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)



INSECTICIDA RTU PER ZNZ

Product type 18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-RX023281-16

Evaluating Competent Authority: Spain

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Table of Contents

[1 CONCLUSION 4](#_Toc163122895)

[2 ASSESSMENT REPORT 13](#_Toc163122896)

[2.1 Summary of the product assessment 13](#_Toc163122897)

[2.1.1 Administrative information 13](#_Toc163122898)

[2.1.1.1 Identifier of the product 13](#_Toc163122899)

[2.1.1.2 Authorisation holder 13](#_Toc163122900)

[2.1.1.3 Manufacturer(s) of the products 13](#_Toc163122901)

[2.1.1.4 Manufacturer(s) of the active substance 13](#_Toc163122902)

[2.1.2 Product composition and formulation 14](#_Toc163122903)

[2.1.2.1 Identity of the active substance 14](#_Toc163122904)

[2.1.2.2 Candidate(s) for substitution 15](#_Toc163122905)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 15](#_Toc163122906)

[2.1.2.4 Information on technical equivalence 15](#_Toc163122907)

[2.1.2.5 Information on the substance(s) of concern 15](#_Toc163122908)

[2.1.2.6 Type of formulation 16](#_Toc163122909)

[2.1.3 Hazard and precautionary statements 16](#_Toc163122910)

[2.1.4 Authorised use(s) 17](#_Toc163122911)

[2.1.4.1 Use description 17](#_Toc163122912)

[2.1.4.2 Use description 19](#_Toc163122913)

[2.1.4.3 Use description 21](#_Toc163122914)

[2.1.4.4 Use description 23](#_Toc163122915)

[2.1.4.5 Use description 24](#_Toc163122916)

[2.1.5 General directions for use 26](#_Toc163122917)

[2.1.5.1 Instructions for use 26](#_Toc163122918)

[2.1.5.2 Risk mitigation measures 26](#_Toc163122919)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 26](#_Toc163122920)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 27](#_Toc163122921)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 27](#_Toc163122922)

[2.1.6 Other information 27](#_Toc163122923)

[2.1.7 Packaging of the biocidal product 28](#_Toc163122924)

[2.1.8 Documentation 28](#_Toc163122925)

[2.1.8.1 Data submitted in relation to product application 28](#_Toc163122926)

[2.1.8.2 Access to documentation 29](#_Toc163122927)

[2.2 Assessment of the biocidal product 29](#_Toc163122928)

[2.2.1 Intended uses as applied for by the applicant 29](#_Toc163122929)

[2.2.2 Physical, chemical and technical properties 33](#_Toc163122930)

[2.2.3 Physical hazards and respective characteristics 40](#_Toc163122931)

[2.2.4 Methods for detection and identification 42](#_Toc163122932)

[2.2.5 Efficacy against target organisms 52](#_Toc163122933)

[2.2.5.1 Function and field of use 52](#_Toc163122934)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 52](#_Toc163122935)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 52](#_Toc163122936)

[2.2.5.4 Mode of action, including time delay 52](#_Toc163122937)

[2.2.5.5 Efficacy data 53](#_Toc163122938)

[2.2.5.6 Occurrence of resistance and resistance management 75](#_Toc163122939)

[2.2.5.7 Known limitations 76](#_Toc163122940)

[2.2.5.8 Evaluation of the label claims 76](#_Toc163122941)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 76](#_Toc163122942)

[2.2.6 Risk assessment for human health 76](#_Toc163122943)

[2.2.6.1 Assessment of effects on Human Health 76](#_Toc163122944)

[2.2.6.2 Exposure assessment 81](#_Toc163122945)

[2.2.6.3 Risk characterisation for human health 95](#_Toc163122946)

[2.2.7 Risk assessment for animal health 100](#_Toc163122947)

[2.2.8 Risk assessment for the environment 100](#_Toc163122948)

[2.2.8.1 Effects assessment on the environment 101](#_Toc163122949)

[2.2.8.2 Exposure assessment 107](#_Toc163122950)

[2.2.8.3 Risk characterisation 141](#_Toc163122951)

[2.2.9 Measures to protect man, animals and the environment 159](#_Toc163122952)

[2.2.10 Assessment of a combination of biocidal products 159](#_Toc163122953)

[2.2.11 Comparative assessment 160](#_Toc163122954)

[3 Annexes 160](#_Toc163122955)

[3.1 List of studies for the biocidal product 160](#_Toc163122956)

[3.2 Model used and exposure calculations 160](#_Toc163122957)

[3.2.1 Human expousere model 160](#_Toc163122958)

[3.2.2 Emission Environmental expousere calculation 160](#_Toc163122959)

[3.3 New information on the active substance 160](#_Toc163122960)

[3.4 Residue behaviour 160](#_Toc163122961)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 160](#_Toc163122962)

[3.6 Confidential annex 160](#_Toc163122963)

[3.7 Other 161](#_Toc163122964)

# CONCLUSION

The biocidal product INSECTICIDA RTU PER ZNZ is a ready to use water-based formulation to be used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction as PT 18.

**Physical, chemical and technical properties**

The biocidal product contains 0.4 %w/w permethrin and given the nature of the formulation it is not considered explosive, oxidizing, corrosive, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are not substances of concern in the biocidal product, hence there are some substances different to the active substance that do not contribute to the product hazard classification with regard to physical chemical properties according to hazardous (Regulation (EC) No 1272/2008).

A validated analytical method is available for determining the concentration of permethrin in the biocidal product. Validated analytical methods are also available for the determination of permethrin in soil, water and air matrices. Other analytical methods are not required.

**Efficacy:**

ES CA considers that the tests provided in the dossier demonstrate the efficacy of the biocidal product INSECTIDA RTU PER ZNZ by spraying for the following uses:

* against crawling insects, cockroaches, ants and silverfishes, as spot in hiding places (including crack and crevices) for general public and professionals (indoors). Application rate for cockroaches and ants: 15 mL/m2. Application rate for silverfishes: 25.5 mL/m2. The product shown residual efficacy against ants (3 weeks) and silverfishes (3 weeks on non-porous surfaces and 1 week on pororus surfaces);
* against crawling insects, cockroaches and silverfishes, as spot in hiding places (including crack and crevices) (indoors) for trained professionals. Application rate for cockroaches and ants: 15 mL/m2. Application rate for silverfishes: 25.5 mL/m2. The product showed residual efficacy against silverfishes (3 weeks on non-porous surfaces and 1 week on pororus surfaces).
* against ants as nest application and in surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), 15 mL/m2 ; and
* against cat fleas, house dust mites and ticks on non-washable textile surfaces. Application rate: 15 mL/m2.

**Human health:**

The biocidal product has not been tested in any in vivo studies but it has been tested in vitro for eye corrosion. It was considered that the acute oral, dermal, inhalation, skin corrosion and irritation, eye irritation and the sensitisation studies on the active ingredient were adequate for the classification and labelling of the product and for the human health risk assessment

Based on the existing knowledge there is no indication of concern regarding the ED properties of the substances used in the biocidal product if one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Finally, evaluating the exposure and characterizing the risk to human health of the biocidal products according to the pattern of use requested by the applicant, the conclusions for each scenario are:

| **Summary table risk assessment for human health** | | | |
| --- | --- | --- | --- |
| **Scenario** | **Scenario** | **Conclusion** | **Exposed group** |
| 1. | Indoor application by trigger spray. | A **safe** situation has been identified for spraying application in indoor areas when the corresponding PPEs and instruction for use are used. | Professional / Trained professional users |
| 2. | Outdoor application by trigger spray. | A **safe** situation has been identified for spraying application in outdoor areas when the corresponding PPEs and instruction for use are used. | Professional / Trained professional users |
| 3. | Indoor application by trigger spray. | A **safe** situation has been identified for spraying application in indoor areas when the corresponding instruction for use is used. | Non-professional users |
| 4. | Outdoor application by trigger spray. | A **safe** situation has been identified for spraying application in outdoor areas when the corresponding instruction for use is used. | Non-professional users |
| 5. | Indoor application by trigger spray on non-washable textile surfaces. | A **safe** situation has been identified for spraying application in indoor areas when the corresponding instruction for use is used. | Non-professional users |
| Combined scenarios  3 + 4 + 5 | Indoor / outdor applications | A **safe** situation has been identified for spraying applications in indoor / outdoor areas when the corresponding instruction for use is used. | Non-professional users |
| 6. | Inhalation of volatilized residues | A **safe** situation has been identified for inhalation of volatilized residues. | General public |
| 7. | Adults/Toddler playing on treated surfaces | A **safe** situation has been identified for adult / toddler playing and/or crawling on treated surfaces when the corresponding instruction for use and RMMs are used. | General public (chronic) |
| 8. | Laundering | A **safe** situation has been identified for adults laundering contaminated work clothing when the corresponding instruction for use and RMMs are used. | General public (chronic) |
| Combined scenarios  1 + 2 + 8 | Indoor / outdor applications + laundering | A **safe** situation has been identified for spraying applications in indoor / outdoor areas and laundering contaminated work clothing when the corresponding PPEs, instruction for use and RMMs are used. | General public (adult-chronic) |
| Combined scenarios  3 + 4 + 5 + 7 | Indoor / outdoor applications + Adults playing / crawling on treated surfaces | A **safe** situation has been identified for spraying applications in indoor / outdoor areas and adult playing and/or crawling on treated surfaces when the corresponding instruction for use and RMMs are used. | General public (adult-chronic) |

All scenarios resulted in acceptable risk taking. In addition, risk assessment for consumers via residues in food and animal health is not foreseen when RMM are set on the product label.

**Environment:**

From environmental perspective, an acceptable risk should be foreseen for all scenarios at the assessed environmental compartments when the use instructions given in the product’s label and the proposed risk mitigations measures are followed for each use.

***Overall conclusion***

According to the assessment performed for the biocidal product, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the table below:

| **Uses** | **Target organisms** | **User categories** | **Authorised application rates** | **Use conditions:** | |
| --- | --- | --- | --- | --- | --- |
| **Specific risk mitigations measures** | **General risk mitigations measures** |
| Use # 1 – Indoor – spot in hiding places including crack and crevices– crawling insects – cockroaches, ants and silverfishes – General public / Professionals | Crawling insects  Cockroaches:  *Blattella germanica* (adults and nymphs)  *Blatta orientalis* (adults and nymphs)  Ants:  *Lasius niger* (adults)  Silverfishes:  *Lepisma saccharina* (adults) | General public / Professional | For cockroaches and ants: 15 mL/m² (equivalent to 10 sprayings)  For silverfishes: 25.5 mL/m2 (equivalent to 17 sprayings)  The product showed residual efficacy against ants (3 weeks) and silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces).  The product has no residual action against cockroaches.  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a (trained) professional. | The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.  Professional:  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  (Trained) Professionals are not allowed to wash contaminated clothes at home.  General public:  Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed:  "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional." | Do not spray directly on people, animals or bedding.  Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.  Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.  Contains Permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).  Do not apply in rooms where fish tanks and/or terrariums are present.  Keep uninvolved persons, children and pets away from treated surfaces/areas until dried. |
| Use # 2 – Indoor – spot in hiding places including crack and crevices – crawling insects – cockroaches and silverfishes – Trained professionals | Crawling insects  Cockroaches:  *Blattella germanica* (adults and nymphs)  *Blatta orientalis* (adults and nymphs)  Silverfishes:  *Lepisma saccharina* (adults) | Trained Professional | For cockroaches: 15 mL/m² (equivalent to 10 sprayings with the trigger spray)  For silverfishes: 25.5 mL/m2 (equivalent to 17 sprayings with the trigger spray)  The product showed residual efficacy against silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces)  The product has no residual action against cockroaches.  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). | The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  (Trained) Professionals are not allowed to wash contaminated clothes at home. |
| Use # 3 – Outdoor – Directly application in ant nests – Trained professionals / Professionals | Black ant (*Lasius niger)* - adults, larvae, nymphs, queen | Trained professionals / Professionals | 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), equivalent to 2 sprayings) with the trigger spray.  Information only for trained-professionals: Application rate: 15 mL/m2 | Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  (Trained) Professionals are not allowed to wash contaminated clothes at home.  Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.  Do not use where release to drains (sewer) and/or surface water cannot be prevented. |
| Use # 4 – Outdoor – Directly application in ant nests – General public (non-professional users) | Black ant (*Lasius niger)* - adults, larvae, nymphs, queen | General public (non-professional users) | 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), equivalent to 2 sprayings) with the trigger spray. Application rate: 15 mL/m2 | Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.  Do not use where release to drains (sewer) and/or surface waters cannot be prevented. |
| Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional." |
| Use # 5 – Indoor – Non-washable textile surfaces–General public (non-professional users) | *Dermatophagoides pteronyssinus* – adults and nymphs  *Rhipicephalus sanguineus* – adults and nymphs  *Ixodes ricinus*– adults and nymphs  *Ctenocephalides felis –* Cat fleas - adults | General public (non-professional users) | 15 mL/m² (equivalent to 10 sprayings)  This use is intended to be applied once per year or in those cases where infestation exists. Do not apply more than two times per year. If the infestation persists contact a (trained) professional. |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| INSECTICIDA RTU PER ZNZ | Spain (rMS) |
| EL MATON INSECTICIDA LIQUIDO | Spain (rMS) |
| SPLASH INSECTICIDA LIQUIDO |
| VETE INSECTICIDA LIQUIDO |
| X-TERMIN INSECTICIDA LIQUIDO |
| CARREFOUR INSECTICIDA LIQUIDO |
| ALIADA INSECTICIDA LIQUIDO PULVERIZABLE |
| EROSKI INSECTICIDA LIQUIDO |
| BLOCK MAGIC INSECTICIDA LIQUIDO PULVERIZABLE |
| CASA JARDIN INSECTICIDA LIQUIDO |
| ZZ PAFF INSECTICIDA LIQUIDO |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | ZELNOVA ZELTIA SA |
| **Address** | Poligono Torneiros s/n  36400 O Porriño, Pontevedra, Spain |
| **Authorisation number** | ES-APP(NA)-2024-18-00915 | |
| **Date of the authorisation** | 01/04/2024 | |
| **Expiry date of the authorisation** | 19/03/2034 | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | ZELNOVA ZELTIA SA |
| **Address of manufacturer** | Poligono Torneiros s/n  36400 O Porriño, Pontevedra, Spain |
| **Location of manufacturing sites** | Poligono Torneiros s/n  36400 O Porriño, Pontevedra, Spain. |

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

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | TAGROS CHEMICALS INDIA LIMITED |
| **Address of manufacturer** | Jhaver Center", IV Floor, Rajha Annamalai Building , No. 72, Marshalls Road, Egmore,  Chennai - 600 008,  India |
| **Location of manufacturing sites** | A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore – 607 005  Tamil Nadu,  India |

### Product composition and formulation

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** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | Specification ≥ 93.0% w/w sum of all permethrin isomers. |
| **Structural formula** | 1Rcis isomer    1Scis isomer    1Rtrans isomer    1Strans isomer |

#### Candidate(s) for substitution

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

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.4 |
| Propan 2-ol | 2-Propanol | Solvent | 67-63-0 | 200-661-7 | 0.24 |
| Other components | For further details on product composition please refer to the Confidential PAR. | | | | up to 100 |

|  |  |
| --- | --- |
|  | **AS content** |
| **Formulation recipe:**  **Content of the AS used for the formulation of the BP (%)** | 0.4 |
| **AS content in the BP to be indicated in the SPC (%)** | **0.4** |
| **Minimum purity in the source of the AS (%)** | 93 |
| **"Minimum pure" AS content (%)** | **0.372** |

#### Information on technical equivalence

The source of permethrin active substance supplied by Tagros Chemicals India Limited is the known source from the BPD/BPR process for the active substance permethrin. Therefore, this source is not a technical equivalence

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

Based on the BPR Art. 3.1(f) definition of ‘substance of concern’ which includes the condition «*and is present or is produced in a biocidal* *product in sufficient concentration to present risks of such an effect*» no ‘substances of concern’ are present in the biocidal product.

Regarding to the environment, besides the active substance permethrin, this product contains another substance of concern, Propan-2-ol, this substance is an active substance for other product types (PT1, PT2 and PT4) and it is in a concentration higher than 0.1% in the biocidal product. Therefore, although it is not considered as toxic for the environment, applying the specifications of Art. 3 (1f) of Regulation (EU) No 528/2012, this substance must be considered a Substance of Concern (SoC) and included into the environmental risk assessment.

Information on the complete composition is provided in the Confidential PAR.

#### Type of formulation

|  |
| --- |
| AL - Any other liquid. |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard pictogram | GHS09 |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P103: Read label before use.  P273: Avoid release to the environment.  P391: Collect spillage.  P501:  • Trained professional and Professional users: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.  • Non-professional users: Dispose of content and / or its container as hazardous waste according to the regulations in force. |
|  | |
| Note | EUH208 Contains permethrin. May produce an allergic reaction. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Indoor – spot in hiding places including crack and crevices– crawling insects – cockroaches, ants and silverfishes – General public / Professionals

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is a ready-for-use formulation to be applied by trigger sprayer into spot and/or crack and crevices treatments against crawling insects in empty rooms at domestic facilities as kitchens and food store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. |
| **Target organism (including development stage)** | Crawling insects  Cockroaches:  *Blattella germanica* (adults and nymphs)  *Blatta orientalis* (adults and nymphs)  Ants:  *Lasius niger* (adults)  Silverfishes:  *Lepisma saccharina* (adults) |
| **Field of use** | Indoor – spot in hiding places including crack and crevices on restricted areas not regularly cleaning |
| **Application method(s)** | Spraying.  The product is applied by spraying downwards on corners (spot treatment) and in hiding places including crack and crevices wherein the insects use to pass or hide using trigger or handheld sprayers. |
| **Application rate(s) and frequency** | For cockroaches and ants: 15 mL/m² (equivalent to 10 sprayings)  For silverfishes: 25.5 mL/m2 (equivalent to 17 sprayings)  The product showed residual efficacy against ants (3 weeks) and silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces).  The product has no residual action against cockroaches.  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a (trained) professional. |
| **Category(ies) of users** | General public / Professional |
| **Pack sizes and packaging material** | Professional:  Plastic bottle (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  Jerry can (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  General public:  Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL) |

##### Use-specific instructions for use

|  |
| --- |
| Refer to general direction of use (section 2.1.5). |

##### Use-specific risk mitigation measures

|  |
| --- |
| The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.  Professional:  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  (Trained) Professionals are not allowed to wash contaminated clothes at home.  General public:  Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed:  "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."  Please refer to general direction of use for further information. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

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

|  |
| --- |
| (Trained) Professional users:  Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.  Code the waste according to Decision 2014/955 / EU.  Do not release to soil, ground, surface water or any kind of sewer  Non professional users:  Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.  Do not release into soil, ground, surface water or any kind of sewer. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

#### Use description

Table 2. Use # 2 – Indoor – spot in hiding places including crack and crevices – crawling insects – cockroaches and silverfishes – Trained professionals

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is a ready-for-use formulation to be applied by spraying into spot and/or crack and crevices treatments against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) of garages, lofts, attics, garrets, kitchens… where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. |
| **Target organism (including development stage)** | Crawling insects  Cockroaches:  *Blattella germanica* (adults and nymphs)  *Blatta orientalis* (adults and nymphs)  Silverfishes:  *Lepisma saccharina* (adults) |
| **Field of use** | Indoor – spot in hiding places including crack and crevices on restricted areas not regularly cleaning |
| **Application method(s)** | Spraying.  The product is applied by spraying downwards on corners (spot treatment) and in hiding places including crack and crevices wherein the insects use to pass or hide using hand held or backpack sprayers (low pressure 1-3 bars). |
| **Application rate(s) and frequency** | For cockroaches: 15 mL/m² (equivalent to 10 sprayings with the trigger spray)  For silverfishes: 25.5 mL/m2 (equivalent to 17 sprayings with the trigger spray)  The product showed residual efficacy against silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces)  The product has no residual action against cockroaches.  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). |
| **Category(ies) of users** | Trained professionals |
| **Pack sizes and packaging material** | Plastic bottle (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL; 1, 2, 3, 5, 10 and 25 L)  Jerry can (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL; 1, 2, 3, 5, 10 and 25 L)  Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL) |

##### Use-specific instructions for use

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

##### Use-specific risk mitigation measures

|  |
| --- |
| The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.  Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  Trained Professionals are not allowed to wash contaminated clothes at home.  Please refer to general direction of use for further information. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

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

|  |
| --- |
| Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.  Code the waste according Decision 2014/955/EU.  Do not release to soil, ground, surface water or any kind of sewer. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

#### Use description

Table 3. Use # 3 – Outdoor – Directly application in ant nests – Trained professionals / Professionals

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is sprayed directly into the ant nests. |
| **Target organism (including development stage)** | Black ant (*Lasius niger)* - adults, larvae, nymphs, queen |
| **Field of use** | Outdoor  The product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located. |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), equivalent to 2 sprayings with the trigger spray.  Information only for trained-professionals: Application rate: 15 mL/m2 |
| **Category(ies) of users** | Trained professionals / Professionals |
| **Pack sizes and packaging material** | Trained professionals:  Plastic bottle (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL; 1, 2, 3, 5, 10 and 25 L)  Jerry can (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL; 1, 2, 3, 5, 10 and 25 L)  Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  Professionals:  Plastic bottle (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  Jerry can (250, 300, 400, 500, 600, 700, 800, 900, 1000 mL)  Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL) |

##### Use-specific instructions for use

|  |
| --- |
| To achieve full effect, identify the ant nest's location carefully and apply the product there.  For use only in areas that are inaccessible to infants, children, pets and non-target animals.  Secure the treated area so that no one can access the nests during product application and action.  After product’s application, cover the treated area with a plastic tarp or small bucket to avoid that the product could be carried away by rainwater or air.  Please refer to general direction of use for further information. |

##### Use-specific risk mitigation measures

|  |
| --- |
| Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). New gloves for each work shift.  Wear a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).  Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).  (Trained) Professionals are not allowed to wash contaminated clothes at home.  Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.  Do not use where release to drains (sewer) and/or surface water cannot be prevented.  Please refer to general direction of use for further information. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

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

|  |
| --- |
| (Trained) Professional users:  Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.  Code the waste according Decision 2014/955/EU.  Do not release to soil, ground, surface water or any kind of sewer. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

