53E-02 | 3.73E-03 | 2.90E-02 | 5.06E-02 | 7.47E-03 | 5.80E-02 |
| **RCRsediment** | 2.70E-02 | 3.73E-02 | 6.43E-02 | 5.40E-02 | 7.47E-02 | 1.29E-01 |
| **RCRsoil** | 9.11E-06 | 9.41E-05 | 1.03E-04 | 1.82E-05 | 1.88E-04 | 2.06E-04 |
| **RCRoral,mammal,water** | - | n.c | - | - | n.c | - |
| **RCRoral,mammal,soil** | - | n.c | - | - | n.c | - |
| **PECGW** [μg/l] | 2.37E-05 | 1.54E-07 | 2.39E-05 | 4.74E-05 | 3.08E-07 | 4.77E-05 |

n.c : not calculated, covered by Scenario 1 (a.)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated RCR values for Scenario 2** | | | | | | |
|  | Scenario 2: Restricted (spot) treatment on indoor cracks and crevices, (**a.**) | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 2.11E-06 | 1.82E-05 | 2.03E-05 | 4.22E-06 | 3.64E-05 | 4.06E-05 |
| **RCRwater** | **2.69E+00** | 3.98E-01 | **3.09E+00** | **5.39E+00** | 7.96E-01 | **6.18E+00** |
| **RCRsediment** | **2.88E+00** | **3.98E+00** | **6.86E+00** | **5.75E+00** | **7.96E+00** | **1.37E+01** |
| **RCRsoil** | 9.71E-04 | 1.00E-02 | 1.10E-02 | 1.94E-03 | 2.01E-02 | 2.20E-02 |
| **RCRoral,mammal,water** | - | n.c | - | - | n.c | - |
| **RCRoral,mammal,soil** | - | n.c | - | - | n.c | - |
| **PECGW** [μg/l] | 2.53E-03 | 1.64E-05 | 2.54E-03 | 5.05E-03 | 3.29E-05 | 5.09E-03 |
|  | Scenario 2: Restricted (Spot) treatment on indoor cracks and crevices, (**b.**), considering emissions from the applicator only | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 2.30E-07 | 1.98E-06 | 2.21E-06 | 4.60E-07 | 3.96E-06 | 4.42E-06 |
| **RCRwater** | 2.93E-01 | 4.33E-02 | 3.37E-01 | 5.87E-01 | 8.66E-02 | 6.73E-01 |
| **RCRsediment** | 3.13E-01 | 4.33E-01 | 7.46E-01 | 6.26E-01 | 8.66E-01 | **1.49E+00** |
| **RCRsoil** | 1.06E-04 | 1.09E-03 | 1.20E-03 | 2.11E-04 | 2.18E-03 | 2.39E-03 |
| **RCRoral,mammal,water** | - | n.c | - | - | n.c | - |
| **RCRoral,mammal,soil** | - | n.c | - | - | n.c | - |
| **PECGW** [μg/l] | 2.75E-04 | 1.79E-06 | 2.77E-04 | 5.50E-04 | 3.58E-06 | 5.54E-04 |
|  | Scenario 2: Restricted (Spot) treatment on indoor cracks and crevices, (**c.**), considering emissions from floor after mixing and loading only | | | | | |
|  | Dilution 1% | | | Dilution 2% | | |
|  | Imidacloprid | Cypermethrin | Aggregated risks | Imidacloprid | Cypermethrin | Aggregated risks |
| **RCRSTP** | 1.55E-08 | 1.33E-07 | 1.49E-07 | 3.10E-08 | 2.67E-07 | 2.98E-07 |
| **RCRwater** | 1.98E-02 | 2.92E-03 | 2.27E-02 | 3.95E-02 | 5.84E-03 | 4.54E-02 |
| **RCRsediment** | 2.11E-02 | 2.92E-02 | 5.03E-02 | 4.22E-02 | 5.84E-02 | 1.01E-01 |
| **RCRsoil** | 7.13E-06 | 7.36E-05 | 8.07E-05 | 1.43E-05 | 1.47E-04 | 1.61E-04 |
| **RCRoral,mammal,water** | - | n.c | - | - | n.c | - |
| **RCRoral,mammal,soil** | - | n.c | - | - | n.c | - |
| **PECGW** [μg/l] | 1.85E-05 | 1.21E-07 | 1.87E-05 | 3.71E-05 | 2.41E-07 | 3.73E-05 |

n.c: not calculated, covered by Scenario 1 (a.)

***Atmosphere***

No PNEC value can be derived for the air compartment. Moreover, according to the information from the revised AR of Imidacloprid and Cypermethrin, direct evaporation is not expected and a low volatility from water is foreseen:

* Imidacloprid: vapour pressure of 4.00E-10 Pa at 20°C and the Henry’s law constant of 1.70E-10 Pa m3/mol (calculated value),
* Cypermethrin: vapour pressure of 6.00E-07 Pa at 25°C and the Henry's law constant of 2.40E-02 Pa.m3/mol at 20°C.

Therefore, exposure to air is expected to be insignificant and no risk assessment is conducted for this compartment.

***Sewage Treatment plant***

The RCRSTP for all the scenarios are <1. Therefore, the uses lead to acceptable risks for the STP microorganisms.

***Aquatic compartment***

* The use of product HC6 EC as a barrier treatment (i.e a medium-sized area treatment) on surfaces leads to unacceptable risks for the surface water and sediment compartments, even if only emissions from the applicator cloths washing are taken into account.
* The use as a spot treatment (i.e in restricted areas) in cracks and crevices leads also to unacceptable risks for the environment and emissions from washing of applicator cloths after use of the product at the dilution of 2% also leads to unacceptable risks.

Hence, the use of the product must be restricted to applications that leads to no emission to the environment. The following risk mitigation measures must be applied:

* The product is only for indoor use in restricted areas and to be strictly applied in non-wet-cleaned surfaces (cellars, ventilation vents or ducts, wall boxes of electrical system, in the thin cracks and crevices between furniture, or where insects may harbour).
* The applicator must wear disposable protective clothes to avoid emissions to the sewer system due to washing of contaminated clothes.

***Terrestrial compartment***

The RCRsoil for all the scenarios are <1 for all the scenarios.

***Groundwater***

Emissions of the product results in concentrations in groundwater lower than the threshold value of 0.1 µg/. Therefore, no risk are foreseen for the groundwater compartment.

***Primary and secondary poisoning***

Primary Poisoning:

According to the ESD for PT18 (2008), primary poisoning mainly occurs with insecticides applied as granular formulations or with food attractant.

The product HC6 EC is a liquid applied indoor, therefore, no primary poisoning is expected.

Bees:

The risk assessment for pollinators will be further detailed when the corresponding guidance will be available. In the meantime, data and arguments from the CAR of both active substances are considered sufficient to cover the use.

*Cypermethrin:*

No data are available in the CAR.

*Imidacloprid:*

Imidacloprid is highly toxic to bees, with a LD50oral 48h = 0.0037 µg/bee. However, as the product is applied indoor, the potential exposure for pollinators will only be through residues in flowering crops/plants grown in fields which have received sludge containing imidacloprid. In field studies, analysis of nectar and pollen was conducted on flowering crops grown on soils treated formerly with imidacloprid. No imidacloprid or its metabolites could be detected or quantified and no adverse effect were observed on honey bees colonies placed in the field during flowering periods (Imidacloprid CAR). Thus, very low probability of primary poisoning through this way of exposure is foreseen for this product.

Secondary poisoning

*Imidacloprid:*

Considering the low BCF values for Imidacloprid (0.61 for fish and 0.88 for earthworms), a risk characterisation of secondary poisoning is deemed not relevant as there is no concern for bioaccumulation.

*Cypermethrin:*

The RCRoral,mammal,soil and RCRoral,mammal,water for scenario 1 are <1 and cover the ones of Scenario 2, therefore, the use of the product leads to acceptable risks for soil and water non-target mammals *via* secondary poisoning. As the risk assessment for mammals covers the one for birds, no risk are foreseen for birds as well.