#### Use description

Table 4. Use # 4 – Outdoor – Directly application in ant nests – General public (non-professional users)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is sprayed directly into the ant nests. |
| **Target organism (including development stage)** | Black ant (*Lasius niger)* - adults, larvae, nymphs, queen |
| **Field of use** | Outdoor  The product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located. |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), equivalent to 2 sprayings) with the trigger spray. |
| **Category(ies) of users** | General public (non-professional users) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL) |

##### Use-specific instructions for use

|  |
| --- |
| To achieve full effect, identify the ant nest's location carefully and apply the product there.  For use only in areas that are inaccessible to infants, children, pets and non-target animals.  Secure the area so that no one can access the nests during product application and action.  After product’s application, cover the treated area with a plastic tarp or small bucket to avoid that the product could be carried away by rainwater or air.  Please refer to general direction of use for further information. |

##### Use-specific risk mitigation measures

|  |
| --- |
| Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.  Do not use where release to drains (sewer) and/or surface waters cannot be prevented.  Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional".  Please refer to general direction of use for further information. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

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

|  |
| --- |
| Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations  Do not release to soil, ground, surface water or any kind of sewer. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

#### Use description

Table 5. Use # 5 – Indoor – Non-washable textile surfaces–General public (non-professional users)

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette… |
| **Target organism (including development stage)** | *Dermatophagoides pteronyssinus* – adults and nymphs  *Rhipicephalus sanguineus* – adults and nymphs  *Ixodes ricinus*– adults and nymphs  *Ctenocephalides felis –* Cat fleas - adults |
| **Field of use** | Indoors – non-washable textile surfaces (surface treatment) |
| **Application method(s)** | Spraying with a hand held trigger spray.  The product is sprayed over the mattresses, carpet, moquette,… directly from the ready-to-use trigger sprayer. |
| **Application rate(s) and frequency** | 15 mL/m² (equivalent to 10 sprayings)  This use is intended to be applied once per year or in those cases where infestation exists. Do not apply more than two times per year. If the infestation persists contact a (trained) professional. |
| **Category(ies) of users** | General public (non-professional users) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL) |

##### Use-specific instructions for use

|  |
| --- |
| This use involves the following steps of application:   1. First step consists in spraying the product on the surfaces to be treated (mattresses, blankets, bedspreads, bedsteads, pillows, carpets …). 2. The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste. 3. For cleaning, do not use wet cleaning procedures. Use only dry-cleaning procedures such as vacuum, damp paper, broom... After cleaning, dispose the collected residues or the damp papers used as solid wastes. |

##### Use-specific risk mitigation measures

|  |
| --- |
| Due to the fact that the product is intended for use by consumers (non-professionals), it is necessary to make clear that there might be a risk of building up resistance and that this can be reduced. Since consumers have no knowledge of resistance issues the label claim should contain information to prevent it. The following phrase is proposed: "To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."  Please refer to general direction of use for further information. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

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

|  |
| --- |
| Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.  Do not release into soil, ground, surface water or any kind of sewer. |

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

|  |
| --- |
| Refer to general direction of use (section 2.1.5) |

### General directions for use

#### Instructions for use

|  |
| --- |
| Always read the label or leaflet before use and follow all the instructions provided.  The biocidal product contains permethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds.  Further specific information for each use can be found in respective section of the use. |

#### Risk mitigation measures

|  |
| --- |
| Do not spray directly on people, animals or bedding.  Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.  Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.  Contains Permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).  Do not apply in rooms where fish tanks and/or terrariums are present.  Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.  Further specific information for each use can be found in respective section of the use. |

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

|  |
| --- |
| Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.  **IF INHALED:** If symptoms occur call a POISON CENTRE or a doctor.  **IF SWALLOWED**: If symptoms occur call a POISON CENTRE or a doctor.  **IF ON SKIN:** Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.  **IF IN EYES:** If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  **IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.**  **IF PETS/ANIMALS EXPOSURE**, get veterinary advice/attention.  Emergency measures to protect the environment:  - Avoid to contaminate soil/subsoil.  - Prevent spills into surface water or the drainage system.  - Retain contaminated washing water and discard.  - If the product gets into water or soil, it should be removed mechanically. Transfer to a suitably labelled container and dispose of as hazardous waste according to local legislation.  - Suitable material for containment: absorbing material, organic, sand. |

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

|  |
| --- |
| Please, see specific instructions for safe disposal of the product and its packaging provided above. |

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

|  |
| --- |
| Shelf life: 2 years.  Store in the original container in dry well-ventilated place.  Store the original container tightly closed.  Keep away from sun radiation and all others heat sources.  Keep out of reach of children and non target animals/pets  Keep/store away from food, drink and animal feedstuffs. |

### Other information

|  |
| --- |
| This product contains a bittering agent that makes it repulsive to people or pets.  **Only for Spain:**  According to national legislation, in Spain there are until three user categories:  • Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.  • Professional users (P or NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.  • Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.  At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional and non-professional users the maximum size that can be authorized is 1 L.  In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:  1. The hazardousness of the product under evaluation.  2. The use being requested.  3. The frequency of use.  4. Complexity of control measures |

### 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 | 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL | plastic | Cap or trigger spray | Trained Professional and Professional users | Yes |
| Bottle | 2, 3, 5, 10 and 25 L | plastic | Cap or trigger spray | Trained Professional users | Yes |
| Jerry can | 250, 300, 400, 500, 600, 700, 800, 900, 1000 mL | plastic | Cap | Trained Professional and Professional users | Yes |
| Jerry can | 2, 3, 5, 10 and 25 L | plastic | Cap | Trained Professional users | Yes |
| Bottle | 100, 150, 200, 250, 300, 400, 500, 600, 700, 800, 900,  1000 mL | plastic | Trigger spray | Trained Professional, Professional and Non-professional users | Yes |

### Documentation

#### Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.

The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential PAR.

#### Access to documentation

The applicant “Zelnova Zeltia” has submitted a letter of access for the active substance included in biocidal product submitted; Limaru NV formerly by Tagros Chemicals India Limited as owner of data dossiers for Permethrin active substance.

## Assessment of the biocidal product

### Intended uses as applied for by the applicant

Table 1. Use # 1 – Indoor – voids/cavities treatment – crawling insects - Professional

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is a ready-for-use formulation to be applied by spraying into spot and/or crack and crevices treatments against crawling insects in empty rooms at industrial and domestic facilities as kitchens and store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) of garages, lofts, attics, garrets, kitchens… where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. |
| **Target organism (including development stage)** | *Blattella germanica* – Cockroaches (adult + nymphs)  *Blatta orientalis* - Cockroaches (adult + nymphs)  *Lasius niger* - Ants (adult + larvae + nymphs + queen)  *Lepisma saccharina* – Silverfishes (adult)  *Dermatophagoides pteronyssinus* – Mites (adult + nymphs)  *Acarus siro* (flour mite) – adults  *Ixodes ricinus* – Ticks (adult + nymphs)  *Rhipicephalus sanguineus* – Ticks (adult + nymphs)  *Ctenocephalides felis –* Cat fleas (adults + larvae) |
| **Field of use** | Indoor – voids/cavities treatment |
| **Application method(s)** | Spraying.  The product is applied directly on voids and cavities particularly the corners (spot treatment) or cracks and crevices wherein the insects use to pass or hide using professional spraying equipment. |
| **Application rate(s) and frequency** | 15 mL/m²  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). |
| **Category(ies) of users** | Professional (trained and non-trained professional) |
| **Pack sizes and packaging material** | Plastic bottle (from 250 mL to 25 L)  Jerry can (from 250 mL to 25 L)  Plastic bottle with trigger spray (≤ 1000 mL) |

Table 2. Use # 2 – Indoor – voids/cavities treatment – Crawling insects – General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is a ready-for-use formulation to be applied by trigger sprayer into spot and/or crack and crevices treatments against crawling insects in empty rooms at domestic facilities as kitchens and food store rooms. It is applied in hiding places (e.g. voids, grooves, crack and crevices) where crawling insects are looking for food, paying special attention to grooves and cracks and areas behind or under machinery, kitchen equipment or pipes. |
| **Target organism (including development stage)** | *Blattella germanica* – Cockroaches (adult + nymphs)  *Blatta orientalis* - Cockroaches (adult + nymphs)  *Lasius niger* - Ants (adult + larvae + nymphs + queen)  *Lepisma saccharina* – Silverfishes (adult)  *Dermatophagoides pteronyssinus* – Mites (adult + nymphs)  *Acarus siro* (flour mite) – adults  *Ixodes ricinus* – Ticks (adult + nymphs)  *Rhipicephalus sanguineus* – Ticks (adult + nymphs)  *Ctenocephalides felis –* Cat fleas (adults + larvae) |
| **Field of use** | Indoor – voids/cavities treatment |
| **Application method(s)** | Spraying.  The product is applied by spraying using a trigger spray on voids and cavities and particularly the corners (spot treatment) or cracks and crevices wherein the insects use to pass or hide using a trigger sprayer. |
| **Application rate(s) and frequency** | 15 mL/m² (equivalent to 10 pulverizations)  In case of re-invasion, re-apply the product if necessary every 4 weeks (maximum 12 applications per year). If the infestation persists, contact a professional. |
| **Category(ies) of users** | General public (non-Professional) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

Table 3. Use # 3 – Indoor – Non-washable textile surfaces – General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments once the product formulation is dried. It is intended to be applied in textile materials as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette… |
| **Target organism (including development stage)** | *Dermatophagoides pteronyssinus* – Mites (adult + nymphs)  *Ixodes ricinus* – Ticks (adult + nymphs)  *Rhipicephalus sanguineus* – Ticks (adult + nymphs)  *Ctenocephalides felis –* Cat fleas (adults + larvae) |
| **Field of use** | Indoor – surface treatment |
| **Application method(s)** | Spraying  The product is sprayed over the mattresses, carpet, moquette,… directly from the ready-to-use trigger sprayer. Once the efficacy time is over (set by the efficacy trials which are ongoing), the treated surface is vacuumed with the vacuum cleaner in order to release killed insects and product’s residue. |
| **Application rate(s) and frequency** | 15 mL/m² (equivalent to 10 pulverizations).  This use is intended to be applied once per year or in those cases where infestation exists. Do not apply more than two times per year. If the infestation persists contact a professional. |
| **Category(ies) of users** | General public (non-Professional) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

Table 4. Use # 4 – Outdoor – Directly application in ant nests – Professional

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is sprayed directly into the ants’ nest. |
| **Target organism (including development stage)** | *Lasius niger* - Ants (adult + larvae + nymphs + queen) |
| **Field of use** | Outdoor  Around houses on paved ways, balconies and terraces where ant nests are located. |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 3.75 mL of average amount for a nest\*  Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks. |
| **Category(ies) of users** | Professional (Trained and non-trained professional) |
| **Pack sizes and packaging material** | Plastic bottle (from 250 mL to 25 L)  Jerry can (from 250 mL to 25 L)  Plastic bottle with trigger spray (≤ 1000 mL) |

\* an average area of 0.25 m2 is deemed for a nest (0.5 m x 0.5 m)

Table 5. Use # 5 – Outdoor – Directly application in ant nests – General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is sprayed directly into the ants’ nest. |
| **Target organism (including development stage)** | *Lasius niger* - Ants (adult + larvae + nymphs + queen) |
| **Field of use** | Outdoor (Ant’s nest) |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 3.75 mL/nest (approx. 2-3 pulverizations/nest\*)  Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks and if the infestation persist, contact with Pest Control Operator (PCO). |
| **Category(ies) of users** | General public (non-Professional) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

\* an average area of 0.25 m2 is deemed for a nest (0.5 m x 0.5 m)

Table 6. Use # 6 – Outdoor – Around paved and rain protected areas of buildings – Ants - Professional

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is intended to be applied around buildings on small surfaces as spots and crack and crevice paved surfaces where ants stay or wander around. These intended locations to be treated must be located on places protected from the rain, floods and cleaning water. |
| **Target organism (including development stage)** | *Lasius niger* – Ants (adult) |
| **Field of use** | Outdoor  On spots and crack and crevices around houses on paved ways, balconies and terraces not connected to STP and protected from rain, flood and water courses. |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 15 mL/m²  Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks. Up to 2 applications per year. |
| **Category(ies) of users** | Professional (trained and non-trained) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

Table 7. Use # 7 – Outdoor –Around paved and rain protected buildings – Ants - General public

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| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is intended to be applied by spraying around buildings on small surfaces as spots and crack and crevice paved surfaces where ants stay or wander around. These intended locations to be treated must be located on places protected from the rain, floods and cleaning water. |
| **Target organism (including development stage)** | *Lasius niger* – Ants (adult) |
| **Field of use** | Outdoor  On spots and crack and crevices around houses of paved ways, balconies and terraces not connected to STP and protected from rain, flood and water courses. |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | 15 mL/m² (equivalent to 10 pulverizations)  Residual efficiency is proved during 4 weeks. If the infestation persist, apply a second time after 4 weeks. Up to 2 applications per year. If infestation persists contact a professional. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

Table 8. Use # 8 – Indoor – Spot surface application against flies and mosquitoes – General public

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| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product is a ready-for-use formulation to be applied by spot spraying against flies and mosquitoes for use in empty premises at homes. |
| **Target organism (including development stage)** | *Musca domestica* – Flies (adult)  *Culex pipiens* – Mosquito (adult, female)  *Aedes aegypti –* Mosquito (adult, female)  *Aedes albopictus* – Tiger mosquito (adult, female) |
| **Field of use** | Indoor |
| **Application method(s)** | Spraying.  The product is applied by using a trigger spray directly on surface areas and particularly the windows corners or frames (spot treatment) or cracks and crevices wherein the flies and mosquitoes use to lay. |
| **Application rate(s) and frequency** | 15 mL/m² (equivalent to 10 pulverizations)  It is intended to be applied once the infestation appears. Maximum 12 applications per year. If infestation persist contact a Pest Control Operator. |
| **Category(ies) of users** | General public (non-Professional) |
| **Pack sizes and packaging material** | Plastic bottle with trigger spray (≤ 1000 mL) |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 | Permethrin RTU 0.4%  Batch No: V267A-LAB | Initially, after 14 days at 54ºC and after 2 years at 20ºC:  Opalescent Liquid | CH-621/2015 |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | Permethrin RTU 0.4%  Batch No: V267A-LAB | Initially, after 14 days at 54ºC and after 2 years at 20ºC:  White | CH-621/2015 |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | Permethrin RTU 0.4%  Batch No: V267A-LAB | Initially, after 14 days at 54ºC and after 2 years at 20ºC:  Characteristic odour | CH-621/2015 |
| Acidity / alkalinity | CIPAC MT 75.3  OECD 122 | Permethrin RTU 0.4%  Batch No: V267A-LAB | Initially:  6.4  After 14 days at 54ºC:  6.7  After 2 years at 20ºC:  4.6 | CH-621/2015 |
| Relative density / bulk density | CIPAC MT 186 | Permethrin RTU 0.4%  Batch No: V267A-LAB | 1.0008 g/mL at 20°C | CH-621/2015 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | Permethrin RTU 0.4%  Batch No: V267A-LAB | The product is stable after 14 days at 54°C. | CH-624/2015 |
| Active substance content |  |  | Initially:  Sum: 0.37±0.01 % w/w  Cis: 0.10±0.01 % w/w  Trans: 0.27±0.01 % w/w  After 14 days at 54ºC:  Sum: 0.38±0.01 % w/w  Difference:  2.70 % w/w  Cis: 0.10±0.01 % w/w  Difference:  0.00 % w/w  Trans: 0.28±0.01 % w/w  Difference:  3.70 % w/w |  |
| Homogeneity of application |  |  | No changes were observed. |  |
| Appearance and stability of the package |  |  | No changes were observed. |  |
| Storage stability test – **long term storage at ambient temperature** | EPA OPPTS 830.6313 | Permethrin RTU 0.4%  Batch No: V267A-LAB | The product is stable after two years at ambient temperature. | CH-625/2015 |
| Active substance content |  |  | Initially:  Sum: 0.37±0.01 % w/w  Cis: 0.10±0.01 % w/w  Trans: 0.27±0.01 % w/w  After 2 years at 20ºC:  Sum: 0.38±0.01 % w/w  Difference:  2.70 % w/w  Cis: 0.10±0.01 % w/w  Difference:  0.00 % w/w Trans: 0.28±0.01 % w/w  Difference:  3.70 % w/w |  |
| Homogeneity of application |  |  | No changes were observed. |  |
| Appearance and stability of the package |  |  | No changes were observed. |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Permethrin RTU 0.4%  Batch No: V267A-LAB | The product is stable after 7 days at 0 ± 2°C. | CH-621/2015 |
| Effects on content of the active substance and technical characteristics of the biocidal product – **light** |  | - | Not applicable. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | CIPAC MT 46.3 | Permethrin RTU 0.4%  Batch No: V267A-LAB | No changes were observed. | CH-624/2015 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 | Permethrin RTU 0.4%  Batch No: V267A-LAB | No changes were observed. | CH-624/2015 |
| Wettability |  | - | Not applicable. | - |
| Suspensibility, spontaneity and dispersion stability |  | - | Not applicable. | - |
| Wet sieve analysis and dry sieve test |  | - | Not applicable. | - |
| Emulsifiability, re-emulsifiability and emulsion stability |  | - | Not applicable. | - |
| Disintegration time |  | - | Not applicable. | - |
| Particle size distribution, content of dust/fines, attrition, friability |  | - | Not applicable. | - |
| Persistent foaming |  | - | Not applicable. | - |
| Flowability/Pourability/Dustability |  | - | Not applicable. | - |
| Burning rate — smoke generators |  | - | Not applicable. | - |
| Burning completeness — smoke generators |  | - | Not applicable. | - |
| Composition of smoke — smoke generators |  | - | Not applicable. | - |
| Spraying pattern — trigger spray/aerosols | -- | Permethrin RTU 0.4%  Batch No: V267A-LAB | Initially, after 14 days at 54ºC and after 2 years at 20 ºC:  Mean diameter = 28.5 cm  Discharge rate = 1.5 g/hub | CH-624/2015  CH-625/2015  D.0106.13 |
| Physical compatibility |  | - | Not applicable. | - |
| Chemical compatibility |  | - | Not applicable. | - |
| Degree of dissolution and dilution stability |  | - | Not applicable. | - |
| Surface tension | OECD 115 EU 440/2008 No A.5 | Permethrin (0.4%) | 37.5 mN/m at 20°C | CH-621/2015 |
| Viscosity | CIPAC MT 22.1 OECD 114 | Permethrin (0.4%) | Kinematic viscosity: 1.264 cSt at 20°C; 0.913 at cSt at 40°  Dynamic viscosity: 1.265 cP at 20°C; 0.913 at cP at 40° | CH-621/2015 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| **NOTE**:  The applicant has noted that the studied batches have the same composition as the marketed formulation.  **Appearance**  The preparation is an opalescent white liquid with characteristic odour.  **Acidity / alkalinity**  The pH is determined in the pure product at 100% concentration. Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed.  **Relative density / bulk density**  From the experimental data obtained according to the guideline A.3 in Council Regulation (EC) No 440/2008 part A, CIPAC method MT 3.2 and OECD Test No 109, it can be concluded that the density of the Permetrina RTU 0,4% formulation sample is 1.0008 g/mL at 20°C; the specific gravity is 1.0026 at 20°C, and the relative density (D204) is 1.0008.  **Accelerated storage**  The Permetrina RTU 0,4% formulation sample is stable in its commercial packaging under the tested accelerated storage conditions.  **Long term storage at ambient temperature**  The Permetrina RTU 0,4% formulation sample is stable in its commercial packaging under the tested two years storage conditions.  **Low temperature stability test for liquids**  The Permetrina RTU 0,4% formulation sample, after 7 days at 0 ± 2°C, did not show separation of solid or liquid material, nor changes in its physical state.  **Effects of light**  The formulation is contained in a closed bottle and no expousure with light is expected during storage and uses, thus the test is not performed.  The product application is not affected by light. According with the experience of the registrant, effects of light in the product stability are not expected.  **Effects of temperature and humidity**  The product is not affected by temperature and humidity if stored at room temperature.  **Effects of the reactivity towards container material**  No effects and reactivity on container material was observed after 14 days of storage at 54°C: the container didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena.  **Technical characteristics of the biocidal**  The studies do not need to be conducted because the formulation is a ready-to-use water emulsion and the product is not diluted before the application.  **Spraying pattern**  Four plastic bottle with trigger spray filled with the test item were weighted using the technical balance; then each bottle was sprayed 20 times and re-weighting after each spray. The trigger status was inspected visually and possible blockage of the nozzle are detected.  **Physical and chemical compatibility with other products**  The formulation is not expected to be used with other product, thus the test is not required.  **Surface Tension**  The surface tension is lower than 60 mN/m under the conditions of the plate method, therefore the biocidal product should be regarded as a surface-active material.  **Viscosity**  Viscosity was determined by two different U-Tube viscosimeters at 20ºC and 40ºC.  **Conclusions**  The preparation is an opalescent white liquid with characteristic odour, containing 0.4 % w/w of permetrin. Its density is 1.0008 g/mL. It has a pH of 6.4.  The viscosity measurement at 20ºC determined a mean value of 1.26 mPa s whereas the other measurement at 40ºC provided mean results of 0.91 mP s. Moreover, the product is surface active.  After 14 days of storage at 54°C, the active ingredient content and the physical-chemical properties of the test item are comparable to the relevant values obtained in the initial characterisation. No change in the sample appearance, colour or odour, was found in the formulation stored in plastic bottle with trigger for 14 days of storage at 54°C and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena.  Moreover, no significant changes in pH value, trigger spray head performance and spray diameter were found in the test item stored in plastic bottle with trigger for 14 days of storage at 54°C  After 7 days at 0 ± 2°C, the sample did not show changes, so the phrase “protect from frost” is not necessary in the label.  After two years of storage at ambient temperature, the test item did not show any significant difference in terms of active ingredient content, aspect and emulsion characteristic, respect the initial conditions. The variation on the pH is acceptable to this kind of product once it is ensured the active ingredient content and the compatibility with the packaging is not affected. Thus the test item can be considered stable and a shelf life of two years is proposed.  There is no effect at high and low temperature on the stability of the formulation, since neither the active ingredient content nor the technical properties were changed. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | CHETAH software | Permethrin RTU 0.4%  Batch No: V267A-LAB | Not explosive. | CH-622/2015 |
| Flammable gases |  | - | Not applicable | - |
| Flammable aerosols |  | - | Not applicable | - |
| Oxidising gases |  |  | Not applicable | - |
| Gases under pressure |  |  | Not applicable | - |
| Flammable liquids | EU Method A.9 | Permethrin RTU 0.4%  Batch No: V267A-LAB | Not flammable | CH-622/2015 |
| Flammable solids |  |  | Not applicable | - |
| Self-reactive substances and mixtures |  | - | Not applicable | - |
| Pyrophoric liquids |  | - | Not applicable | - |
| Pyrophoric solids |  |  | Not applicable | - |
| Self-heating substances and mixtures |  | - | Not applicable | - |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not applicable | - |
| Oxidising liquids | CHETAH software | Permethrin RTU 0.4%  Batch No: V267A-LAB | Not oxidizing properties. | CH-622/2015 |
| Oxidising solids |  |  | Not applicable | - |
| Organic peroxides |  | - | Not applicable | - |
| Corrosive to metals | UN Manual of Tests and Criteria - Test  C.1 UN-MTC, Part III, Section 37, Paragraph 37.4 method | Pistola insetticida Permetrina 0,4% - Pertrin RTU | No corrosive to metals | R-FD-22-008577 |
| Auto-ignition temperatures of products (liquids and gases) | EC 440/2008 No A.15 | Permethrin RTU 0.4%  Batch No: V267A-LAB | No auto-ignition until 600°C | CH-621/2015 |
| Relative self-ignition temperature for solids |  | - | Not applicable | - |
| Dust explosion hazard |  | - | Not applicable | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| **Note:**  The applicant has noted that the studied batches have the same composition as the marketed formulation.  **Explosives**  From the criteria results obtained with CHETAH (Chemical Thermodynamic And Hazard evaluation) software based on the molecular structure of the active ingredient and main co-formulant of the test item, it can be concluded that the formulation sample should not exhibit an explosive behaviour.  **Flammability**  No typical flammability phenomena was observed upto 130°C. The pilot flame was extinguished at this temperature. Thus the preparation is not classifeid as Flammable.  **Self-reactive substances and mixtures**  The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.  **Pyrophoric liquids**  The test does not need to be conducted because the formulation does not contain any pyrophoric substance.  **Self-heating substances and mixtures**  The study does not need to be conducted because none of the components is classified as explosive or associated with self-reactive properties and hence, the classification procedure does not need to be applied.  **Oxidising properties**  From the criteria results obtained with CHETAH (Chemical Thermodynamic And Hazard evaluation) software based on the molecular structure of the active ingredient and main co-formulant of the test item, it can be concluded that the formulation sample should not exhibit an oxidizing behaviour.  **Organic peroxides**  The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.  **Corrosive to metals**  It is not possible to waive an endpoint on physical hazards by the structure of the BP components, when one of the components (permethrin comprises chlorine) comprises a chemical group which indicates that the BP may corrode metals. Therefore, the test needs to be applied.  Corrosion has not present on either fully immersed or partially immersed samples or in samples exposed to vapour. Furthermore, the data, photos in the report clearly show that the biocidal product is not corrosive.  **Auto-ignition temperature (liquids and gases)**  The auto-ignition temperature of the sample is 600°C at 1010 mbar (ignition delay time: 12 seconds), according to the A.9 method.  **Conclusions**  The biocidal product has not been classified as flammable, corrosive, explosive and oxidising.  Therefore, it does not need to be classified regarding physical and chemical hazards as it is not flammable and not corrosive to metals, not oxidising or explosive and does not self-ignite. |

### Methods for detection and identification

| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin sum of isomers* | HPLC-UV | 75 % of the nominal concentration of active ingredient / 2 | 128.3 to 299.4 g/mL  n = 5  r2 = 0.99 | Yes | 98.21 – 100.00 | 99.1 | -- | -- | CH-623/2015 |
| 100 % of the nominal concentration of active ingredient / 2 | 96.62 – 99.43 | 98.0 | -- |
| 125 % of the nominal concentration of active ingredient / 2 | 95.71 – 98.46 | 97.1 | -- |
| All four permethrin stereoisomers in an EW formulation | Chiral HPLC-DAD | CIPAC Validated | CIPAC Validated | CIPAC/4946\* | CIPAC Validated | CIPAC Validated | CIPAC Validated | CIPAC Validated | AR/CAR (IE CA, 2014, 2017 addendum). |
| All four permethrin stereoisomers in an EC formulation | Chiral HPLC-DAD | 1S-cis Permethrin (S,S)  0.69 %w - 4.63%w  1R-cis Permethrin (R,R)  0.69 %w -4.59 %w  1S-trans Permethrin (S,R)  1.93 %w -  12.9 %w  1R-trans Permethrin (R,S)  1.91 %w -  12.8 %w | R2 = 1.000 for all  1S-cis Permethrin (S,S):  0.013-0.34 mg/mL (n = 6 points)  1R-cis Permethrin (R,R):  0.013-0.33 mg/mL (n = 6 points)  1S-trans Permethrin (S,R):  0.035-0.93 mg/mL (n = 6 points)  1R-trans Permethrin (R,S):  0.035-0.93 mg/mL (n = 6 points) | No significant interference | n = 2 at each level – 3 levels  1S-cis Permethrin (S,S)  97.3 – 98.7%  1R-cis Permethrin (R,R)  98.2 – 99.5%  1S-trans Permethrin (S,R)  97.5 – 99.5%  1R-trans Permethrin (R,S)  96.6 – 99.1% | n = 2 at each level – 3 levels  1S-cis Permethrin (S,S)  Recovery level (0.69 %w): 97.3 %  Recovery level (2.31%w): 98.7 %  Recovery level (4.63%w): 98.3 %  1R-cis Permethrin (R,R) (n = 2)  Recovery level (0.69 %w): 98.6 %  Recovery level (2.30 %w): 99.5 %  Recovery level (4.59 %w):98.2%  1S-trans Permethrin (S,R) (n = 2)  Recovery level (1.93 %w): 97.5 %  Recovery level (6.43 %w): 99.5 %  Recovery level (12.9 %w): 98.1 %  1R-trans Permethrin (R,S) (n = 2)  Recovery level (1.91 %w): 96.6 %  Recovery level (6.38 %w): 99.1 %  Recovery level (12.8 %w): 98.0 % | Six samples (single injection) from 1 batch –  1S-cis Permethrin (S,S): 0.46 %.  1R-cis Permethrin (R,R): 0.41 %  1S-trans Permethrin (S,R): 0.34 %  1R-trans Permethrin (R,S): 0.62 % | Not applicable | AR/CAR (IE CA, 2014, 2017 addendum). |
| All four permethrin stereoisomers in an WP formulation | Chiral HPLC-DAD | 1S-cis Permethrin (S,S)  0.99 %w – 6.57%w  1R-cis Permethrin (R,R)  0.98 %w -6.52 %w  1S-trans Permethrin (S,R)  2.74 %w -  18.3 %w  1R-trans Permethrin (R,S)  2.72 %w -  18.3 %w | As for EC formulation above | No significant interference | n = 2 at each level – 3 levels  1S-cis Permethrin (S,S)  98.8 – 101.2%  1R-cis Permethrin (R,R)  98.0 – 101.4%  1S-trans Permethrin (S,R)  99.3 – 100.9%  1R-trans Permethrin (R,S)  99.4 – 101.0% | n = 2 at each level – 3 levels  1S-cis Permethrin (S,S)  Recovery level (0.99% w/w): 98.8 %  Recovery level (3.29%): 100.7 %  Recovery level (6.57%): 101.2 %  1R-cis Permethrin (R,R)  Recovery level (0.98% w/w): 98.0 % Recovery level (3.26%): 100.8 % Recovery level (6.52%): 101.4 %  1S-trans Permethrin (S,R)  Recovery level (2.74%): 99.3 % Recovery level (9.13%): 100.9 % Recovery level (18.3% w/w): 100.8 %  1R-trans Permethrin (R,S)  Recovery level (2.72% w/w): 99.4 % Recovery level (9.05% w/w): 101.0 % Recovery level  (18.1 % w/w): 100.9 % | Six samples (single injection) from 1 batch –  1S-cis Permethrin (S,S): 1.08%.  1R-cis Permethrin (R,R): 1.11 %  1S-trans Permethrin (S,R): 0.96 %  1R-trans Permethrin (R,S): 0.93 % | Not applicable | AR/CAR (IE CA, 2014, 2017 addendum). |
| All four permethrin stereoisomers in wood preservatives with common co-formulants | Chiral HPLC-DAD | No data provided | No data provided | No significant interference for TC or basic product formulation, however significant interference when formulations became more complex (higher number of actives and or higher number of common co-formulants found in wood preservatives. | No data provided | No data provided | No data provided | Not applicable | AR/CAR (IE CA, 2014, 2017 addendum). |
| *Impurities in Permethrin* | GC-FID, HPLC-UV, and GC-MS |  |  |  |  |  |  |  | AR/CAR (IE CA, 2014, 2017 addendum). |
| \* The method has been peer-validated by CIPAC for EW formulations and is available under the pre-publication scheme (CIPAC/4946). | | | | | | | | | |

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| **Analytical methods for monitoring** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| **Analytical methods for soil** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin in silt and sandy loam* | HPLC/MS/MS | 5 μg/kg (= LOQ level), and 50 μg/kg | 1 μg/L to 100 μg/L (2 to 200 μg/kg)  r > 0.9992 | No signals / peaks interfering with the detection of the analyte were observed in extracts of untreated blank control specimens. | 70-110 |  | <20 | 5.0 μg/kg | AR/CAR (IE CA, 2014, 2017 addendum). |

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| **Analytical methods for air** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin* | HPLC/MS/MS | LOQ and 10-fold LOQ  n = 5 | 5.0 ng/mL to 500 ng/mL  r = 0.997 | The chromatograms of the control specimens showed no signals (<1 μg/m3) at the retention time of permethrin. | 87-92 | 89.63 | ≤6 % | 5 μg/m3 | AR/CAR (IE CA, 2014, 2017 addendum). |
| GC-MS/MS | 0.0001 and 0.001 mg/m3 | 0.05-10 mg/L.  y = 152187.4x + 1081.4  r = 1.0 | The method is specific for the determination of Permethrin in air since no interferences were observed in the chromatograms of solvent, control samples and fortification levels. | 72-74 | 73 | 1.85-3.35 | 0.0001 mg/m3 |

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| **Analytical methods for water** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin in drinking and surface water* | HPLC/MS/MS | 0.05 µg/L and 0.5 µg/L  n = 10 | 0.04 µg/L -10 µg/L  r > 0.9995 | The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest. | 70-110 |  | 1.7-2.2 | 0.05 µg/L | AR/CAR (IE CA, 2014, 2017 addendum). |

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| **Analytical methods for animal and human body fluids and tisues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
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| **Conclusion on the methods for detection and identification of the product** |
| **Note:**  The applicant has noted that the studied batches have the same composition as the marketed formulation.  **Analytical methods for the analysis of the product as such including the active substance, impurities and residues**  A suitable combination method (achiral and chiral) was peer-validated by CIPAC.  The validation study reports (EC, EW and WP) indicated that the chiral CIPAC method of analysis was considered acceptable for EC, EW and WP formulations. However the study indicated that considerable interference can occur with some complex wood preservative formulations, and that the CIPAC chiral method may not be suitable under these more complex conditions.  The method submitted by the applicant for analising the active substance in the biocidal product could be considered acceptable.  **Analytical methods for soil**  An acceptable validated method for residues of Permethrin in soil was presented.  **Analytical methods for air**  Acceptable validated methods were provided for residues of Permethrin in air.  **Analytical methods for water**  Acceptable validated methods were provided for residues of permethrin in water.  **Analytical methods for animal and human body fluids and tisues**  Not relevant as the active substances are neither toxic nor highly toxic.  **Analytical methods for monitoring of active substances and residues in food and feeding stuff**  Food and feeding stuff will not be exposed to permethrin based on the proposed usage.  **Conclusion**  The methods are indicated in the Assessment Report for the inclusion in Annex I (PT18).  The applicant has also submitted the letter of access granted by Lanxess Deutschland GmbH for information on analytical methods for the Permethrin active substance.  Finally, the analytical method submitted for the analyses of the active substance in the formulation is deemed sufficiently specific and precise. |

### 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 INSECTICIDE RTU PER ZNZ is intended to be used against cockroaches, silverfishes and ants in private/commercial buildings and hospitals and against cat fleas, mites and ticks on non-washable textile surfaces indoors, as well against ant nests outdoors.

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

The organisms to be controlled are:

-crawling insects, cockroaches (*Blatella germanica* and *Blatta orientalis*, adults and nymphs), ants and silverfishes as spot application in hiding surfaces (including crack and crevices) indoors.

- ants (*Lasius niger*, adults, larvae, nymphs, queen) as nest application outdoors, around houses on paved ways, balconies and terraces where ant nests are located.

-cat fleas (*Ctenocephalides felis*), house dust mite (*Dermatophagoides pteronyssinus*) and mites (*Rhipicephalus sanguineus* and *Ixodes ricinus*) on non-washable textile surfaces indoors.

The biocidal product is applied in empty rooms at industrial and domestic facilities as kitchens and store rooms, outdoors against ant nests and over textile surfaces indoors.

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

INSECTICIDA RTU PER ZNZ produces mortality and knockdown of all organisms. These effects were seen when the organisms were exposed to the biocidal product. It is not possible to assess unacceptable suffering.

#### Mode of action, including time delay

INSECTICIDA RTU PER ZNZ is formulated with the active substance permethrin (synthetic pyrethroid).

According to the CAR, permethrin is a synthetic pyrethroid that acts as a contact insecticide that causes convulsions, paralysis and ultimately death in target organisms. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive sodium channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of sodium channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Permethrin belongs to the type 1 pyrethroids which produce a poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