***Mixture toxicity***

Not relevant as no substance of concern has been defined for the environment.

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



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

As one use is claimed, the aggregated exposure of use is not relevant.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| * The use of product HC6 EC as a barrier treatment (i.e a medium-sized area treatment) on surfaces leads to unacceptable risks for the surface water and sediment compartments, even if only emissions from the applicator cloths washing are taken into account. * The use as a spot treatment (i.e in restricted areas) in cracks and crevices leads also to unacceptable risks for the environment and emissions from washing of applicator cloths after use of the product at the dilution of 2% also leads to unacceptable risks.   Hence, the use of the product must be restricted to applications that leads to no emission to the environment. The following risk mitigation measures must be applied:   * The product is only for indoor use in restricted areas and to be strictly applied in non-wet-cleaned surfaces (cellars, ventilation vents or ducts, wall boxes of electrical system, in the thin cracks and crevices between furniture, or where insects may harbour). * The applicator must wear disposable protective clothes to avoid emissions to the sewer system due to washing of contaminated clothes.   In the table below, the intended treated areas associated to the pests are presented. Applications that do not fit the restrictions mentioned above are **shaded**.   |  |  |  |  | | --- | --- | --- | --- | | **Use** | **Dilution** | **Targets** | **Initially claimed treated areas** | | 1 | 1%-2% | Bed bugs, adults and nymphs | Under bed and night table structures, furniture, around picture, window and door frames, behind skirting boards and electrical sockets | | Cockroaches and Silverfishes, adults and nymphs  Garden ants, adults | In damp or warm indoor areas, such us cellars, garages, ventilation vents or ducts, wall boxes of electrical system, behind the skirting boards, in the thin cracks and crevices between furniture, or where insects may harbour |   As the bedbug control cannot be effective without the treatment of wet cleaned areas such as skirting boards, the use against bedbugs is not proposed for authorisation. All the initially claimed treated areas for this pest are also deleted from the SPC. |

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

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

**Overall conclusion**

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

* a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
* as a general rule, at least three different and independent “active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Considering that no products have been identified as potential better alternatives for HC6 EC, FR CA concludes that there is currently no products with significantly lower overall risks for human health, animal health or the environment.

Since imidacloprid does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point.