#### Efficacy data

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Periplaneta americana,* adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product .  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (10 insects per both treated and control group).  Application rates:  25 mL/m2 (Non-porous surface)  31.25 mL/m2 (porous surface) | Non-porous surfaces:  T0: 100% knockdown (20 minutes)  T1: 92% knockdown (20 minutes) and 100% knockdown (30 minutes)  T2: 94% knockdown (25 minutes) and 100% knockdown (35 minutes)  T3: 94% knockdown (30 minutes) and 100% knockdown (35 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 100% knockdown (40 minutes)  T1: 100% knockdown (60 minutes)  T2: 64% knockdown (60 minutes):  Mortality (T0 and T1 after 24 hours): 100%  Mortality (T2 after 24 hours): 84%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Periplaneta americana* (adults) in laboratory conditions until 3 weeks on non-porous surfaces** **at the application rate of 25 ml/m2 and until 1 week on porous surfaces at the application rate of 31.25 ml/m2.** | Test report:  CHEPER071015 – 08  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Blatta orientalis,* adults | Laboratory test: Residual efficacy  According to TNsG 18-19 | Non- porous surfaces (ceramic tiles- side up) were treated with the product  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (10 insects per both treated and control group).  Application rate:  20 mL/m2 | Non-porous surfaces:  T0: 96% knockdown (60 minutes)  T1: 98% knockdown (50 minutes)  T2: 90% knockdown (40 minutes) and 98% knockdown (60 minutes)  T3: 96% knockdown (60 minutes)  Mortality (T0, T1, T2, after 24 hours): 100%  Mortality (T3, after 24 hours): 98%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Blatta orientalis* (adults) until 3 weeks on non-porous surfaces in laboratory conditions at the application rate of 20 mL/m2.** | Test report:  CHEPER071015 – 01  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Blattella germanica,* adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 35, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (10 insects per both treated and control group).  Application rates:  20 mL/m2 (Non-porous surface)  25 mL/m2 (porous surface) | Non-porous surfaces:  T0: 90% knockdown (7 minutes) and 100% knockdown (15 minutes)  T1: 100% knockdown (10 minutes)  T2: 90% knockdown (10 minutes) and 100% knockdown (15 minutes)  T3: 92% knockdown (10 minutes) and 100% knockdown (15 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 98% knockdown (15 minutes) and 100% knockdown (20 minutes)  T1: 100% knockdown (15 minutes)  T2: 92% knockdown (40 minutes) and 96% knockdown (60 minutes)  Mortality (T0 and T1, after 24 hours): 100%  Mortality (T2, after 24 hours): 72%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Blattella germanica* (adults) until 3 weeks on porous and until 1 week on non-porous surfaces in laboratory conditions at the application rates of 20 mL/m2 (Non-porous surface) and 25 mL/m2 (porous surface).** | Test report:  CHEPER071015 – 02  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Lasius niger,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15 and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (20 insects per both treated and control group).  Application rates:  14 mL/m2 (Non-porous surface)  16 mL/m2 (porous surface) | Non-porous surfaces:  T0 and T1: 100% knockdown (7 minutes)  T2: 92% knockdown (7 minutes) and 100% knockdown (10 minutes)  T3: 94% knockdown (10 minutes) and 100% knockdown (15 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 98% knockdown (20 minutes) and 100% knockdown (25 minutes)  T1: 94% knockdown (20 minutes) and 100% knockdown (30 minutes)  T2: 94% knockdown (30 minutes)  T3: 93% knockdown (25 minutes) and 100% knockdown (30 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Lasius niger* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 14 mL/m2 (Non-porous surface) and 16 mL/m2 (porous surface).** | Test report:  CHEPER071015 – 10  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Ctenocephalides felis,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature:25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0) and one week after the treatment (T1).  5 replicates (10 insects per both treated and control group).  Application rates:  18 mL/m2 (Non-porous surface)  20 mL/m2 (porous surface) | Non-porous surfaces:  T0: 100% knockdown (10 minutes)  T1: 100% knockdown (15 minutes)  Mortality (after 24 hours): 100% (T0) and 98% (T1)  Controls: 0% knockdown, ≤2% mortality  Porous surfaces:  T0: 98% knockdown (60 minutes)  T1: 94% knockdown (50 minutes)  Mortality (after 24 hours): 92% (T0) and 100% (T1)  Controls: 0% knockdown, ≤6% mortality  **The efficacy is demonstrated against *Ctenocephalides felis* (adults) until 1 week on non-porous surfaces in laboratory conditions at the application rate of 18 mL/m2.** | Test report:  CHEPER071015 - 04  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Lepisma saccharina,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous surfaces (ceramic side) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25 and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (10 insects per both treated and control group).  Application rate: 18 mL/m2 | Non-porous surfaces:  T0: 100% knockdown (10 minutes)  T1: 100% knockdown (15 minutes)  T2: 90% knockdown (15 minutes) and 100% knockdown (20 minutes)  T3: 100% knockdown (20 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Lepisma saccharina* (adults) until 3 weeks on non-porous surfaces in laboratory conditions at the application rate of 18 mL/m2** | Test report:  CHEPER071015 – 05a  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Lepisma saccharina,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Porous surfaces (marble) were treated with the product.  Temperature:25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0) and one week after the treatment (T1).  5 replicates (10 insects per both treated and control group).  Application rate: 25 mL/m2 | Porous surfaces:  T0: 92% knockdown (20 minutes) and 100% knockdown (25 minutes)  T1: 100% knockdown (25 minutes)  Mortality (after 24 hours): 100% (T0) and 90% (T1)  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Lepisma saccharina* (adults) until 1 week on porous surfaces in laboratory conditions at the application rate of 25 mL/m2** | Test report:  CHEPER071015 – 05c  See confidential annex |
| Insecticide | Indoors  Flies | PERMETRINA RTU 0.4% | *Musca domestica,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 10, 15, 20, 25, 30, 40, 50 and 60 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (10 insects per both treated and control group).  Application rates:  14 mL/m2 (Non-porous surface)  16 mL/m2 (porous surface) | Non-porous surfaces:  T0: 92% knockdown (20 minutes) and 100% knockdown (25 minutes)  T1: 94% knockdown (20 minutes) and 100% knockdown (25 minutes)  T2: 88% knockdown (20 minutes) and 100% knockdown (50 minutes)  T3: 84% knockdown (20 minutes) and 100% knockdown (25 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 84% knockdown (35 minutes) and 96% knockdown (60 minutes)  T1: 82% knockdown (50 minutes) and 90% knockdown (60 minutes)  T2: 84% knockdown (40 minutes) and 96% knockdown (60 minutes)  T3: 86% knockdown (40 minutes) and 96% knockdown (60 minutes)  Mortality (T0, T1 after 24 hours): >90% and 90% (T2, T3)  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Musca domestica* (adults) until 3 weeks on porous surfaces and until 1 week on non-porous surfaces in laboratory conditions at the application rates of 14 mL/m2 (non-porous surface) and 16 mL/m2 (porous surface).** | Test report:  CHEPER071015 - 03  See confidential annex |
| Insecticide | Indoor  Mosquitoes | PERMETRINA RTU 0.4% | *Culex pipiens,*  adults | Laboratory test:  Residual efficacy  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20 (only porous surfaces), 25 (only porous surfaces) and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (20 females per both treated and control group).  Application rates:  18 mL/m2 (Non-porous surface)  20 mL/m2 (porous surface) | Non-porous surfaces:  T0: 100% knockdown (7 minutes)  T1: 87% knockdown (7 minutes) and 100% knockdown (10 minutes)  T2: 82% knockdown (7 minutes) and 100% knockdown (10 minutes)  T3: 88% knockdown (7 minutes) and 100% knockdown (10 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 92% knockdown (15 minutes) and 100% knockdown (20 minutes)  T1: 84% knockdown (15 minutes) and 100% knockdown (20 minutes)  T2: 100% knockdown (20 minutes)  T3: 98% knockdown (20 minutes) and 100% knockdown (25 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Culex pipiens* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 18 mL/m2 (non-porous surface) and 20 mL/m2 (porous surface).** | Test report:  CHEPER071015 - 09  See confidential annex |
| Insecticide | Indoor  Mosquitoes | PERMETRINA RTU 0.4% | *Aedes albopictus,*  adults | *Laboratory test:*  *Residual efficacy*  *According to TNsG 18-19* | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20 (only porous surfaces), 25 (only porous surfaces) and 30 minutes) andmortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replicates (20 females per both treated and control group).  Application rates:  18 mL/m2 (Non-porous surface)  20 mL/m2 (porous surface) | Non-porous surfaces:  T0: 100% knockdown (7 minutes)  T1: 100% knockdown (10 minutes)  T2: 83% knockdown (7 minutes) and 100% knockdown (10 minutes)  T3: 87% knockdown (7 minutes) and 100% knockdown (15 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 83% knockdown (15 minutes) and 100% knockdown (25 minutes)  T1: 97% knockdown (20 minutes) and 100% knockdown (25 minutes)  T2: 100% knockdown (20 minutes)  T3: 90% knockdown (20 minutes) and 98% knockdown (30 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Aedes albopictus* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 18 mL/m2 (non-porous surface) and 20 mL/m2 (porous surface).** | Test report:  CHEPER071015 - 07  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Dermatophagoides pteronyssinus,*  adults | Laboratory test:  No-choice test  According to TNsG 18-19 | Non-porous surfaces (ceramic tile) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Mortality (24 hours) was assessed after the application.  5 replicates (20 insects per both treated and control group).  Application rate: 20 mL/m2 | Non-porous surfaces:  91% mortality  Controls: 0% mortality  **The efficacy is demonstrated against *Dermatophagoides pteronyssinus* (adults) on non-porous surfaces in laboratory conditions at the application rate of 20 ml/m2.** | Test report:  CHEPER071015 - 11  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Dermatophagoides pteronyssinus,*  adults | Laboratory test:  No-choice test  According to TNsG 18-19 | Porous surfaces (parquet tile) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Mortality (24 hours) was assessed after the application.  5 replicates (around 30 insects (26-35) per both treated and control group).  Application rate: 31.5 mL/m2 | Porous surfaces:  98.14% mortality  Controls: ≥18.76% mortality  **The efficacy is NOT demonstrated against *Dermatophagoides pteronyssinus* (adults) on porous surfaces in laboratory conditions at the application rate of 31.5 ml/m2 due to the high mortality in the control groups.** | Test report:  CHEPER07 1015 – 11B  See confidential annex |
| Insecticide | Indoors | PERMETRINA RTU 0.4% | *Ixodes ricinus,*  adults | Laboratory test:  No-choice test  According to TNsG 18-19 | Non- porous (ceramic side) and porous surfaces (marble) were treated with the product.  Temperature: 25±1°C  Relative humidity: 60±5%.  Knockdown (2, 5, 7, 10, 15, 20, 25 and 30 minutes) and mortality (24 hours) were assessed after treatment and tile drying (T0), one week after the treatment (T1), two weeks after the treatment (T2) and three weeks after treatment (T3).  5 replications (10 insects per both treated and control group).  Application rates:  20 mL/m2 (Non-porous surface)  25 mL/m2 (porous surface) | Non-porous surfaces:  T0: 90% knockdown (7 minutes) and 100% knockdown (10 minutes)  T1: 94% knockdown (10 minutes) and 100% knockdown (20 minutes)  T2 and T3: 90% knockdown (10 minutes) and 100% knockdown (15 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  Porous surfaces:  T0: 100% knockdown (15 minutes)  T1: 90% knockdown (10 minutes) and 100% knockdown (15 minutes)  T2 and T3: 100% knockdown (15 minutes)  Mortality (T0, T1, T2 and T3, after 24 hours): 100%  Controls: 0% knockdown, 0% mortality  **The efficacy is demonstrated against *Ixodes ricinus* (adults) until 3 weeks on porous and non-porous surfaces in laboratory conditions at the application rates of 20 mL/m2 (non-porous surface) and 25 mL/m2 (porous surface).** | Test report:  CHEPER071015 - 06  See confidential annex |
| Insecticide | Indoors | PERTRIN RTU – 0.4% permethrin w/w | *Musca domestica,* adults (MDa)  *Aedes aegypti,* femaleadults (AAa)  *Aedes albopictus,* femaleadults(AAa’*)*  *Culex pipiens,* femaleadults (CPa)  *Blattella germanica,* adults and nymphs (BGa and BGn)  *Blatta orientalis,* adults and nymphs (BOa and BOn)  *Lasius niger,* adults (LNa)  *Lepisma saccharina,* adults (LSa)  *Ctenocephalides felis,* adults and larvae (CFa and CFl)  *Ixodes Ricinus,* adults and nymphs (IRa and IRn)  *Ripicephalus sanguineus,* adults and nymphs (RSa and RSn)  *Dermatophagoides pteronyssinus,* adults+nymphs (DPan)  *Acarus siro,* adults+nymphs (ASan) | Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 1.0 - February 2017 | Two trials were conducted: on non-porous (ceramic tiles) and on porous surfaces (blocks of concrete).  Test chamber: 15 m3 (6 m² floor, the treated area was 3m²) kept at a temperature 26°C+1°C, a relative humidity of 70%+5%, smooth ventilation (< 10 m3/h) and light: 700 lux 12 hours + 12 hours darkness.  The product was used to treat only spots crack&crevices (non barriers and non surfaces) located within the 3m² area where cardboards and polystyrene blocks were piled simulating furniture and crack and crevices, to mimic the reality of use.  For ticks, a mouse was a bite target*.*  Knockdown (10, 20, 30, 40 and 60 minutes) and mortality (24 hours) were assessed.  5 replicates of 25 insects for surface and for specie.  Application rate: 15 mL/m2 (the product was applied using a trigger spray). | 100% knockdown on non-porous and porous surfaces   |  |  |  | | --- | --- | --- | |  | Non-porous surfaces (min) | Porous surfaces (min) | | MDa | 10 | 10 | | AAa | 10 | 10 | | AAa’ | 10 | 10 | | CPa | 10 | 10 | | BGa | 30 | 30 | | BGn | 30 | 30 | | BOa | 30 | 30 | | BOn | 30 | 30 | | LNa | 10 | 10 | | LSa | 30 | 40 | | CFa | 30 | 40 | | CFl1 | 10 | 10 | | IRa | 30 | 10 | | IRn | 10 | 10 | | RSa | 20 | 30 | | RSn | 30 | 30 | | DPan | 30 | 30 | | ASan | 30 | 30 |   1The inhibition of the development of larvae into adult fleas was not demonstrated.  Controls: <1 % knockdown (4hours)  100 % mortality in both surfaces.  Controls: ≤4 % mortality  For ticks, blood-feeding ticks were observed in the control groups, but not in the treated groups.  **The test demonstrated the efficacy of all organisms tested (except for flea larvae) in simulated use conditions on porous and non-porous surfaces at the application rate of 15 ml/m2.** | Test report:  2296–RTU-SIM/0118-04  See confidential annex |
| Insecticide | Indoors | PERTRIN RTU - 0.4% permethrin w/w | *Blattella germanica,* adults  *Blatta orientalis,* adults | -Guidance on the Biocidal Products Regulation. Volume II Efficacy – Assessment and Evaluation (Parts B&C). Version 1.0. February 2017  - CEB French standard n° 249 | Apartments: 60-80 m² (treated area (kitchen): 12-15 m²)  5 replicates (for treated areas and controls).  Pre-assessment monitoring: 5 sticky traps (placed during 24 hours)/site  Two pre-counts at Day 14 and Day 7: the mean of these values gave the pre-treatment infestation level.  Product application: The product was applied as a cracks and crevices and spot treatment: under the fridge, under the kitchen sink, under the oven and the water-heater, on all cracks and crevices that can be an harbourage for cockroaches).  Application rate: 15 mL/m² (The product was applied using a professional sprayer with an anti-drop nozzle, pressurized)  Assessments were carried out 1, 7, 14 and 28 days after treatment. | Blattella germanica-Population reduction:  D1: 74.5%  D7: 91.2%  D14: 92.2%  D28: 97.4%  Control groups≤4.6 %  Blatta orientalis-Population reduction:  D1: 92.3%  D7: 95.3%  D14: 98.5%  D28: 98.1%  Control groups ≤2.4%  **The field test demonstrates the efficacy of the product against cockroaches at the application rate of 15 ml/m2** | Test report: 2296-RTU-FIELDCO/0118  See confidential annex |
| Insecticide | Ant nests | PERTRIN RTU - 0.4% permethrin w/w | *Lasius niger* | - Guidance on the Biocidal Products Regulation. Volume II Efficacy – Assessment and Evaluation (Parts B&C). Version 3.0. April 2018 - ECHA  - C.E.B. method No. 196 (1997)  - C.E.B. method MG1  - EPPO guidelines | Frequency of crossing in surface was measured before and after the treatment, then to open the nest after 4 weeks.  Temperature: average 22.6 ºC  Rain: 67 mm  Hours of sun: 248  The observation was done in a square of 1 m² around the main nest entry.  Application rate: 15 ml/m2. Nests and surrounding areas from 0.252 m2 (3.78 ml)to 0.188 m2 (2.83 ml) were treated. (The product was applied using a professional pressurized sprayer with an anti-drop nozzle (1 bar))  5 nests were monitored (as for the untreated controls).  6 assessments were done: -1, and +1, 7, 14, 21, 28 days after treatment. | Population reduction  Test product: 93.8% (day 1 after the treatment) and 100% (days 14, 21 and 28 after the treatment)  After 4 weeks the nest was open, 100% mortality.  Control groups≤2.5 %  For control groups > 500 ants were found alive.  **The field test demonstrates the efficacy of the product as nest ants application (and surrounding areas) at the application rate of 15 ml/m2.** | Test report:  2296-RTU-FIELDANT/0118-03  See confidential annex |
| Insecticide | Indoors | PERTRIN RTU - 0.4% permethrin w/w | *Ctenocephalides felis,* male adults, female adults and larvae  *Ixodes Ricinus,* male adults, female adults and nymphs  *Ripicephalus sanguineus,* male adults, female adults and nymphs  *Dermatophagoides pteronyssinus,* male adults, female adults and nymphs | Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B&C) – Version 3.0 – April 2018 - ECHA | Two trials were conducted: on carpet and on wood.  Test chamber: 15 m3 (6 m² floor, the treated area was 3m²) kept at a temperature 26°C+1°C, a relative humidity of 70%+5%, smooth ventilation (< 10 m3/h) and light: 700 lux 12 hours + 12 hours darkness.  Cardboards and polystyrene blocks and a water and food source were set on the floor of the test chamber.  For ticks, the bite target was a mouse.  Knockdown (30 minutes, 1 and 4 hours) and mortality (24 hours) were assessed.  5 replicates of 25 male insects, female insects and nymphs/larvae for surface and for specie.  Application rate: 15 ml/m2 (the product was applied using a trigger spray). | 100% knockdown (30 minutes) on both surfaces  Controls: ≤5% (4 hours)  Mortality (24 hours): 100 % (on both surfaces).  Controls: ≤2%  For ticks, blood-fed ticks were observed in the control groups, but not in the treated groups.  Fleas (larvae):  The inhibition of the development of larvae into adult fleas was not demonstrated.  **The test demonstrated the efficacy of all organisms tested (except for flea larvae) in sumulated use conditions on carpet and wood at the application rate of 15 ml/m2.** | Test report:  2296–RTU-SIM-HDMFT/0118-01  See confidential annex |
| Insecticide | - | Permethrin RTU 0,4% | - | The aim of this study is to determine the amount of product applied in each discharge (trigger spray) | Four plastic bottles with trigger spray filled with the test item were weighed using the technical balance. Then, each bottle was weighed ten times (after each discharge). | The mean value of product discharged in discharge is 1.5 ml.  The number of rotations to reach the application rate of 15 ml/m2 are 10. | See confidential annex |

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| **Conclusion on the efficacy of the product** |
| It should be noted that there are three categories of users in Spain: general public, professionals and trained professionals. Therefore, the norms and criteria in the guidance for consumers are considered for the general public and professional users, and the norms and criteria for professionals indicated in the guidance are considered for trained professional users.  According to the evaluation of the results of the above studies, the eCA concludes that:  **Efficacy against cockroaches (*Periplaneta Americana, Blattella germanica*, *Blatta orientalis)***  The applicant withdrew the claim for *Periplaneta americana*. Therefore, this claim has not been assessed.  The applicant has submitted laboratory, simulated-use and field tests against *Blattella germanica* and *Blatta orientalis*:   * The product has shown KD > 90% in 15 minutes for adult *Blattella germanica* on porous and non-porous surfaces (ceramic tiles, side down and side up) and in 60 minutes for adult *Blatta orientalis* on non-porous surfaces. The residual efficacy for both species on non-porous surfaces was demonstrated until 3 weeks and for *Blattella germanica* on porous surfaces until 1 week. It should be note that these tests were carried out at a higher application rate (20-25 ml/m2) than claimed by the applicant (15 mL/m2). * The simulated-use test 2296–RTU-SIM/0118-04 resulted in 100% knockdown (in 30 minutes) and 100% mortality after 24h at an application rate of 15 mL/m2 (on ceramic tiles and blocks of concrete) for both adult and nymph cockroaches after the product application as spot in crack and crevices. * In the field test 2296-RTU-FIELDCO/0118, the product was applied as spot application and crack and crevices treatment in apartments of 60-80 m2 (treated area (kitchen): 12-15 m²)at an application rate of 15 mL/m2. After 4 weeks, the population reduction exceeds ≥90% relative to pre-treatment levels.   The requirements of the guidance are met for the use as spot including crack and crevices for the general public and professional users as well as for trained professional users (laboratory and simulated-use tests reached 100% mortality and field tests a population reduction ≥90% within 4 weeks).  It should be noted that laboratory tests were carried out at a higher application rate (20-25 ml/m2) than claimed by the applicant (15 mL/m2). However, the simulated-uses test and the field test were conducted with 15 mL/m2. Therefore, we consider that the data package is complete.  On the other hand, although the applicant claimed residual efficacy, it was only demonstrated at 20-25 ml/m2, not at 15 ml/m2 and it was not be considered.  **Therefore,the eCA concludes that the product INSECTICIDE RTU PER ZNZ is effective against cockroaches (*Blattella germanica* and *Blatta orientalis,* adults and nymphs*)* by spraying as spot in hiding places (including crack and crevices) for the general public, professionals and trained professional users (indoors).**  **Efficacy against Black ants (*Lasius niger*)**  The applicant has provided laboratory, simulated-use and field tests.   * The laboratory test showed KD > 90% in 7 minutes on non-porous surfaces and 20 minutes on porous surfaces (ceramic tiles, side down and side up), mortality of 100% in 24 hours and residual efficacy until 3 weeks on both surfaces. * In the simulated-use test, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 mL/m2 against adult black ants. This test demonstrated the efficacy of the product as spot in crack and crevices indoors. * The field trial 2296-RTU-FIELDANT/0118-03 investigated the efficacy of the product applied by spraying on ant nests. This test was conducted in summer although the guidance recommends performing the test preferably during the early springs. As no population decline was observed in control groups, ES CA concluded that the population decrease in the treated groups was not due to natural causes, it was due to the effects of the insecticide. The study demonstrated the efficacy of the product against black ants (ant nests application) at the application rate of 15 mL/m2 (3 mL maximum per nest (in 0.2 m2, e.g. 45cm\*45cm)).   According to the guidance, products intended for use as general surface treatment for the general public and professional users require results in laboratory tests and simulated-use tests (≥90% knockdown and mortality ≥90% in 24 hours). These criteria are met. Furthermore, the requirements for the use of the product as nest ants application was demonstrated (laboratory test reached 100% mortality and field tests a population reduction of 100% within 4 weeks) for the general public, professionals and trained professional users.  The requirements of the guidance are not met for the use outdoors (around and rain protected areas of buildings) since neither simulated-use test nor field test were carried out in outdoor conditions.  It should be noted that laboratory tests on porous surfaces were carried out at a higher application rate (16 mL/m2) than claimed by the applicant (15 mL/m2). However, we consider the difference between the dose claimed and the dose tested to be negligible. Furthermore, the simulated-uses test and the field test were conducted with 15 mL/m2. Therefore, we consider that the data package is complete.  The applicant claimed residual efficacy in ant nest application but due to the weather conditions it cannot be guaranteed and was discarded.  **The eCA concludes that the product INSECTICIDE RTU PER ZNZ is effective against *Lasius niger* by spraying as spot in crack and crevices for the general public and professional users (adult ants, indoors) and as nest application including surrounding areas (against adults, larvae, nymphs and queen fleas) for the general public and professionals and trained professional users.**  **Efficacy against silverfishes (*Lepisma saccharina*)**  Considering that there are no specific requirements for silverfishes in the guidance and comparing with those required for other insects, ES CA considers that laboratory and simulated tests are necessary to demonstrate the efficacy of a product against silverfishes (surface application).  The laboratory tests have shown KD of 100% in 10 minutes on non-porous surfaces and > 90% in 20 minutes on porous surfaces. Mortality of 100% in 24 hours was reached on both surfaces. The product showed residual efficacy up to 3 weeks on non-porous surfaces and up to 1 week on porous surfaces. The application rate was 18-25 mL/m2.  In the simulated-use test (2296–RTU-SIM/0118-04) was obtained 100% mortality and 100% KD in 30 minutes on non-porous and in 40 minutes on porous surfaces and 100% mortality after 24h (on both surfaces) was achieved at an application rate of 15 mL/m2.  It should be noted that the application rate is established in 25 mL/m2 taking into account both laboratory and simulated-use tests.  **The eCA concludes that the product INSECTICIDE RTU PER ZNZ is effective against adult silverfishes (*Lepisma saccharina)* by spraying as spot in crack and crevices treatment indoors for the general public, professionals and trained professional users.**  **Efficacy against houseflies (*Musca domestica*)**  The applicant has submitted a laboratory test and a simulated-use tests:   * The laboratory test has demonstrated KD ≥80 % in 20 minutes on non-porous surfaces and in 35 minutes on porous surfaces. The mortality in both cases was >90%. The product showed residual efficacy up to 3 weeks on non-porous surfaces and up to 1 week on porous surfaces. * In the simulated-use test, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 mL/m2. However, this test was carried out applying the product as spot in crack and crevices in hiding places. **Due to this use for houseflies is not relevant, this use was not considered valid.**   **Efficacy against mosquitoes (*Culex pipiens,* *Aedes albopictus* and *Aedes aegypti)***  Two laboratory tests were submitted against mosquitoes (for *Culex pipiens* and for *Aedes albopictus*) where were observed KD > 90% in 7 minutes on non-porous surfaces and in 15 minutes on porous surfaces. Mortality of 100% was reached on both surfaces. The product showed residual efficacy up to 3 weeks on both surfaces.  In the simulated-use test against *Culex pipiens, Aedes albopictus* and *Aedes aegypti*, 2296–RTU-SIM/0118-04, 100% knockdown in 10 minutes and 100% mortality after 24h were achieved on ceramic tiles and blocks of concrete with an application rate of 15 ml/m2. However, this test was carried out applying the product as spot in crack and crevices in hiding places. **Due to this use for mosquitoes is not relevant, this use was not considered valid.**  **Efficacy against cat fleas *(Ctenocephalides felis)***  Laboratory and simulated-use tests were provided by the applicant:   * The laboratory test has shown 100% KD in 10 minutes on non-porous surfaces and 98% in 60 minutes on porous surfaces and 100% mortality (24 hours) on non-porous surfaces and 92% on porous surfaces (100% KD is not reached and then, the efficacy in laboratory conditions is only demonstrated on non-porous surfaces). The residual efficacy on non-porous surfaces was observed until 1 week. * Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were provided by the applicant to demonstrate the efficacy against cat fleas at an application rate of 15 mL/m2. The test report 2296–RTU-SIM/0118-04 demonstrated the efficacy of the product against adult fleas on ceramic tiles and blocks of concrete as spot in crack and crevices (100% KD in 30 minutes on non-porous surfaces and 40 minutes on porous surfaces and 100% mortality in 24 hours for both surfaces). However, taking into account the flea lifecycle, ES CA does not consider that ceramic tiles and blocks of concrete are representative surfaces. In the second simulated-use test submitted (test report 2296–RTU-SIM-HDMFT/0118-01), the product was tested on representative surfaces: carpet and wood. This test showed 100% KD in 30 minutes and 100% mortality for adult fleas on both surfaces. The inhibition of the development of larvae into adult fleas was not demonstrated in any of the trials.   The results obtained in the tests (simulated-use test for both surface and laboratory tests on non-porous surfaces) are in line with the requirements of the guidance for an adulticidal product against fleas (100% knockdown within 24 hours and ≥90% mortality within 48 hours). However, the ovicidal/larvicidal effect was not demonstrated because no inhibition of the development of eggs/larvae into adult fleas was shown. The only representative surface considered for fleas was carpet, therefore the only use to be authorised is on non-washable textile surfaces and only for the general public (the applicant has only claimed this user).  It should be noted that laboratory tests on non-porous surfaces were carried out at a higher application rate (20 mL/m2) than claimed by the applicant (15 mL/m2). However, since two simulated-use tests were provided, we consider that the data package is complete.  **The eCA concludes that the product INSECTICIDE RTU PER ZNZ is effective against adult cat fleas (*Ctenocephalides felis)* by spraying on non-washable textile surfaces for general public (only category of user required by the applicant).**  **Efficacy against mites (*Dermatophagoides pteronyssinus* and *Acarus siro*)**  Laboratory and simulated-use tests were provided by the applicant:   * The laboratory test demonstrates the efficacy of the product against *Dermatophagoides pteronyssinus* at 20 mL/m2 on ceramic tiles (non-porous surfaces) (91% mortality). By contrast, the efficacy is not demonstrated in laboratory conditions on porous surfaces due to the high mortality in control groups. * Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were submitted at an application rate of 15 mL/m2. The test report 2296–RTU-SIM/0118-04 was carried out on ceramic and concrete surfaces against *Dermatophagoides pteronyssinus* and *Acarus siro* as spot in crack and crevices.The test report 2296–DUST-SIM-HDMFT /0118R was carried out on wood and carpet against *Dermatophagoides pteronyssinus.* The results in both tests were 100% KD in 30 minutes and 100% mortality in 24 hours in adults and nymphs.   The efficacy against *Acarus siro* has not been demonstrated. There is no laboratory test. Furthermore, the simulated-use test was carried out on ceramic and concrete surfaces (not representative surfaces).  The laboratory test against *Dermatophagoides pteronyssinus* was carried out at an application rate of 20 mL/m2. This application rate is higher than the actual conditions of use of the biocidal product. Nevertheless, ES CA considers that as the efficacy was demonstrated in two semi-field tests, the laboratory test is not required. Due to mites survive well in surfaces as mattresses, carpets, or bedding, these types of surfaces were considered for the use of the biocidal product against *Dermatophagoides pteronyssinus* taking into account the surfaces were mites survive well.  The results for laboratory test and simulated-use test for *Dermatophagoides pteronyssinus* met the requirements of the guidance for the use on non-washable textile surfaces: laboratory tests ≥90% mortality in 24 hours and simulated-use tests ≥90% mortality in 1 week. This use is only requested for the general public.  **The eCA concludes that the product INSECTICIDE RTU PER ZNZ is effective against house dust mites (*Dermatophagoides pteronyssinus,*** **adults and nymphs) by spraying on non-washable textile surfaces for the general public.**  **Efficacy against ticks (*Rhipicephalus sanguineus and Ixodes ricinus)***  The applicant provides a laboratory trial for *Ixodes ricinus* and two simulated-use tests with both ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*).   * The laboratory test has demonstrated the efficacy of the product against *Ixodus ricinus* on ceramic tiles and marble (100% knockdown in 10 minutes on porous surfaces and 15 minutes on non-porous surfaces. 100% mortality in 24 hours). The residual efficacy was demonstrated until 3 weeks. * Two simulated-use tests (test reports 2296–RTU-SIM/0118-04 and 2296–RTU-SIM-HDMFT/0118-01) were submitted at an application rate of 15 mL/m2: one of them on ceramic and concrete surfaces as spot in crack and crevices (not representative surfaces taking into account the tick lifecycle) and the other one on wood and carpet. The two tests demonstrated the efficacy against *Rhipicephalus sanguineus* and *Ixodes ricinus* (100% KD within 30 minutes and 100% mortality in 24 hours in adults and nymphs).   The laboratory test against *Ixodes ricinus* was carried out at an application rate of 20 ml/m2 for non-porous surfaces and 25 mL/m2 for porous surfaces. This application rate is higher than the actual conditions of use of the biocidal product. Furthermore, the applicant did not provide a laboratory test for *Rhipicephalus sanguineus*. Nevertheless, ES CA considers that laboratory tests can be waived as the efficacy has been demonstrated in two semi-field test for both ticks (≥95% mortality before ticks start feeding) with similar conditions to the intended use of the biocidal product.  **The eCA concludes that the product INSECTICIDA RTU PER ZNZ is effective against ticks (*Rhipicephalus sanguineus and Ixodes ricinus,*** **adults and nymphs) by spraying on non-washable textile surfaces for the general public (only category of user required by the applicant).**  **Application rate**  The applicant has provided a test to determinate the number of sprayings to apply 15mL/m2 of biocidal product. The number of sprayings required are 10 (1.5 mL/in each spraying). Therefore, for 3 mL the number of aprayings are 2, and for an application rate of 25 mL as the number of sparyings are 16.6, the application rate should be adjusted to 25.5 mL (17 sprayings)  In conclusion, the following claimed uses are compliant with the requirements of the TNsG on product evaluation for PT18/19 (2012):   * Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*),* ants (*L. niger,* adults) and silverfishes (*L. saccharina,* adults)as spot in hiding places (including crack and crevices) for the general public and professionals (indoor). Application rate for cockroaches and ants: 15 mL/m2. Application rate for silverfishes: 25.5 mL/m2. The product showed residual efficacy against ants (3 weeks) and silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces). * Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*)* and silverfishes as spot in hiding places (including crack and crevices) for trained professionals (indoor). Application rate for cockroaches: 15 mL/m2. Appliction rate for silverfishes: 25.5 mL/m2. The product showed residual efficacy against silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces) * Use against *Lasius niger* (adults, larvae, nymphs and queens)as nest application and surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), 15 mL/m2. * Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by spraying on non-washable textile surfaces for the general public. Application rate: 15 mL/m2. |

#### Occurrence of resistance and resistance management

According to the CAR, resistance to permethrin has been documented in wide varieties of insects: pear psylla, german cockroach, spotted tentiform leafminer, diamondback moth, house fly, Stable fly, headlice or tobacco budworm. The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold), lice (up to 385 fold), and budworm (1400 fold).

In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists. Application of permethrin synergists such as Piperonyl butoxide (PBO) or Triphenyl phosphate (TPP) to permethrin resistant head lice suggests that monooxygenases (cytochrome P-450s) and the esterase enzyme systems were responsible for some pyrethroid resistance. A lack of synergism of D-phenothrin resistance by Piperonyl butoxide suggests that a non-oxidative mechanism, such as nerve insensitivity is also present in resistant lice.

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

The principles of strategies for managing the development of resistance are as follow:"To avoid resistance occurrence, keep the label instructions and avoid repeated use of products containing permethrin. Alternate with products containing different active substances. When the infestation persists contact a (trained) professional."

#### Known limitations

None.

#### Evaluation of the label claims

In conclusion, the following claimed uses are compliant with the requirements of the TNsG on product evaluation for PT18/19 (2012):

* Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*),* ants (*L. niger,* adults) and silverfishes (*L. saccharina,* adults)as spot in hiding places (including crack and crevices) for the general public and professionals (indoor). Application rate for cockroaches and ants: 15 mL/m2. Application rate for silverfishes: 25.5 mL/m2. The product showed residual efficacy against ants (3 weeks) and silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces).
* Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults and nymphs*)* and silverfishes as spot in hiding places (including crack and crevices) for trained professionals (indoor). Application rate for cockroaches: 15 mL/m2. Appliction rate for silverfishes: 25.5 mL/m2. The product showed residual efficacy against silverfishes (3 weeks on non-porous surfaces and 1 week on porous surfaces)
* Use against *Lasius niger* (adults, larvae, nymphs and queens)as nest application and surrounding areas for the general public, professionals and trained professionals. Application rate: 3 mL per nest (in 0.2 m2, e.g. 45cm\*45cm), 15 mL/m2.
* Use against adult cat fleas (*Ctenocephalides felis),* house dust mite (*Dermatophagoides pteronyssinus*) and ticks (*Rhipicephalus sanguineus* and *Ixodes ricinus*) by spraying on non-washable textile surfaces for the general public. Application rate: 15 mL/m2.

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

INSECTICIDARTU PER ZNZ is not intended to be use with other biocidal products.

### Risk assessment for human health

#### Assessment of effects on Human Health

The biocidal product, INSECTICIDARTU PER ZNZ , has not been tested in any in vivo studies but it has been tested in vitro for eye corrosion. It was considered that the acute oral, dermal, inhalation, skin corrosion and irritation, eye irritation and the sensitisation studies on the active ingredient were adequate for the classification and labelling of the product and for the human health risk assessment.

The results of the in vitro test for eye corrosion (Andres, I., 2016) performed with the biocidal product PERMETHRIN 0.4 RTU, identical to INSECTICIDARTU PER ZNZ and in conformity with OECD Guideline 437 on bovine corneas (BCOP) demonstrated that the product is non-corrosive for the eye and therefore, it does not require any classification for eye irritation or serious eye damage.

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | No skin corrosion and irritation. |
| Justification for the value/conclusion | Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP Regulation | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required |

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| **Data waiving** | |
| Information requirement | Skin Irritation |
| Justification | Skin irritation toxicity studies for INSECTICIDARTU PER ZNZ have not been performed.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted.  Therefore, INSECTICIDA DUST PER ZNZ can be considered as no irritant to skin and do not meet the criteria for classification as irritant or corrosive.  It is therefore proposed that the preparation INSECTICIDARTU PER ZNZ is not a skin irritant and is not classified. |

***Eye irritation***

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| **Summary table of in vitro studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Dose levels, Duration of exposure** | **Results** | **Remarks** | **Reference** |
| OECD Guideline no. 437  EU method B.47, GLP | fresh bovine corneas / *Bos primigenius* Taurus / 9 corneas (3 for each treatment group); exposure time: 10 min at 32 ± 1 °C. | PERMETHRIN 0.4 RTU | cornea opacity score mean IVIS:  -0.17 (Test item)  0.21 (Neg CTRL)  60.84 (Pos CTRL)  Reversability: not specified | Max score:  -0.27 (Test item)  0.44 (Neg CTRL)  80.06 (Pos CTRL) | Study No.: 15102905G850 |

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| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | No ocular irritant. |
| Justification for the value/conclusion | The test item PERMETHRIN 0.4 RTU showed no effects on the cornea of the bovine eye. The calculated IVIS (in vitro irritancy score) is -0.17 at time point 10 min. According to OECD Guideline no. 437 (Jul. 2013), a substance with an IVIS ≤ 3 requires no classification for eye irritation or serious eye damage. |
| Classification of the product according to CLP Regulation | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye Irritation |
| Justification | Eye irritation study for INSECTICIDARTU PER ZNZ have been performed. The test item PERMETHRIN 0.4% RTU showed no effects on the cornea of the bovine eye.  PERMETHRIN 0.4% RTU is the same product than INSECTICIDARTU PER ZNZ therefore can be considered as no irritant to eye. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory Tract Irritation |
| Justification for the conclusion | No study on the respiratory tract irritation of the formulation INSECTICIDARTU PER ZNZ has been performed.  No data on respiratory tract irritation is submitted. Furthermore, this data is not required under Biocides Regulation. However, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation).No classification is required for respiratory tract irritation. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | No skin sensitizer |
| Justification for the value/conclusion | Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | The preparation INSECTICIDARTU PER ZNZ is not classified as skin sensitiser.  According to the CLP regulation, no H phrase is applicable (being permethrin content in the biocidal product lower than 1%) and EUH208 special precautionary phrase should be added on the label. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitisation |
| Justification | Skin sensitisation studies for have not been performed.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted.No classification is required for skin sensitization.  According to the CLP regulation, no H phrase is applicable (being permethrin content in the biocidal product lower than 1%) and EUH208 special precautionary phrase should be added on the label. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not respiratory sensitiser |
| Justification for the value/conclusion | Based on the classification of Permethrin and the coformulants, and their respective content in the final formulation. |
| Classification of the product according to CLP and DSD | The preparation INSECTICIDARTU PER ZNZ is not classified as respiratory sensitiser. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | No data on the respiratory sensitisation of the product INSECTICIDARTU PER ZNZ has been submitted  According CLP the preparation INSECTICIDARTU PER ZNZ is not classified as respiratory sensitiser. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | LD50>2000mg/kg bw |
| Justification for the selected value | Permethrin is classified H302 , regarding the content of a.s no toxicity effects at the maximum dose rate of 2000 mg/Kg bw |
| Classification of the product according to CLP and DSD | Based on the available data on active substance, The acute toxicity estimate (ATE) of the mixture is >2000 mg/Kg bw. Also, according to CLP Regulation, the formulation INSECTICIDARTU PER ZNZ is not classified as harmful by the oral route |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity |
| Justification | Acute oral toxicity studies for product INSECTICIDARTU PER ZNZ have not been performed.  According to CLP Regulation,the product is not classified for Acute oral toxicity. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not harmful by the inhalation route |
| Justification for the selected value | Based on the classification of a.s and coformulants |
| Classification of the product according to CLP and DSD | According to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity |
| Justification | Acute inhalation toxicity studies for INSECTICIDARTU PER ZNZ have not been performed.  According to CLP Regulation,the product INSECTICIDARTU PER ZNZ is not classified for Acute inhalation toxicity. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | No study is available. |
| Justification for the selected value | The acute dermal toxicity studies on the active ingredient are adequate for the classification and labelling of the product and for the human health risk assessment. In fact, neither the active substance, nor the coformulants are classified for acute dermal toxicity. |
| Classification of the product according to CLP Regulation | Not classified under CLP Regulation. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 50 % |
| Justification for the selected value(s) | No study has been performed on INSECTICIDARTU PER ZNZ, thus the default value of 50 % according to Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873) was considered in the current risk assessment. |

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

Based on the BPR Art. 3.1(f) definition of ‘substance of concern’ which includes the condition «*and is present or is produced in a biocidal* *product in sufficient concentration to present risks of such an effect*» no ‘substances of concern’ are present in the biocidal product.

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

No data.

***Other***

***Endocrine disruption***

**Assessment of the ED properties of the active substance:**

The biocidal product contains Permethrin. According to the CAR for Permethrin there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the “Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption” will need to be performed at the renewal stage.

**Assessment of the ED properties of non-active substances (co-formulants):**

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of co-formulants is mandatory according to the article 19. According to the document “*Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA*” agreed at CG-41, the following sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product, see confidential Annex.

**Overall conclusion on the biocidal product regarding ED properties:**

Based on the existing knowledge there is no indication of concern regarding the ED properties of the substances used in the biocidal product INSECTICIDARTU PER ZNZ If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

#### Exposure assessment

General Remarks

The assessment of occupational exposure towards permethrin as insecticide is based on information provided by the Applicant. In the absence of human exposure data, the exposure estimation to permethrin is based on the selected models and default values from the Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations and the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017.

If no appropriate models are available in the BHHEM, surrogate models are chosen and a justification is provided.

The proposed tiered approach for human exposure assessment is applied as follows. In several cases it is considered not to be appropriate to calculate a “reasonable worst case” exposure (Tier 1) according to the Guidelines. The dermal absorption of permethrin in humans is well established as outlined above. Assuming no protection by the human skin (as proposed for Tier 1 estimates) is considered not to be reasonable. For all of the following calculations the established dermal absorption figure for humans is applied. Despite the fact that protective measures could be supposed to be carefully observed in a professional environment, a Tier 1 is proposed as a worst case. Then, personal protective equipment will be assumed to be worn as second scenario (Tier 2).

Unless otherwise specified, a default penetration value of 10% for gloves and clothing was assumed, which is in accordance with HEEG Opinion on “Default protection factors for protective clothing and gloves” (when potential hand exposure data are available, a factor of 10 -90 % reduction of exposure by gloves manufactured from appropriate material- can be used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves: MOTA v6, 4.2.9.9 HEEG Opinion 9). On the other hand, if data on exposure inside protective gloves is available, these will be used for exposure assessment (MOTA v6, 4.2.9.2 HEEG Opinion 2).

Where exposure is calculated based on empirical data (Biocides Human Health Exposure Methodology (BHHEM 2015) along with HEEG recommendations), these data are applied in agreement with the recommendations given by the guidelines as follows: In case of continuous (chronic) exposure scenarios the typical exposure is calculated based on the 75%-ile of the data. The 95%-ile is considered to represent the typical case when recommended by applicable guidelines. Where 95%-iles are not given, the maximum values are used instead.

INSECTICIDA RTU PER ZNZ is a ready-to-use water-based formulation containing 0.4% w/w permethrin, for indoor and outdoor use by (trained) professionals (e.g. PCO) and general public for the control of crawling insects, cat fleas, house dust mites and ticks.

Human exposure towards the active substance from its use in the biocidal product can take place via different “routes of exposure”, i.e. via inhalation, dermal contact and/or ingestion (see below).

**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** | **Professi onal use** | **Non- professio nal use** | **Industrial use** | **Professio nal use** | **General public** | **Via food** |
| Inhalation | n.a. | Yes | Yes | n.a. | Yes | Yes | n.a. |
| Dermal | n.a. | Yes | Yes | n.a. | Yes | Yes | n.a. |
| Oral | n.a. | No | No | n.a. | No | Yes | n.a. |
| *n.a. = not applicable* | | | | | | | |

Exposure resulting from the production of the active substance is not considered as the manufacturing processes are not performed in the EU. Exposure resulting from the formulation and packaging processes which take place in Italy is also not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

In the exposure assessment presented below, the following stages have been considered.

**PRIMARY EXPOSURE**

* Loading of biocidal product into a hand-held spraying equipment. The Biocidal product is a RTU product therefore the exposure is considered to be negligible. (Professional Use & Consumer Use)
* Professional and non-professional use of biocidal product by spraying (Professional Use & Consumer Use).

**SECONDARY EXPOSURE**

* Inhalation exposure: inhalation of volatilized residues of active substance. The active substance in water-based formulations is a substance with an extremely low vapour pressure, and are therefore not very volatile. The inhalation exposure due to evaporation is therefore considered to be negligible. (Professional & Consumer Indirect Exposure)
* Indirect exposure: exposure of consumers to materials or articles containing residues of biocide: dermal exposure in treated areas, skin contact with working clothes. (Professional & Consumer Indirect Exposure)

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure / Description of scenario** | **Exposed group** |
| 1. | Application | **Primary exposure.**  Indoor application by spraying. | Trained Professional / Professional |
| 2. | Application | **Primary exposure.**  Outdoor application of product in ant’s nest entries. | Professional / Trained professional |
| 3. | Application | **Primary exposure.**  Indoor application by spraying. | Non-professional |
| 4. | Application | **Primary exposure.**  Outdoor application of product in ant’s nest entries. | Non-professional |
| 5. | Application | **Primary exposure.**  Indoor application by spraying on non-washable textile surfaces. | Non-professional |
| 6. | Post-application | **Secondary exposure:**  Inhalation of volatilized residues | General public |
| 7. | Post-application | **Secundary exposure.**  Adults/toddlers playing/crawling on treated surfaces and hand to mouth contact after insecticide treatments. | General public |
| 8. | Post-application | **Secondary exposure.**  Persons laundering contaminated work clothing | General public |

***Industrial exposure***

Industrial users are involved in manufacturing, handling and/or packaging of actives or products in industry and in producing end-products containing biocidal products. Industrial users have received suitable information, instruction and training in their use. Thus no industrial exposure is foreseen and it is not considered since adequate protective clothing and equipment are used to prevent exposure of the workforce.

***Professional exposure***

*Scenario [1] – Indoor application*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [1]** | | | |
| Exposure estimates for workers were calculated according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types. Spraying Model 1, TNsG 2002 user guidance for professionals was considered appropriate for the intended use of B.P. by hand-held spraying equipment. The model reflects mixing and loading liquids in compression sprayers or dusting applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards.  The Tier 1 assessment assumes that no personal protective equipment is worn by workers. Hence clothing penetration is set to 100% for dermal exposure.  The Tier 2 assessment assumes that workers wear additionally protective clothing such as a coverall and/or respiratory protective equipment (RPE). Accordingly Tier 2a calculation considers workers wearing a coated coverall, gloves and respiratory protection and Tier 2b workers wearing impermeable coverall, gloves (inside new gloves) and respiratory protection. Protection factor for clothing was adopted from the HEEG opinion 9 on default protection factors for protective clothing and gloves (cotated coverall – 10 % penetration, impermeable coverall – 5 % penetration, protective gloves [new gloves for each work shift] – reduce exposure aprox. factor of 0.52). A respiratory protection factor of 10 (10% penetration) by a mask is assumed.  The model is partially based on measured data on occupational exposure to Permethrin during its use as a public hygiene insecticide published in a HSE, UK study by Llewllyn et al (1996). According to this data, typically, less than two hours a day is spent using pesticides, thus, a task duration of 2 hours was used to refine the worst case risk assessment.  In general, a body weight of 60 kg was assumed and an inhalation rate of 0.0208 m³/min for light activity (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products). Dermal penetration of Permethrin was set to 50% according to the EFSA guidance. | | | |
|  | **Parameters** | **Value / Units** | **Justification / Source** |
| **Tier 1** | Weight fraction of active substance | 0.4 % | Section 2.1.2 |
| Body weight | 60kg | Recommendation no. 14, 2017 |
| Expected duration of actual exposure | 120 minutes | Recommendation no. 6, 2020 |
| *Dermal exposure* | | |
| Potential dermal exposure | 92 mg/min | Recommendation no. 6, 2020 |
| Hand exposure without gloves | 181 mg/min | Recommendation no. 6, 2020 |
| Dermal Absorption | 50% | Guidance on Dermal Absorption (EFSA, 2017) |
| *Inhalation exposure* | | |
| Potential Inhalation exposure | 104 mg/m3 | Recommendation no. 6, 2020 |
| Inhalation rate | 1.25 m3/h | Recommendation no. 14, 2017 |
| Inhalation absorption | 100% | Default value. |
| **Tier 2a** | Hand exposure with gloves\* | 10.7 mg/min | Recommendation no. 6, 2020 |
| Coated coverall | 10% | HEEG Opinion 9 (2010) |
| RPE | APF = 10 | TNsG |
| **Tier 2b** | Hand exposure with gloves\*\* | 10.7 mg/min | Recommendation no. 6, 2020 |
| Impermeable coverall | 5% | HEEG Opinion 9 (2010) |
| RPE | APF = 10 | TNsG |
| \* assuming only protective gloves (5% penetration)  \*\* assuming protective gloves (5% penetration) and new gloves for each work shift (exposure is reduced a factor of 0.52 approx.). | | | |

**Calculations for Scenario [1]**

Systemic effects

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: systemic exposure from professional uses** | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg a.s./kg/day)** | **Estimated dermal uptake**  **(mg a.s./kg/day)** | **Estimated total uptake**  **(mg a.s./kg/day)** |
| **Scenario 1** | 1 / none | 1.73E-02 | 1.09E-00 | 1.11E-00 |
| **Scenario 1** | 2a / PPEs | 1.73E-03 | 7.96E-02 | 8.13E-02 |
| **Scenario 1** | 2b / PPEs | 1.73E-03 | 4.07E-02 | 4.24E-02 |

**Further information and considerations on scenario [1]**

None.

*Scenario [2] – Outdoor application*

|  |
| --- |
| **Description of Scenario [2]** |
| The biocidal product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located for the outdoor use. Exposure for the (trained) professional user is only during application since, being a ready to use formulation, no mixing and loading is foreseen.  Assuming that the work is peripatetic, with lone working most common. Typically, less than two hours a day is spent using pesticides, with some applications being seasonal.  Therefore, this scenario is deemed to be covered by scenario 1. |

*Combined scenarios*

Not applicable.