**The authorization for the product HC6 EC can be granted in accordance with the BPR 528/2012.**

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Nichetti S. | 2019 | HC6 EC: Validation of the Analytical Method for the Determination of Cypermethrin Active Ingredient Content. Chemservice, CH0569/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 | HC6 EC: Validation of the Analytical Method for the Determination of Imidacloprid Active Ingredient Content. Chemservice, CH0568/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 | HC6 EC: Determination of the Physico-chemical Properties. Chemservice, CH0567/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 | HC6 EC: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH0675/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 | HC6 EC: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH0677/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 | HC6 EC: Determination of the Accelerated Storage Stability and Corrosion Characteristics. Chemservice, CH0679/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 (ongoing) | HC6 EC: Three Years Storage Stability and Corrosion Characteristics. Chemservice, CH0676/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 (ongoing) | HC6 EC: Three Years Storage Stability and Corrosion Characteristics. Chemservice, CH0678/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2019 (ongoing) | HC6 EC: Three Years Storage Stability and Corrosion Characteristics. Chemservice, CH0680/2019. GLP (unpublished) | YES | ZAPI S.p.A. |
| Nichetti S. | 2021 | HC6 EC: Determination of the Low temperature stability. Chemservice, CH0116/2021. GLP (unpublished) | YES | ZAPI S.p.A. |
| Halbwachs P. | 2020 | Determination of exothermic reactions by DSC method and test for oxidizing liquids on HC6 EC. Defitraces, 19-926005-004. GLP (unpublished) | YES | ZAPI S.p.A. |
| Fragomeni V. | 2019 | CORROSIVE TO METALS ON THE TEST ITEM "HC6 EC". Eurofins Biolab, STULV19AA4472-1 GLP (unpublished) | YES | ZAPI S.p.A. |
| Serrano B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT AGAINST ANTS. T.E.C. Laboratory, 2332-LAB/0518. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2018 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT AGAINST ANTS. T.E.C. Laboratory, 2332-FIELD/0518. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2019 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT AGAINST COCKROACHES AND BED BUGS. T.E.C. Laboratory, 2450-LAB/0419. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2019 | FIELD TRIAL OF THE EFFICACY OF A RESIDUAL INSECTICIDE SPRAY TREATMENT TO CONTROL BED BUGS. T.E.C. Laboratory, 2450-FTBB/0419. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2019 | FIELD TESTING OF THE EFFICACY OF AN INSECTICIDAL PRODUCT INTENDED TO CONTROL GERMAN AND ORIENTAL COCKROACHES*.* T.E.C. Laboratory, 2450-FTCO/0419. Unpublished. | YES | ZAPI S.p.A. |
| Guicherd A. | 2019 | EFFICACY STUDY OF HC6 EC DILUTED AT 1% FOR NON-POROUS SURFACES AND 2% FOR POROUS SURFACES IN PRACTICAL USE SITUATION AGAINST SILVERFISH (*Lepisma saccharina*). Izinovation, 19ZAPLsLab001. Unpublished. | YES | ZAPI S.p.A. |
| Guicherd A. | 2019 | EVALUATION OF THE EFFICACY OF THE “HC6 EC” DILUTED AND SPRAYED IN CRACK & CREVICES FOR THE CONTROL OF SILVERFISH INFESTATIONS. Izinovation, 19ZAPLsF001. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2021 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT AGAINST ANTS. T.E.C. Laboratory, 2644-ANT/0221. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2021 | FIELD TRIAL OF THE EFFICACY OF A RESIDUAL INSECTICIDE SPRAY TREATMENT TO CONTROL SILVERFISHES*.* T.E.C. Laboratory, 2644-SF/0221. Unpublished. | YES | ZAPI S.p.A. |
| Serrano B. | 2021 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL PRODUCT AGAINST COCKROACHES*.* T.E.C. Laboratory, 2644-CO/0221. Unpublished. | YES | ZAPI S.p.A. |

## Output tables from exposure assessment tools

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## New information on the active substance

Not relevant

## Residue behaviour

There are no further residue behaviours that are not taken into account in previous section of the document to be reported in this section.

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

See IUCLID files

## Confidential annex

See the confidential annex

1. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [↑](#footnote-ref-2)
2. The document is available in CIRCABC at <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>. [↑](#footnote-ref-3)
3. The document is available in CIRCABC at <https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3>. [↑](#footnote-ref-4)
4. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-5)
5. Insecticide Resistance of Several Field-Collected German Cockroach (Dictyoptera: Blattellidae) Strains. Xiaoyan Wu et al 2017: doi: 10.1093/jee/tox072 [↑](#footnote-ref-6)
6. High Levels of Resistance in the Common Bed Bug, Cimex lectularius (Hemiptera: Cimicidae), to Neonicotinoid Insecticides. Alvaro et al 2016: , <https://doi.org/10.1093/jme/tjv253> [↑](#footnote-ref-7)
7. Measuring Cypermethrin Resistance in the German Cockroach (Orthoptera: Blattellidae). [J Zhai](https://pubmed.ncbi.nlm.nih.gov/?term=Zhai+J&cauthor_id=1593010)  [1](https://pubmed.ncbi.nlm.nih.gov/1593010/#affiliation-1) and [W H Robinson](https://pubmed.ncbi.nlm.nih.gov/?term=Robinson+WH&cauthor_id=1593010) 1992: DOI: [10.1093/jee/85.2.348](https://doi.org/10.1093/jee/85.2.348)  [↑](#footnote-ref-8)
8. Insecticide Resistance in Bedbugs in Thailand and Laboratory Evaluation of Insecticides for the Control of Cimex hemipterus and Cimex lectularius (Hemiptera: Cimicidae). Apiwat Tawatsin et al 2011: DOI: [10.1603/me11003](https://doi.org/10.1603/me11003)  [↑](#footnote-ref-9)