***Non-professional exposure***

*Scenario [3] – Indoor application by trigger spray.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3]** | | | |
| The biocidal product is a ready to use water-based formulation containing 0.4% w/w permethrin for crack and crevice / targeted spot against crawling insects, intended for use by the general public (non-professional users).  The default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevice /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case.  The inhalation exposure ‘spray’ model and the dermal exposure model ‘constant rate’ from ConsExpo Web are used to describe the scenario. The oral exposure is handled in the inhalation exposure model. ConsExpo assumes that the non-respirable fraction is taken in orally. Hence exposure via dermal, oral and inhalation route is expected.  Parameters for the inhalation model are taken from RIVM report 320005002/2006 Pest Control Products Fact Sheet.  The model assumes that:   1. the product is used 9 times a year maximum. 2. the trigger spray is applied during 4 minutes with a mass generation rate of 0.38 g/s. Also, the scenario considers that this product is applied in a 20 m3 room (with 8 m2 floor surface). Hence the total amount applied according to this model would be 0.38 g/s x 4 min / 8 m2 = 11.4 g/m2   To our case:   1. the product is used 12 times a year. 2. The mass generation rate would be: 25.5 mL/m2 x 1.0008 g/mL x 8 m2 / 4 min = 0.85 g/s   for Tier 1. | | | |
|  | **Parameters** | **Value / Units** | **Justification / Source** |
| **Tier 1** | Weight fraction of a.s. | 0.4% | Section 2.1.2. |
| Application rate | 25.5 g/m2 | Section 2.2.5 (worst case) |
| Frequency of use | 12 days/year | Section 2.2.8 |
| Body weight | 60kg | Recommendation 14, 2017 |
| *Dermal exposure* | | |
| Exposed body surface area | 8300 cm2 | Recommendation no. 14, 2017 (half of total adult body surface area) |
| Contact rate | 46 mg/min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Release duration | 4 min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Dermal absorption | 50% | Guidance on Dermal Absorption (EFSA, 2017) |
| *Inhalation exposure* | | |
| Spray duration | 4 min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Exposure duration | 240 min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Room volume | 20 m3 | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Room height | 2.5 m | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Ventilation Rate | 0.6 / h | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Inhalation rate | 1.25 m3/h | Recommendation 14, 2017 |
| Mass generation rate | 0.85 g/s | Calculated value. |
| Airborne fraction | 0.008 | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Density non-volatile | 1.8 g/cc | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Inhalation cut off diameter | 15 µm | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Aerosol diameter distribution | logNormal | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Median diameter | 7.7 µm | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Arithmetic coefficient of variation | 1.9 | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Maximum diameter | 50 µm | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Inhalation absorption | 100% | Default value. |
| Oral exposure | | |
| No parameters | Parameters are set in inhalation exposure route | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Oral absorption | 100% | Default value |

**Calculations for Scenario [3]**

| **Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] | Tier 1/ no PPE | 2.86E-03 | 6.13E-03 | 4.25E-05 | 9.03E-03 |

**Further information and considerations on scenario [3]**

None.

*Scenario [4] – Outdoor application by trigger spray*

|  |
| --- |
| **Description of Scenario [4]** |
| The biocidal product is applied directly to the ant nests, around houses on paved ways, balconies, and terraces where ant nests are located for the outdoor use.  In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevices /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case and hence to cover exposure from directly to the ant nests spraying. |

**Calculations for Scenario [4]**

| **Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | Tier 1/ no PPE | 2.86E-03 | 6.13E-03 | 4.25E-05 | 9.03E-03 |

**Further information and considerations on scenario [4]**

None.

*Scenario [5] – Indoor application by trigger spray on non-washable textile surfaces*

|  |
| --- |
| **Description of Scenario [5]** |
| The biocidal product is applied at domestic use (houses, flats, apartments) over textile surfaces that must be cleaned by dry treatments as mattresses, blankets, bedspreads, bedsteads, pillows, carpets, moquette…  In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /Crack & Crevices /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case and hence to cover exposure from over textile surfaces spraying. |

**Calculations for Scenario [5]**

| **Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [5] | Tier 1/ no PPE | 2.86E-03 | 6.13E-03 | 4.25E-05 | 9.03E-03 |

**Further information and considerations on scenario [5]**

None.

*Combined scenarios*

There is the possibility that the scenarios 3, 4 and 5 will be developed by the same user in the same day so the exposure of combined scenario should be estimated for these scenarios:

| **Summary table: combined systemic exposure from professional uses to permethrin** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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]** |
| Scenarios [3, 4, 5] | 1/no PPE | 8.58E-03 | 1.84E-02 | 1.28E-04 | 2.71E-02 |

***Exposure of the general public***

Secondary exposure to the active substances as a result of biocidal product use can occur.

*Scenario [6] - Inhalation of volatilized residues*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [6]** | | | |
| Professional and general public may be exposed to volatilised residues from permethrin residues will vaporise and could be available for inhalation by people present in the room. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues:   * For permethrin: 0.328 x (391.29 x 2.16E-06 / 0.05) = 5.53E-03 ≤ 1   **The result of this equation is lower than 1 for permethrin**. **The exposure to volatilised residues indoor can be considered negligible for non-professionals and general public for the biocidal product according to the assessment of effects on human health conclusions.**  Chronic inhalation exposure to volatilised residues indoors should be assessed for adult considering the scenario ”assessment of Inhalation Exposure of Volatilised Biocide Active Substance” from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula:  SVC = (Mw x Vp) / (R x T) (mg/m3)  The exposure would be calculated with the following formula:  Exposure = SVC x inhalation rate / body weight (mg/kg bw/d) | | | |
|  | **Parameters1** | **Value / Units** | **Justification / Source** |
| Tier 1 | Weight fraction | 0.4% | Section 2.1.2. |
| Body weight | 60 kg (adults)  23.9 kg (children)  10 kg (toddlers)  8 kg (infants) | Recommendation no. 14, 2017. |
| Inhalation rate | 16 m3/24h (adults)  12 m3/24h (children)  8 m3/24h (toddlers)  5.4 m3/24h (infants) | Recommendation no. 14, 2017. |
| Vapour pressure (Vp) | 2.16E-06 Pa | AR/CAR (IE CA, 2014, 2017 addendum). |
| Molecular weight (Mw) | 391.29 g/mol | AR/CAR (IE CA, 2014, 2017 addendum). |
| Gas constant (R) | 8.31451 J.mol-1.K-1 | HEEG opinion no. 13 (2011) |
| Temperature (T) | 293 K | HEEG opinion no. 13 (2011) |

**Calculations for Scenario [6]**

No calculations are needed.

**Further information and considerations on scenario [6]**

None.

*Scenario [7] – Adults/toddlers re-entry period / Adults/toddlers playing/crawling on treated surfaces*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [7]** | | | |
| The exposure after application is described for crawling children who are present in the room after a crack and crevice / targeted spot treatment has been carried out. Crack and crevice application represents the worst case scenario and therefore no further assessment will be performed for targeted spot use. It is assumed that a toddler (worst case) crawls over the treated surface for 1 hour a day and the model is also used to estimate the possible adult exposure after application playing with a toddler on the treated surface. Exposure is modelled using the dermal exposure model ‘rubbing off’ and the oral exposure model ‘constant rate’ from RIVM ConsExpo Web, version 1.1.0 described in Pest control Fact Sheet RIVM report 320005002/2006 (crack and crevice application – Post Application).  Total amount sprayed is 25.5 g/m2 as indicated by the maximum application rate. The scenario assumes that 25% of the floor area is taken to be the treated surface; for the room mentioned above (surface 8 m2), this is equivalent to 2 m2. The model also assumes that 85% of the amount sprayed ends up on the floor surface and 30% of this amount is dislodgeable (default values for exposure during general surface application with a trigger spray, RIVM Report 320005002/2006).  Hence, if the amount of formulation per surface unit is 25.5 g/m2, assuming that 85% of the amount sprayed ends up and 30% thereof will be dislodgeable, a dislodgeable amount of   * 25.5 g/m2 x 0.85 x 0.3 = 6.5 g/m2   is calculated.  In addition, dermal exposure of adults/toddlers can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The ConsExpo model gives a transfer coefficient of 0.6 m²/h but a transfer factor of 0.20 m²/h for toddlers and 0.78 m2/h for adults according to the Recommendation for indoor transfer coefficients no. 12 (2016) is considered. The ingestion rate is calculated based on the assumption that 10 % of dermal load (ConsExpo) will be ingested by hand-to-mouth transfer:   * 6.5 g/m2 x 0.20 m2/h x 0.1 / 60 min = 2.17E-03 g/min for toddlers. * 6.5 g/m2 x 0.78 m2/h x 0.1 / 60 min = 8.45E-03 g/min for adults.   These data are included in Tier 1, for Tier 2 the dislodgeable residue can be refined taking into account the US EPA Residential SOPs (2012), where, after the revision of complete datasets for some chemicals, it is concluded in table 7-9 that the dislodgeable residue for permethrin in hard surfaces is 3% (75th percentile). Therefore:   * the dislodgeable amount would be: 25.5 g/m2 x 0.85 x 0.03 = 0.65 g/m2   and   * the ingestion rate would be: 0.65 g/m2x 0.2 m2/h x 0.1 / 60 min = 2.17E-04 g/min for toddlers. * the ingestion rate would be: 0.65 g/m2x 0.78 m2/h x 0.1 / 60 min = 8.45E-04 g/min for adults.   For exposure assessment purposes chronic exposure is considered (i.e., exposure is not averaged over a year). | | | |
| Tier 1 | **Parameters** | **Value / Units** | **Justification / Source** |
| Weight fraction of permethrin | 0.4% | Section 2.1.2 |
| Application rate | 25.5 g/m2 | Section 2.2.5 (worts case) |
| Frequency of use | 126 days/year | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Transfer coefficient adults | 0.78 m2/h (adults)  0.20 m2/h (toddlers) | Recommendation no. 12, 2016. |
| Body weight | 60 kg (adults)  10 kg (toddlers) | Recommendation no. 14, 2017. |
| *Dermal exposure* | | |
| Exposed body area toddlers | 2410 cm2 | Recommendation no. 14, 2017 |
| Exposed body area adults | 9520 cm2 | Recommendation no. 14, 2017 |
| Contact time | 60 min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Contact surface | 2 m2 | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Dermal absorption | 50% | Guidance on Dermal Absorption (EFSA, 2017) |
| Dislodgeable residue | 30% | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Dislodgeable amount | 6.5 g/m2 | Calculated value. |
| *Oral exposure* | | |
| Exposure duration | 60 min | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Transfer hand to mouth | 10% | RIVM report 320005002/2006 Pest Control Products Fact Sheet |
| Oral absorption | 100% | Default value |
| Ingestion rate | 8.45E-03 g/min (adults)  2.17E-03 g/min (toddlers) | Calculated value. |
| Tier 2 | Dislodgeable residue | 3% | Standard Operating Procedures for Residential Pesticide Exposure Assessment - October 2012 |
| Dislodgeable amount | 0.65 g/m2 | Calculated value. |
| Ingestion rate | 8.45E-04 g/min (adults)  2.17E-04 g/min (toddlers) | Calculated value. |

**Calculations for Scenario [7]**

| **Summary table: indirect exposure of general public [mg/kg bw/d]** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [7] (toddlers) | Tier 1/ none | - | 2.60E-01 | 5.21E-02 | 3.12E-01 |
| Scenario [7] (adults) | Tier 1/ none | - | 1.69E-01 | 3.38E-02 | 2.03E-01 |
| Scenario [7] (toddlers) | Tier 2/ none | - | 2.60E-02 | 5.21E-03 | 3.12E-02 |
| Scenario [7] (adults) | Tier 2/ none | - | 1.69E-02 | 3.38E-03 | 2.03E-02 |

**Further information and considerations on scenario [7]**

None.

*Scenario [8] – Laundering work clothes*

| **Description of Scenario [8]** | | | |
| --- | --- | --- | --- |
| Exposure to product can occur when washing contaminated work clothes. Persons at risk are adults professionals. The exposure is considered acute intermediary, as it does not occur on a daily basis but may be longer-term.  In general, this approach assumes that the washing is carried out in a domestic automatic washing machine, therefore, the exposure will be dermally through the hands, from handling the contaminated clothes before and during the introduction of the clothes in the washing machine. Laundering is considered to be after a five-day work week, hence the total amount of product on work clothes is assumed to be five times the daily contamination associated with the application method used and it is assumed that the clothing to be washed is a coverall worn by a (trained) professional.  The contamination of clothes is based on the professional spraying from which the tier that shows safe use is tier 2b where PPEs are worn.  It is assumed that applicator wear regular clothes which, according to HEEG opinion 9, have a Default Protection Factor of 50%. | | | |
|  | **Parameters** | **Value** | **Justification / Source** |
| **Tier 1** | Weight fraction of active substance | 0.4% | Section 2.1.2. |
| Body weight | 60kg | Recommendation no. 14, 2017 |
| **Dermal exposure** | | |
| Indicative value from model | 5244 mg/d | Indoor Application by spraying for (trained) professionals |
| Surface medium-sized coverall | 22700 cm2 | Estimated parameter usually accepted |
| Regular clothes penetration | 50 % | HEEG Opinion 9 (2010) |
| Dermal Absorption | 50% | Guidance on Dermal Absorption (EFSA, 2017) |
| Skin surface area in contact | 820 cm2 | For an adult, the total area of both hands (front and back) is 820 cm² (Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017) |
| Transfer coefficient | 30 % | BHHEM, 2015 - Cotton, knitwear, plastic, wood Dried fluid - wet hand |

**Calculations for Scenario [8]**

| **Summary table: systemic 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 [8] | 1/no PPE | -- | 9.47E-03 | -- | 9.47E-03 |

**Further information and considerations on scenario [8]**

Not applicable.

*Combined scenarios*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **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]** |
| Scenarios [1, 8] | 1.73E-03 | 5.01E-02 | -- | 5.19E-02 |
| Scenarios [3, 4, 5, 7] | 8.58E-03 | 3.53E-02 | 3.51E-03 | 4.74E-02 |

***Monitoring data***

No monitoring data available.

***Dietary exposure***

No dietary exposure is foreseen since the product is not intended for the use on food, drinking water or livestock. Moreover dietary exposure is considered as not relevant, as the biocidal product is sprayed only in a band around the perimeter of the room in a directed manner and should not be applied in areas where food for human consumption is exposed at the time of treatment. Thus dietary exposure has not been assessed.

*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. Permethrin | Plant protection products | IN - Insecticide | Not approved (1)  MRL (2) |
| 2. Permethrin | Veterinary use | Antiparasitic agents/Agents againstectoparasites | MRL (3) |
| (1) Commission Decision of 27 December 2000 concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.  (2) COMMISSION REGULATION (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products  (3) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. For milk further provisions in Commission Directive 98/82/EC are to be observed. | | | |

Residue definitions

Pharmacologically active substances and their classification regarding maximum residue limits (MRL) (COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pharmacologically active Substance** | **Marker residue** | **Animal Species** | **MRL** | **Target Tissues** |
| Permethrin | Permethrin (sum of isomers) | Bovine | 50 μg/kg  500 μg/kg  50 μg/kg  50 μg/kg  50 μg/kg | Muscle  Fat  Liver  Kidney  Milk |

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

Based on intended uses, human exposure through residues in livestock is expected to be very limited and feeding and metabolism studies in livestock to permit evaluation of residues in food of animal origin are not required

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

No transfer of active substance into foods as results of professional and/or industrial application of PISTOLA INS PER04 is expected since the product is not applied by spraying such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

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

No transfer of active substance into foods as results of non-professional use of PISTOLA INS PER04 is expected since the product is not applied in such a way that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess potential residues on foodstuffs.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses, the following risk mitigation measures are added to PAR required:

* *Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*

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

Exposure during the production and formulation of the biocidal product should be addressed under other EU legislation (e.g. REACH).

Disposal should be done as described according to label instructions.

***Aggregated exposure***

No guidance neither methodology are available to assess human aggregated exposure. Moreover exposure calculations have been conducted taking into account worst case assumptions. Thus an adequate margin of safety can be anticipated even for aggregated exposure and no furter data are provided. Risk characterisation for human health.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment to permethrin** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake [mg/kg bw/d]** |
| 1. Indoor application | Professionals / Trained professionals | Tier 1 / no PPE | 1.11E+00 |
| Tier 2a / protective gloves (inside used gloves), coated coverall and RPE (APF = 10) | 8.13E-02 |
| Tier 2b / protective gloves (inside new gloves), impermeable coverall and RPE (APF = 10) | 4.24E-02 |
| 2. Outdoor application | Professionals / Trained professionals | Tier 1 / no PPE | Cover by scenario 1 |
| Tier 2a / protective gloves (inside used gloves), coated coverall and RPE (APF = 10) | Cover by scenario 1 |
| Tier 2b / protective gloves (inside new gloves), impermeable coverall and RPE (APF = 10) | Cover by scenario 1 |
| 3. Indoor application | Non-professionals | Tier 1 / no PPE | 9.03E-03 |
| 4. Outdoor application | Non-professionals | Tier 1 / no PPE | 9.03E-03 |
| 5. Indoor application | Non-professionals | Tier 1 / no PPE | 9.03E-03 |
| 3 + 4 + 5. | Non-professionals | Tier 1 / no PPE | 2.71E-02 |
| 6. Inhalation of volatilized residues | Non-professionals | Tier 1 / no PPE | Negligible. |
| 7. Adults/toddlers playing/crawling on treated surfaces | General public (adults) | Tier 1 / no PPE | 2.03E-01 |
| General public (adults) | Tier 2 / no PPE | 2.03E-02 |
| General public (toddlers) | Tier 1 / no PPE | 3.12E-01 |
| General public (toddlers) | Tier 2 / no PPE | 3.12E-02 |
| 8. Laundering working clothes | General public | Tier 1 / no PPE | 9.47E-03 |
| 1 + 8. | Non-professionals | Tier 1 / no PPE | 5.19E-02 |
| 3 + 4 + 5 + 7. | General public | Tier 1 / no PPE | 4.74E-02 |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF** | **Correction for oral absorption** | **Value** |
| AEL short term | 2 year oral study rat | 59.46  mg/kg bw/day | 100 | - | 0.5  mg/kg bw/day |
| AEL medium term | 12-month study dog | 5  mg/kg bw/day | 100 | - | 0.05  mg/kg bw/day |
| AEL long term | 12-month study dog | 5  mg/kg bw/day | 100 | - | 0.05  mg/kg bw/day |

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| MRL | EU Reg. 396/2005 (PPP) | All commodities | Cf: Reg. (EU) 2017/623 |
| EU Reg. 470/2009 (VMP) | Food of animal origin (bovine) | Cf: Reg (EU) 37/2010 |

*PPP: plant protection product*

*VMP: veterinary medicinal product*

**Specific reference value for groundwater**

Not applicable.

***Risk for industrial users***

As previously stated, no relevant exposure is foreseen considering that industrial users are adequately trained in the safe handling of the active substance and the product, and adequate protective measures are in place in industrial facilities. Thus no risk is envisaged for industrial users.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1. Indoor application | Tier 1 / no PPE | 5 | 0.05 | 1.11E-00 | 222 | **No** |
| Tier 2a / PPEs\* | 5 | 0.05 | 8.13E-02 | 163 | **No** |
| Tier 2b / PPEs\*\* | 5 | 0.05 | 4.24E-02 | 84.8 | Yes |
| 2. Outdoor application | Tier 1 / no PPE | Cover by scenario 1 | | | | |
| Tier 2a / PPEs\* |
| Tier 2b / PPEs\*\* |
| \* protective gloves (inside used gloves, coated coverall and RPE (APF = 10)  \*\* protective gloves (inside new gloves, impermeable coverall and RPE (APF = 10) | | | | | | |

No unacceptable risk has been identified for different tasks considered when workers wear protective gloves (inside new gloves), impermeable coverall and RPE (APF = 10).

**Local effects**

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

* The biocidal product contains permethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or
* Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

**Combined scenarios**

Not applicable.

**Conclusion**

Based on the results obtained in the risk assessment, the exposure of workers results in level of exposure lower than the relevant reference values for systemic exposure and local inhalation and dermal exposure. Therefore, no unacceptable risk can be identified taking into account the instruction for use and PPEs proposed.

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

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 3. Indoor application | Tier 1 / no PPE | 5 | 0.05 | 9.03E-03 | 18.1 | Yes |
| 4. Outdoor application | Tier 1 / no PPE | 5 | 0.05 | 9.03E-03 | 18.1 | Yes |
| 5. Indoor application | Tier 1 / no PPE | 5 | 0.05 | 9.03E-03 | 18.1 | Yes |

No unacceptable risk has been identified for different tasks considered.

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 3 + 4 + 5. | Tier 1 / no PPE | 5 | 0.05 | 2.71E-02 | 54.2 | Yes |

No unacceptable risk has been identified for different combined tasks considered.

**Local effects**

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

* The biocidal product contains permethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or
* Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

**Conclusion**

Based on the results obtained in the risk assessment, the exposure of general public results in level of exposure lower than the relevant reference values for systemic exposure and local inhalation and dermal exposure. Therefore, no unacceptable risk can be identified taking into account the instruction for use proposed.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 7. Adults/toddlers playing/crawling on treated surfaces | Tier 1 (adults) | 5 | 0.05 | 2.03E-01 | 406 | **No** |
| Tier 2 (adults) | 5 | 0.05 | 2.03E-02 | 40.6 | Yes |
| Tier 1 (toddlers) | 5 | 0.05 | 3.12E-01 | 624 | **No** |
| Tier 2 (toddlers) | 5 | 0.05 | 3.12E-02 | 62.4 | Yes |
| 8. Laundering working clothes | Tier 1 | 5 | 0.05 | 9.47E-03 | 18.9 | Yes |

No unacceptable risk has been identified for different tasks considered.

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1 + 8 | Tier 2b (1)  Tier 1 (8) | 5 | 0.05 | 5.19E-02 | 104 | **No** |
| 3 + 4 + 5 + 7 | Tier 1 (3, 4, 5)  Tier 2 (7) (adults) | 5 | 0.05 | 4.74E-02 | 94.8 | Yes |

No unacceptable risk has been identified for different combined tasks considered with the exception of the combined tasks for workers where the workers cannot wash the contaminated clothes at home to avoid the overexposure to active substance.

**Local effects**

Indirect dermal exposure to BP is possible through contact treated surfaces.

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

* The biocidal product contains permethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or
* Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Residues of permethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of permethrin is assumed to be lower than 4000 ppm.

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

**Conclusion**

The risk derived from the use of biocidal product by general public as secondary exposure appears to be acceptable when the exposure of the user to permethrin is compared to its chronic AEL. Moreover the biocidal product contains denatonium benzoate which is a substance added to the formulation specifically to give it a bitter taste and prevent it from being ingested by the child.

To avoid contact to treated surfaces by children and contaminated clothes by general public, the following RMMs were therefore assigned:

* *Keep out of reach of children and non-target animals/pets.*
* *(Trained) Professionals are not allowed to wash contaminated clothes at home.*

Therefore, no unacceptable risk can be identified taking into account the RMMs and the instruction for use proposed.

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

The biocidal product is not intended for the use on food neither directly nor in areas where food is stored. Moreover no transfer of active substance into foods as results of professional, non-professional and/or industrial application is expected since the product is not applied by spraying or dusting such that food or feeding stuffs could be contaminated. Therefore, there is no requirement to assess risk to consumers via residues in food.

In addition, to prevent any potential risk by its use, the following RMMs are included:

* *Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*
* Keep out of reach of children and non-target animals/pets*.*

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

The biocidal product does not contain any further active substance or substance of concern so a combined exposure is not expected.

### Risk assessment for animal health

The bittering agent is supposed to repel children from orally ingesting dangerous amounts of the biocidal product. It is not acceptable to conclude that it is working the same way on all pet species, limiting the oral uptake. However, due to the lack of appropriate guidance, exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats). Especially cats may even increase their licking behaviour in case they detect unpleasant residues on their fur. Also, cats are known to have a preference to hide in hard to reach places.

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication are very common and may be dangerous. In order to protect cats, the following Risk Mitigation Measure must be added on the label:

* *Keep cats away from treated surfaces. Due to their particular sensitivity to pyrethroids, the product can cause severe adverse reactions in cats.*
* *Contains Permethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).*

In addition, to prevent any exposure of animals the following RMMs are included:

* *Do not spray directly on people, animals or bedding.*
* *Keep out of reach of children and non-target animals/pets.*
* *Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.*
* *Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.*
* *Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.*

### Risk assessment for the environment

|  |
| --- |
| ESCA: The applicant has not provided any new study with the biocidal product. The environmental risk assessment for INSECTICIDA RTU PER ZNZ has been done using the Competent Authority Report on the active substance permethrin. The whole assessment submitted by the applicant has been included and reviewed by the ES CA. The comments of the ES CA are included in grey boxes.  According to the applicant the product is a ready to use spray containing one active substance, permethrin (0.4% w/w). This product is intended to control crawling and flying insects indoor and outdoor by non-professional, professionals and trained professionals. Since the efficacy of this product against flying insects and against ants in areas around buildings have not been supported by efficacy studies, these uses have not been reviewed.  Based on the efficacy studies the product is effective indoor for killing crawling insects as a spot treatment including crack and crevices, and also is effective against cat fleas, house dust mite and ticks by spraying non washable textiles surfaces. This product has shown also to be effective outdoor directly on ant nest.  Besides the active substance permethrin, this product contains another substance of concern Propan-2-ol, this substance is an active substance for other product types (PT1, PT2 and PT4) and it is in a concentration higher than 0.1% in the biocidal product. Therefore, although it is not considered as toxic for the environment, applying the specifications of Art. 3 (1f) of Regulation (EU) No 528/2012, this substance must be considered a Substance of Concern (SoC) and included into the environmental risk assessment. |

#### Effects assessment on the environment

***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***

No environmental fate and behaviour studies were conducted with the product, as it was considered that the studies on the active ingredient were adequate for the purpose. Summary of the fate and distribution in the environmental of the active substance, as reported in the Assessment Report of permethrin (April 2014), is reported in Environmental Risk Assessment document attached in the section 13 of IUCLID data set.

No aquatic, terrestrial or secondary poisoning toxicity studies were conducted with the product PERMETHRIN 0.4% RTU, as it was considered that the acute and chronic studies on the active ingredient were adequate for the classification and labelling of the product and for the environmental risk assessment. Therefore, it is concluded that the product should be classified with respect to aquatic toxicity as Acute Tox 1 (H400) and Chronic Tox 1 (H410).

On the other hand, the biocidal product contains the substance Propan-2-ol (CAS: 67-63-0) which is approved as active substance for other product types (PT1, PT2 and PT4). Therefore, although it is not considered as toxic for the environment, applying the specifications of Art. 3 (1f) of Regulation (EU) No 528/2012, this substance must be considered a Substance of Concern (SoC) and included into the environmental risk assessment.

| **Summary on PNEC used for the risk assessment** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Substance** | **Surface water [PNECaquatic (mg/L)]** | **Sediment [PNECsediment (mg/kg wwt)]** | **STP microorganism [PNECSTP (mg/L)]** | **Soil [PNECsoil (mg/kg wwt)]** | **Birds [PNECoral, birds (mg/kg diet)]** | **Mammals [PNECoral, mammals (mg/kg diet)]** | **Reference** |
| Permethrin | 4.7E-07 | 2.17E-04 | 0.00495 | 0.175 | 16.7 | 120 | AR, 2014 |
| DCVA | 0.015 | 0.012 | - | 4.6 | - | - | AR, 2014 |
| PBA | >0.010 | 0.009 | - | 1.44 | - | - | AR, 2014 |
| PB alcohol | No data available | | | | | | AR, 2014 |
| Propan-2-ol (*as SoC)* | 2.82 | 2.41 | 10 | 0.496\* | - | - | AR, 2015 |

\* by equilibrium partitioning method.

Following propan-2-ol’s AR (2015), propan-2-ol has a low BCF and it is not expected to accumulate in the environment. Therefore, the risk of secondary poisoning is assumed to be negligible via ingestion of contaminated food by birds or mammals.

|  |
| --- |
| ESCA: ES CA agrees with the applicant |

***Further Ecotoxicological studies***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies |
| Justification | Ecotoxicological studies on the formulation are generally not required for biocidal products as long as sufficient information can be extrapolated from the active substance.  Moreover an inhibition of microbial activity (CH-619/2015, Dini R., 2016) and an acute toxicity on earthworm (CH-620/2015, Dini R., 2016) tests have been performed on the Permethrin 0.5% Dust. However, results of these tests, does not modified the endpoint used for the risk assessment.  The ecotoxicological testing of the active substance permethrin were adequately covered in the AR (2014), and there are no other components in the PERMETHRIN 0.4% RTU formulation which are of ecotoxicological relevance (confidential information, see Section B2.2), therefore no additional studies were performed and reference is made to the CAR, document IIA, section 4.2. |

|  |
| --- |
| ESCA: ES CA agrees with the applicant |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

|  |
| --- |
| ESCA: ES CA agrees with the applicant |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

|  |
| --- |
| ESCA: ES CA agrees with the applicant |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

|  |
| --- |
| ESCA: ES CA agrees with the applicant |

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

No data is available.

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

For the biocidal product PERMETHRIN 0.4% RTU used as insecticide and acaricide, the following life cycle stages are identified:

1. Manufacturing of permethrin
2. Formulation of PERMETHRIN 0.4% RTU
3. Intended Use of PERMETHRIN 0.4% RTU
4. Mixing and Loading of PERMETHRIN 0.4% RTU (only for professional users)
5. Application of PERMETHRIN 0.4% RTU (both hand-held equipment and trigger-sprayer).

Due to the intended uses, the following table summarizes the foreseen entries (primarily exposed) into the environment and the likely environmental compartments that may be secondarily exposed:

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Indoors application | n.r.\* | n.r.\* | n.r. | n.r. | n.r.\* | + | ++ | + | (+) |
| Outdoors applications | n.r.\*\* | n.r.\*\* | n.r. | n.r. | n.r.\*\* | + | ++ | + | (+) |

++ Primarily exposed, + secondarily exposed, (+) potentially exposed, n.r. not relevant

\* As it is claimed in the product’s label, the product can only be used on surfaces and textiles that are not going to be cleaned and in those cases where a cleaning treatment hast to be carried out, they must be done using dry cleaning methods. Hence, neither exposure by STP nor surface water exposure are expected by its application and post-application.

\*\*Outdoor applications must be developed on paved surfaces as terraces which must be protected from the rain (roof-covered areas) and not be connected to STP (i.e. not on bare soil and protected from rain fall, flooding or cleaning wash). Therefore, following ENV 158 from Technical Agreements for Biocides (TAB- ENV v.2.1), no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment.

Ant-nest application must be done directly into the nest on summer seasons, taken into account the weather forecast and avoiding raining days. The treated nest must be covered by a plastic tarp in order to avoid that the product could be dragged by the air or water and also to avoid any potential risk for animals by primary or secondary poisoning. After 2 days of application, the plastic tarp can be removed and the nest must be buried.

**1 - Information regarding the environmental exposure during the manufacturing process of the biocidal product/active substance**

According to the “EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0” emissions from active substance production and product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

**2 - Information regarding the environmental exposure during the formulation of the biocidal product**

According to the “EU Evaluation Manual for the Authorisation of Biocidal Products; final version 1.0” emissions from product formulation are considered less significant compared to emissions from the application phase, in service and waste phase of the product and these phases are not part of Regulation (EU) No 528/2012.

The formulation step is not covered by the ESD for PT 18; nevertheless it was no risk is identified for freshwater, air and agricultural soil compartments, provided that solid and liquid spills and cleaning waters are collected and dispose of as dangerous waste and all operations are conducted under aspiration and the collected emissions are treated before any release to air.

**3 - Information regarding expected environmental exposure during application of the formulated product**

PERMETHRIN 0.4% RTU may be used by users (professionals and non-professionals) for indoor and outdoor applications and it is a ready to use liquid formulation containing 0.4% w/w Permethrin which is not diluted prior to use.

The recommended usage concentration of the liquid is 15 mL for square meter, equivalent to 60 mg/m2 of permethrin (assuming density of 1 g/mL), for use against insects.

In the ESD for PT18 it is generally assumed that insecticides used indoors will not directly reach the environmental compartments, but it is concluded that after the application of the insecticide, the cleaning step will lead the releases to waste water through wet cleaning methods. However, PERMETHRIN 0.4% RTU is specifically intended to be applied in areas that are not cleaned and in those cases where they are cleaned, dry cleaning methods are used. Then solid residues must be vacuumed and managed as solid hazardous wastes. Hence, soil is the main environmental compartment of concern deemed in the current assessment.

On this basis, the environmental exposure assessment has been performed for permethrin active substance and its metabolites.

Since no clear recommendations are available for metabolites at the time of writing, the chosen approach was to estimate the concentrations of relevant metabolites as a percentage of the concentrations of the parent compound permethrin. There are only minor differences between molecular weights of permethrin and its metabolites. Hence, correction based on the molecular weights was considered negligible.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  ES CA considers in the following table, according to the intended uses, the foreseen entries (primarily exposed) into the environment and the likely environmental compartments that may be secondarily exposed:   | **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other | | Indoor application | + | + | n.r. | n.r. | ++ | ++ | + | + | (+) | | Outdoor application | + | + | n.r. | n.r. | - | + | ++ | + | (+) |   ++ Primarily exposed, + secondarily exposed, (+) potentially exposed.  Although the applicant proposes some instruction of use which avoid the emissions to the environment, we consider that the table above shows the most realistic emissions to the environment for the intended uses of the biocidal product.  As it is stated by the applicant, the recommended usage concentration of the liquid is 15 mL for square meter, equivalent to 60 mg/m2 of permethrin (assuming density of 1 g/mL), for use against insects but, according to the efficacy tests, there are different application rates depending on the target organism and the use proposed, for the application rate see section 2.2.8.2.  To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. Following the releases to STP, concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water was further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic compartment. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

|  |
| --- |
| ES CA: ES CA agrees with the applicant. |

***Leaching behaviour (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No data required |
| Justification | No further data necessary |

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| --- |
| ES CA: ES CA agrees with the applicant. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for distribution and dissipation in soil has been conducted on PERMETHRIN 0.4% RTU. |
| Justification | The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required. |

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| ES CA: ES CA agrees with the applicant. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for dissipation and distribution in water and sediment has been conducted on PERMETHRIN 0.4% RTU. |
| Justification | The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view that no aquatic environmental exposure must be expected according to formulation uses, testing for distribution and dissipation in the environment is not required. |

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| --- |
| ES CA: ES CA agrees with the applicant. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing for dissipation and distribution in air has been conducted in PERMETHRIN 0.4% RTU |
| Justification | The environmental fate and behaviour of the active substance permethrin has been adequately covered in the AR for the active substance (2014), so reference is made to the said report, document IIA, section 4.1. Therefore, and in view of the low environmental exposure expected following the use of the formulation, testing for distribution and dissipation in the environment is not required. |

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| ES CA: ES CA agrees with the applicant. |

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

No data required.

|  |
| --- |
| ES CA: ES CA agrees with the applicant. |

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

Not relevant

|  |
| --- |
| ES CA: ES CA agrees with the applicant. |

#### Exposure assessment

Formulation and use of the insecticide and acaricide PERMETHRIN 0.4% RTU may lead to harmful emission to the environment. Therefore, an environmental exposure assessment has been done in accordance with the Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008) as well as the technical agreements reached for the evaluation of biocidal products "Technical Agreements for Biocides" v.2.1) and the EUSES 2.2.0 and is based on information relating to the intended uses of PERMETHRIN 0.4% RTU.

The environmental exposure assessment has been performed for the active substance permethrin and their metabolites and was conducted for the local scale only, as required for biocidal products.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | Scenario 1: Indoor – voids/cavities treatment   1. Professional 2. Non-professional   Scenario 2: Indoor – Spot surface application to flying insects by non-professional users  Scenario 3: Indoor – Non-washable textile surfaces  Scenario 4: Outdoor – Ant nests  Scenario 5: Outdoor – Around buildings in voids/cavities paved areas protected from rain and wash. |
| ESD(s) used | * Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) for household and professional use (OECD, 2008 and ESD Excel spreadsheet for PT18 v1.0 (2019)); * Technical Agreements for Biocides (TAB) – ENV v.2.1; * EUSES 2.2.0 |
| Approach | All scenarios by Average consumption |
| Distribution in the environment | Calculated based on TGD 2003 |
| Groundwater simulation | Yes |
| Confidential Annexes | Yes |
| Life cycle steps assessed | For all scenarios:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | According to label mentions:   * Indoor use (scenarios 1, 2 and 3) must be done only in voids/cavities, window frames, spots on walls , or textile surfaces as mattresses, rugs and carpets to be cleaned by dry cleaning methods. This assumption has been deemed in the exposure assessment, so the potential emission derived from cleaning have been considered. * Outdoor use into ant’s nests (Scenario 4) is done by spraying directly into the ant nest and then, the nest must be covered by plastic tarp in order to avoid any loss of liquid from the nest by air or rainfall. * Outdoor use into voids/cavities on paved surfaces (as terraces) around buildings (Scenario 5) is developed on locations non connected to STP and protected from rainfall and flooding. By this way any potential emission to wastewater or surface water sources is avoided and only potential exposure by secondary poisoning is considered of concern for the environment (ENV 158 -TAB v.2.1). |

Following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash. This is one of the main intended outdoor applications of PERMETHRIN 0.4% RTU against ants so the emission from professional applications outdoors (Scenarios 4 and 5) should be considered at safe. In addition, the product is also intended to be applied as spot application on paved surfaces around domestic premises for general public use. Hence, the terrace scenario is deemed by taken into account the urban area location in order to avoid any release to sewer/STP and only considering releases to soil compartment around a terrace.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ESCA considers that the most suitable scenarios to evaluate the environmental risk due to the intended uses of this biocidal product are indicated in the table below:   |  |  | | --- | --- | | Assessed PT | PT18 | | Assessed scenarios | Scenario 1: Indoor – spot to a surface\*- crawling insects -professional  Scenario 2: Indoor – barrier treatment- crawling insect-non-professional users  Scenario 3: Indoor – Non-washable textile surfaces  Scenario 4: Outdoor – Ant nests | | ESD(s) used | * Emission Scenario Document for insecticides, acaricides and products to control arthropods (PT18) * Technical Agreements for Biocides (TAB) – ENV v.2.1; | | Approach | All scenarios by Average consumption | | Distribution in the environment | Calculated based on Guidance on Biocidal product regulation, 2017 | | Groundwater simulation | Yes | | Confidential Annexes | Yes | | Life cycle steps assessed | For all scenarios:  Production: No  Formulation No  Use: Yes  Service life: No | | Remarks | According to efficacy tests uses 1 and 2 correspond to a spot, but, to evaluate the environmental risk assessment, ES CA considers for a professional users the scenario "spot to a surface" (SCENARIO 1) and for non-professional users "the barrier scenario" (SCENARIO 2).  From the environmental section, the use to control flying insects and the application around buildings have not been evaluated since these uses have not been supported by efficacy test.  Scenarios 3 and 4 are the same as those proposed by the applicant. |   ESCA agrees with the applicant: following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash (following label instructions and RMM). This is one of the main intended outdoor applications of INSECTICIDA RTU PER ZNZ against ants so the emission from professional applications outdoors (Scenario 4) should be considered at safe. However, scenario 4 has been also evaluated, when the product is applied by professionals, to calculate the risk to secondary poisoning. |

**Assessed scenarios: Intended uses and application rates for PERMETHRIN 0.4% RTU**

| **Scenarios** | **Uses #1** | **Indoor / Outdoor** | **User** | **Type of application** | **EUSES scenario** | **EUSES treatment** | **Target pest** | **Application rate (a.i.)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | #1 | Indoor | Professional | Spraying in voids/cavities (cracks and crevices) | 18.2.1 | Spot, crack and crevices | Crawling insects 2 | 60 mg/m2 |
| #2 | Indoor | Professional and General public | Spraying – crack and crevice (including foams) – spot, surface | crack and crevice (including foams) |
| 2 | #8 | Indoor | General public | Spraying– crack and crevice (including foams) – spot, surface | 18.2.1 | crack and crevice (including foams) | Flying insects3 | 60 mg/m2 |
| 3 | #3 | Indoor | General public | Spraying on non-washable textile surfaces by wet cleaning methods | 18.2.1 | crack and crevice (including foams) in carpets and/ or furniture surface | Dust mites, bed bugs | 60 mg/m2 |
| 4 | #4 and #5 | Outdoor | Professional and general public4 | Nest spraying directly into the nest | 18.3.4 | Outdoor, spot application | Ants | 510 mg per nest5 |
| 5 | #6 and #7 | Outdoor | Professional and general public | Spraying in voids/cavities of paved surfaces and roof-covered areas | 18.3.2 | Outdoor crawling insects in foundations and soil around the building | Crawling insects | 60 mg/m2 |

1 As indicated in the section 2.1.4 Authorized uses

2 Cockroaches deemed as worst case

3 Flies deemed as representative case

4 General public is deemed in Section 2.1.4 but no considered in the assessment because is not considered an option in EUSES 2.2.0.

5 This amount is estimated according to recommendation from eCA to use 8.5 m2 of surface for ant’s nest scenario, which is based on TAB ENV 154 that assumes a receiving area of 8.5 m2 for bait box scenario on terraces. Hence, a total amount of 127.5gproduct (0.51 ga.s) was deemed in the scenario assessment. The applicant wants to point out that this amount is higher than used in the field efficacy test for ant nest which were developed considering an area of 1m2 for a nest and application rate of the product 15 g/m2. So following the assumption of OECD ESD No.18 where an area of 0.25 m2 (0.5m x 0.5m) is considered for a nest and taken into account the application rate of the product 15 g/m2 a total amount of 3.75gproduct should be applied for a nest, equivalent to 15 mga.s. This amount is much less than the amount used in the assessment (510 mga.s.).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| According to the efficacy tests, the uses and the application rates demonstrated by the applicant for this biocidal product are detailed in the table below:  **Assessed scenarios: Intended uses and application rates for PERMETHRIN 0.4% RTU**   | **Scenarios** | **Uses #1** | **Indoor / Outdoor** | **User** | **Type of application** | **Target pest** | **Application rate2** | | --- | --- | --- | --- | --- | --- | --- | | 1 | #1 | Indoor | Professional | Spot to a surface in hiding places including crack and crevices | Cockroaches and ants | 15 mL/m2 | | Silver fish | 25,5 mL/m2 | | 2 | #2 | Indoor | General public | Spot to a surface in hiding places including crack and crevices | Cockroaches and ants | 15 mL/m2 | | Silver fish | 25,5 mL/m2 | | 3 | #3 | Indoor | General public | Non-washable textiles | Dust mites, bed bugs | 15 mL/m2 | | 4 | #4 and #5 | Outdoor | Professional and general public | Nest spraying directly into the nest | Ants | 3 mL/nest | |  |  |  |  |  |  |  |   1 As indicated in the section 2.1.4 Authorized uses.  2 As a fist tier ES CA has evaluated the lowest dose, 15 mL/m2. |

Emission estimation

In the following, Predicted Environmental Concentrations (PECs) for the active substance permethrin and its metabolites for the relevant compartments are calculated.

All PECs were calculated with EUSES 2.2.0 and for complete calculations see Annex 3.2.

The input parameters for the EUSES calculation are shown in the tables below. All parameters are based on the Assessment Report for the Inclusion of active substance permethrin in Annex I or IA to Directive 98/8/EC (Product Type 18) (AR, 2014).

Scenario 1 - *Indoor – Spraying into voids/cavities (spots, crack and crevice)*

No mixing and loading is deemed for non-trained professional users and general public as the product is a ready-to-use by trigger sprayer. However, for trained professional users, mixing and loading is considered for 3 preparations per day in a large building. As it is mandatory in the product label, dry cleaning methods are deemed in the assessment and as worst case washable coveralls are deemed. The following table shows further inputs considering in the assessment.

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenarios 1:* *Indoor – Spraying into voids/cavities (spots, crack and crevice)* | | | |
| Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed |
| Concentration of active substance in the product | 0.4 | % w/w |  |
| Concentration of the SoC | 0.24 | % w/w |  |
| Area treated, house | 2 | m2 |  |
| Area treated, larger building | 9.31 | m2 | According to ENV142 of TAB-ENV v.2.1 |
| Number of applications per day, house | 1 | d-1 |  |
| Number of applications per day, large building | 1 | d-1 |  |
| Quantity of commercial product used per preparation2 | 139.5 | G | Applicant data |
| Container type/volume | 1 | L | with unspecific design |
| Fraction emitted to floor during mixing and loading (for professional users) | 0.0001 | - |  |
| Fraction emitted to floor during mixing and loading (for non-professional users) | 0.001 | - |  |
| Frequency of application in standard houses and large buildings | 12 | Monthly |  |
| Simultaneity factor for indoor uses of insecticide in standard houses and large buildings | 0.01386 | - |  |
| Fraction emitted to air during application | 0.02 | - | default |
| Fraction emitted to floor during application | 0.11 | - | default |
| Fraction emitted to applicator during application | 0.02 | - | default |
| Fraction emitted to treated surfaces | 0.85 | - | default |
| Cleaning efficiency for professional users and general public as spray formulation to be used in crack and crevice | 0.25 | - | According to ENV149 of TAB-ENV v.2.1. |
| Number of houses per STP | 4000 | - | default |
| Number of buildings per STP | 300 | - | Not relevant for non-professional user |

1 This value is considered by using the same relation between the treated and total surface for the commercial building as for the domestic house. Because the application in voids/cavities can be deemed as spot application, 9.3 m2 has been deemed as the most realistic value.

2 As 9.3 m2 is the highest surface to be treated in large buildings by professional users, then 139.5 ml of product is applied per treated area. As the product’s commercial packaging are above this required volume only one application and one preparation are considered.

Calculations for Scenario 1

The following table summarizes the ways of emission to the environment obtained from EUSES 2.2.0 and ESD guidance (vers 1.0 (2019)):

* For **Permethrin**

| **Local emission** | **Type of area treated** | | | |
| --- | --- | --- | --- | --- |
| **Professional user** | | | **Non-professional user** |
| Standard houses | | Large buildings | Standard houses |
| ***Emissions during Mixing/loading (only should be considered for professional users)*** | | | | |
| Local emission to air [kg.d-1] | 0 | 0 | | - |
| Local emission to applicator [kg.d-1] | 6.70E-07 | 6.70E-07 | | 6.70E-07 |
| Local emission to floor [kg.d-1] | 5.58E-08 | 5.58E-08 | | 5.58E-08 |
| ***Emissions during product’s application*** | | | | |
| Local emission to air [kg.d-1] | 2.4E-06 | | 1.12E-05 | 2.4E-06 |
| Local emission to applicator [kg.d-1] | 2.4E-06 | | 1.12E-05 | 2.4E-06 |
| Local emission to floor [kg.d-1] | 1.32E-05 | | 6.14E-05 | 1.32E-05 |
| Local emission to treated surfaces [kg.d-1] | 1.02E-04 | | 4.74E-04 | 1.02E-04 |
| ***Emissions during cleaning residues of mixing/loading (only for professional users)*** | | | | |
| Local emission to wastewater from washing applicator’s coveralls | 6.70E-07 | | 6.70E-07 | 6.70E-07 |
| Emission to solid waste from disposing of the coveralls | 0 | | 0 | 0 |
| Local emission to wastewater from wet cleaning the floor\* | 5.58E-08 | | 5.58E-08 | 5.58E-07 |
| ***Emissions during cleaning residues from product’s application*** | | | | |
| Local emission to wastewater from washing applicator’s coveralls | 2.4E-06 | | 1.12E-05 | 2.4E-06 |
| Emission to solid waste from disposing of the coveralls | 0 | | 0 | 0 |
| Local emission to wastewater from wet cleaning the floor\* | 3.3E-06 | | 1.53E-05 | 3.3E-06 |
| Local emission to wastewater from wet cleaning the treated | 0 | | 0 | 0 |
| Emission to solid waste from dry cleaning the treated surfaces | 2.55E-05 | | 1.19E-04 | 2.55E-05 |

\* It is important to point out that by default ESD Guidance and hence EUSES 2.2.0 consider that the cleaning task of mixing and loading can only be done by wet cleaning treatments and as it was mentioned before, product residues must be only cleaned by dry cleaning treatment. Therefore, no potential local emission to wastewater should be considered and the outputs from EUSES 2.2.0 should be deemed as overestimation because the estimation model is not in accordance with the real application process of the product.

The following table summarizes the total local emission derived from this scenario

| **Resulting total local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | **Remarks** |
| **Non-professional users (standard houses)** | **Professional users (standard houses and large buildings)** |
| Local emission to air (Eair) | 1.33E-04 | 1.79E-04 | None |
| Local emission to wastewater (Ewater) | 3.84E-04 | 4.70E-04 | None |
| Local emission to solid waste (Ewaste)\* | 1.41E-03 | 1.91E-03 | None |

\*Obtained by ESD PT18 Excel spreadsheet

* For Propan-2-ol as **SoC**

| **Local emission** | **Type of area treated** | | | |
| --- | --- | --- | --- | --- |
| **Professional user** | | | **Non-professional user** |
| Standard houses | | Large buildings | Standard houses |
| ***Emissions during Mixing/loading (only considered for professional users)*** | | | | |
| Local emission to air [kg.d-1] | 0 | 0 | | - |
| Local emission to applicator [kg.d-1] | 4.02E-07 | 4.02E-07 | | 4.02E-07 |
| Local emission to floor [kg.d-1] | 3.35E-08 | 3.35E-08 | | 3.35E-08 |
| ***Emissions during product’s application*** | | | | |
| Local emission to air [kg.d-1] | 1.44E-06 | | 6.7E-06 | 1.44E-06 |
| Local emission to applicator [kg.d-1] | 1.44E-06 | | 6.7E-06 | 1.44E-06 |
| Local emission to floor [kg.d-1] | 7.92E-06 | | 3.68E-05 | 7.92E-06 |
| Local emission to treated surfaces [kg.d-1] | 6.12E-05 | | 2.85E-04 | 6.12E-05 |
| ***Emissions during cleaning residues of mixing/loading (only should be considered for professional users)*** | | | | |
| Local emission to wastewater from washing applicator’s coveralls | 4.02E-07 | | 4.02E-07 | 4.02E-07 |
| Emission to solid waste from disposing of the coveralls | 0 | | 0 | 0 |
| Local emission to wastewater from wet cleaning the floor\* | 3.35E-08 | | 3.35E-08 | 3.35E-07 |
| ***Emissions during cleaning residues from product’s application*** | | | | |
| Local emission to wastewater from washing applicator’s coveralls | 1.44E-06 | | 6.7E-06 | 1.44E-06 |
| Emission to solid waste from disposing of the coveralls | 0 | | 0 | 0 |
| Local emission to wastewater from wet cleaning the floor\* | 1.98E-06 | | 9.21E-06 | 1.98E-06 |
| Local emission to wastewater from wet cleaning the treated | 0 | | 0 | 0 |
| Emission to solid waste from dry cleaning the treated surfaces | 1.53E-05 | | 7.11E-05 | 1.53E-05 |

\* It is important to point out that by default ESD Guidance and hence EUSES 2.2.0 consider that the cleaning task of mixing and loading can only be done by wet cleaning treatments and as it was mentioned before, product residues must be only cleaned by dry cleaning treatment. Therefore, no potential local emission to wastewater should be considered and the outputs from EUSES 2.2.0 should be deemed as overestimation because the estimation model is not in accordance with the real application process of the product.

The following table summarizes the total local emission derived from this scenario

| **Resulting total local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | **Remarks** |
| **Non-professional users (standard houses)** | **Professional users (standard houses and large buildings)** |
| Local emission to air (Eair) | 7.99E-05 | 1.08E-04 | None |
| Local emission to wastewater (Ewater) | 2.30E-04 | 2.82E-04 | None |
| Local emission to solid waste (Ewaste)\* | 8.48E-04 | 1.14E-03 | None |

\*Obtained by ESD PT18 Excel spreadsheet

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ESCA: ESCA does not agree with the scenario proposed by the applicant (crack and crevices) to evaluate the risk of this use (use 1, crawling insect by professional) since, according to the efficacy test, this use is a "spot to a surface" including crack and crevices in hiding places so, ES CA considers that the “spot to a surface” scenario with a FCE of 50% covers the emissions to the environment for this use. Calculation has been performed with the lowest dose 15 mL/m2:  Scenario 1: Spot to a surfaces-professional user – crawling insects   | **Input parameters for calculating the local emission** | | | | | --- | --- | --- | --- | | **Input** | **Value** | **Unit** | **Remarks** | | *Scenarios 1:* *Indoor – Spot to a surface-professional user (cockroaches)* | | | | | Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed. | | Concentration of active substance in the product | 0.4 | % w/w |  | | Concentration of the SoC | 0.24 | % w/w |  | | Area treated, house | 2 | m2 |  | | Area treated, larger building | 9.3 | m2 |  | | Number of applications per day, house | 1 | d-1 |  | | Number of applications per day, large building | 1 | d-1 |  | | Quantity of commercial product used per preparation2 | 139.5 | g | Applicant data | | Container type/volume | 1 | L | with unspecific design | | Fraction emitted to floor during mixing and loading (for professional users) | 0.0001 | - |  | | Fraction emitted to applicator during mixing and loading (for professional users) | 0.0012 | - |  | | Frequency of application in standard houses and large buildings | 12 | Monthly |  | | Simultaneity factor for indoor uses of insecticide in standard houses and large buildings | 0.01386 | - |  | | Fraction emitted to air during application | 0.02 | - | Default | | Fraction emitted to floor during application | 0.128 | - | Default, compressed sprayer 1-3 bars | | Fraction emitted to applicator during application | 0.002 | - | Default, compressed sprayer 1-3 bars | | Fraction emitted to treated surfaces | 0.85 | - | Default | | Cleaning efficiency | 0.50 | - | According to ENV149 of TAB-ENV v.2.1. | | Number of houses per STP | 4000 | - | Default | | Number of buildings per STP | 300 | - | Default |   The following table summarizes the total local emission derived from this scenario:  Permethrin:   | **Resulting total local emission to relevant environmental compartments (permethrin)** | | | | | --- | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | **Remarks** | | **Professional users (standard houses)** | **Professional users (large buildings)** | | Local emission to wastewater (Ewater) | 3.27 E-03 | 1.14 E-03 | None | |  | **Local emission (Elocalcompartment) [kg/d] (large buildings + standard houses)** | |  | | Local emission to wastewater (Ewater) | 4.41 E-03 | |  |   Propan-2-ol:   | **Resulting total local emission to relevant environmental compartments (propan-2-ol)** | | | | | --- | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | **Remarks** | | **Professional users (standard houses)** | **Professional users (large buildings)** | | Local emission to wastewater (Ewater) | 1.96 E-03 | 6.85 E-04 | None | |  | **Local emission (Elocalcompartment) [kg/d] (large buildings + standard houses)** | |  | | Local emission to wastewater (Ewater) | 2.65 E-03 | |  | |

Scenario 2 - *Indoor – Spraying against flying insects as spot surface treatment by non-professional users*

As in the case of scenario before, no mixing and loading is deemed for general public as the product is a ready-to-use by trigger sprayer. As it is mandatory in the product label, dry cleaning methods are deemed in the assessment and as worst case washable coveralls are deemed. The following table shows further inputs considering in the assessment.

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenarios 2:* *Indoor – Spraying against flying insects as spot surface treatment* | | | |
| Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed |
| Concentration of active substance in the product | 0.4 | % w/w |  |
| Concentration of the SoC | 0.24 | % w/w |  |
| Area treated, house | 2 | m2 | Default |
| Wet cleaning zone in a standard house (leading to releases to the STP) | 2 | m2 | Default |
| Number of applications per day, house | 1 | d-1 |  |
| Frequency of application in standard houses and large buildings | 12 | Monthly |  |
| Simultaneity factor for indoor uses of insecticide in standard houses and large buildings | 0.01386 | - |  |
| Fraction emitted to air during application | 0.02 | - | Default |
| Fraction emitted to floor during application | 0.11 | - | Default |
| Fraction emitted to applicator during application | 0.02 | - | Default |
| Fraction emitted to treated surfaces | 0.85 | - | Default |
| Cleaning efficiency for general public as RTU spray formulation to be used in crack and crevice | 0.25 | - | According to ENV149 of TAB-ENV v.2.1. |
| Number of houses per STP | 4000 | - | Default |
| Number of buildings per STP | 300 | - | Not relevant for non-professional user |
| Number of emission days for Non-professional | 12 | d.yr-1 |  |

Calculations for Scenario 2

* For **Permethrin**

The following table summarizes the ways of emission to the environment obtained from EUSES 2.2.0 and corroborated by ECHA's Excel spreadsheets for ESD PT18:

| **Local emission [kg.d-1]** | **Type of area treated** |
| --- | --- |
| **Non-professional user** |
| Standard houses |
| *Emissions during product’s application* |  |
| Local emission to air [Eapplication,air] | 2.4E-06 |
| Local emission to applicator [Eapplication,applicator] | 2.4E-06 |
| Local emission to floor [Eapplication,floor] | 1.32E-05 |
| Local emission to treated surfaces [Eapplication,treated] | 1.02E-04 |
| *Emissions during cleaning residues from product’s application* | |
| Local emission to wastewater from washing applicator’s coveralls [Eww,applic,applicator] | 2.4E-06 |
| Local emission to wastewater from wet cleaning the floor\* [Eww,applic,cleaning\_floor] | 3.30E-06 |
| Local emission to wastewater from wet cleaning the treated surfaces [Eww,applic,cleaning\_treated] | 0 |
| Local emission to solid waste from dry cleaning the treated surfaces [Ewaste,applic,cleaning\_treated] | 2.55E-05 |

The following table summarizes the total local emission derived from this scenario

| **Resulting total local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| **Non-professional users (standard houses)** |
| Local emission to air (Eair) | 1.33E-04 | None |
| Local emission to wastewater (Ewater) | 3.16E-04 | None |
| Local emission to solid waste (Ewaste)\* | 1.41E-03 | None |

\* ECHA's Excel spreadsheets for ESD PT18

Local emission to wastewater (Ewater) are below that local emission from Scenario 1 for non-professional (n-P) users whilst local emissions to air and to solid waste (Eair and Ewaste) are the same for Scenario 1. In view of that, PECs obtained for Scenario 2 are expected to be lower or similar than Scenario 1.

* For **Propan-2-ol as SoC**

The following table summarizes the ways of emission to the environment obtained from EUSES 2.2.0 and corroborated by ECHA's Excel spreadsheets for ESD PT18:

| **Local emission [kg.d-1]** | **Type of area treated** |
| --- | --- |
| **Non-professional user** |
| Standard houses |
| *Emissions during product’s application* |  |
| Local emission to air [Eapplication,air] | 1.44E-06 |
| Local emission to applicator [Eapplication,applicator] | 1.44E-06 |
| Local emission to floor [Eapplication,floor] | 7.92E-06 |
| Local emission to treated surfaces [Eapplication,treated] | 6.12E-05 |
| *Emissions during cleaning residues from product’s application* | |
| Local emission to wastewater from washing applicator’s coveralls [Eww,applic,applicator] | 1.44E-06 |
| Local emission to wastewater from wet cleaning the floor\* [Eww,applic,cleaning\_floor] | 1.98E-06 |
| Local emission to wastewater from wet cleaning the treated surfaces [Eww,applic,cleaning\_treated] | 0 |
| Local emission to solid waste from dry cleaning the treated surfaces [Ewaste,applic,cleaning\_treated] | 1.53E-05 |

The following table summarizes the total local emission derived from this scenario

| **Resulting total local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| **Non-professional users (standard houses)** |
| Local emission to air (Eair) | 7.99E-05 | None |
| Local emission to wastewater (Ewater) | 1.9E-04 | None |
| Local emission to solid waste (Ewaste)\* | 8.48E-04 | None |

\* ECHA's Excel spreadsheets for ESD PT18

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ESCA:  The scenario 2 proposed by the applicant is a scenario to evaluate the risk of controlling flying insects but this use has not been supported by efficacy test, so this scenario has not been reviewed. For scenario 2, ESCA has evaluated the use of this product by non- professionals against crawling insects. Although the efficacy test indicates a treatment as spot to a surface, ES CA considers that the scenario that best represents the emissions due to this use is the barrier scenario.  Scenario 1: Barrier treatment-non-professional user – crawling insects   | **Input parameters for calculating the local emission** | | | | | --- | --- | --- | --- | | **Input** | **Value** | **Unit** | **Remarks** | | *Scenarios 1:* *Indoor – Spot to a surface-professional user (cockroaches)* | | | | | Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed | | Concentration of active substance in the product | 0.4 | % w/w |  | | Concentration of the SoC | 0.24 | % w/w |  | | Area treated, house | 5.9 | m2 |  | | Number of applications per day, house | 1 | d-1 |  | | Frequency of application in standard houses and large buildings | 12 | Monthly |  | | Simultaneity factor for indoor uses of insecticide in standard houses and large buildings | 0.01386 | - | Applicant data | | Fraction emitted to air during application | 0.02 | - | Default, hand held trigger spray | | Fraction emitted to floor during application | 0.124 | - | Default, hand held trigger spray (table 3.3.1 ESD PT18) | | Fraction emitted to applicator during application | 0.006 | - | Default, hand hell trigger spray (table 3.3.3 ESD PT18) | | Fraction emitted to treated surfaces | 0.85 | - | Default, hand held trigger spray | | Cleaning efficiency for professional users and general public as spray formulation to be used in crack and crevice | 0.50 | - | According to ENV149 of TAB-ENV v.2.1. | | Number of houses per STP | 4000 | - | Default |   The following table summarizes the total local emission derived from this scenario:  Permethrin:   | **Resulting total local emission to relevant environmental compartments (permethrin)** | | | | --- | --- | --- | |  | **Local emission (Elocalcompartment) [kg/d]** |  | | Local emission to wastewater (Ewater) | 9.68 E-03 |  |   Propan-2-ol:   | **Resulting total local emission to relevant environmental compartments (propan-2-ol)** | | | | --- | --- | --- | |  | **Local emission (Elocalcompartment) [kg/d]** |  | | Local emission to wastewater (Ewater) | 5.81 E-03 |  | |

Scenario 3 - *Indoor – Spraying over non washable textile surfaces by wet cleaning methods*

No mixing and loading is deemed as the product is a ready-to-use. Moreover dry cleaning methods and washable coveralls (as worst case) are deemed in the assessment. The additional EUSES 2.2.0 scenario 18.2.1 “indoor, spray application“ with the treatment of “carpets and/or furniture surface“ and the formulation/use: “RTU aerosol – crack and crevice (including foams) has been used as the most suitable for this assessment.

| **Input parametes for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario 3:* *Indoor – Spraying over non washable textile surfaces by wet cleaning methods* | | | |
| Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed |
| Concentration of active substance in the product | 0.4 | % w/w |  |
| Concentration of the SoC | 0.24 | % w/w |  |
| Area treated in a standard house | 22 | m2 |  |
| Wet cleaning zone in a standard house (leading to releases to the STP)\* | 5.9 | m2 |  |
| Number of applications per day, house | 1 | - | default |
| Simultaneity factor | 0.002042 | - | 1- 2 times per year |
| Fraction emitted to air | 0.02 | - | default |
| Fraction emitted to floor | 0.11 | - | default |
| Fraction emitted to applicator | 0.02 | - | default |
| Fraction emitted to treated surfaces | 0.85 | - | default |
| Cleaning efficiency | 0.20\* | - | default |
| Number of houses per STP | 4000 | - | default |
| Number of emission days | 365 | d.yr-1 | default |

\* Following the official Task, the endpoint TAB ENV 147 has been taken into account as a real case. It is important to bear in mind, that although the product is intended to be applied on textile surfaces that are not intended to be washed or cleaning by wet methods, there is considered a default surface for wet cleaning. This is not accordance with the intended use of the product and the potential emission to wastewater must be deemed as not in accordance with the right use of the product.

Calculations for Scenario 3

* For **Permethrin**

Emissions from application and cleaning are deemed of concern for the environment. The following table summarizes the application emissions obtained from EUSES 2.2.0:

| **Local emissions from Private use** | |
| --- | --- |
| **Sub-task from scenario** | **Value** |
| ***Application emissions*** |  |
| Local emission to air [kg.d-1] | 2.64E-05 |
| Local emission to applicator [kg.d-1] | 2.64E-05 |
| Local emission to floor [kg.d-1] | 1.45E-04 |
| Local emission to treated surfaces [kg.d-1] | 1.12E-03 |
| ***Cleaning emissions from application*** |  |
| Local emission to wastewater from washing applicator’s coveralls [kg.d-1] | 2.64E-05 |
| Local emission to wastewater from wet cleaning the floor [kg.d-1] | 7.79E-06 |
| Local emission to wastewater from wet cleaning the treated surfaces [kg.d-1] | 0 |

The following table summarizes the total local emission derived from this scenario:

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 2.79E-04 | None |
| Air | 2.16E-04 | None |

* For **Propan-2-ol as SoC**

Emissions from application and cleaning are deemed of concern for the environment. The following table summarizes the application emissions obtained from EUSES 2.2.0:

| **Local emissions from Private use** | |
| --- | --- |
| **Sub-task from scenario** | **Value** |
| ***Application emissions*** |  |
| Local emission to air [kg.d-1] | 1.58E-05 |
| Local emission to applicator [kg.d-1] | 1.58E-05 |
| Local emission to floor [kg.d-1] | 8.71E-05 |
| Local emission to treated surfaces [kg.d-1] | 6.73E-04 |
| ***Cleaning emissions from application*** |  |
| Local emission to wastewater from washing applicator’s coveralls [kg.d-1] | 1.58E-05 |
| Local emission to wastewater from wet cleaning the floor [kg.d-1] | 4.67E-06 |
| Local emission to wastewater from wet cleaning the treated surfaces [kg.d-1] | 0 |

The following table summarizes the total local emission derived from this scenario:

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 1.29E-04 | None |
| Air | 1.68E-04 | None |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA: Scenario 3, *Indoor – Spraying over non washable textile surfaces*  ESCA agrees with the scenario perfomed by the applicant, ESCA has recalculate the values taking into account the specific parameters of a hand trigger spray.   | **Input parameters for calculating the local emission** | | | | | --- | --- | --- | --- | | **Input** | **Value** | **Unit** | **Remarks** | | *Scenario 3: Indoor – Spraying over non washable textile surfaces by wet cleaning methods* | | | | | Fraction emitted to air | 0.02 | - | Default | | Fraction emitted to floor | 0.124 | - | Default, hand hell trigger spray (table 3.3.3 ESD PT18) | | Fraction emitted to applicator | 0.006 | - | Default, hand hell trigger spray (table 3.3.1 ESD PT18) | | Fraction emitted to treated surfaces | 0.85 | - | Default |   Permethrin:  Tier 1 *Spraying over non washable textile surfaces*   | **Resulting local emission to relevant environmental compartments** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 1.21E-04 | None |   ES CA has evaluated a second tier considering the following instruction of use “The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste.”   | **Resulting local emission to relevant environmental compartments** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 1.73E-05 | None |   Propan-2-ol:  Tier 1 *Spraying over non washable textile surfaces*   | **Resulting local emission to relevant environmental compartments** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 7.28E-05 | None |   ES CA has evaluated a second tier considering the following instruction of use “The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste.”   | **Resulting local emission to relevant environmental compartments** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 1.04E-05 | None | |

Scenario 4 - *Outdoor – Spot application into ant’s nest*

Following ESD PT18 No.18, it is expected that direct application into the nest should be considered as spot application on soil. In this case, the possible receiving compartments are the soil and to a lesser extent, the air. Release to the air is considered negligible. It is not current practice to collect unconsumed product.

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario 4:* *Outdoor – Spot application into ant’s nest* | | | |
| Quantity of commercial product applied | 31.875 | G | See note below (density 1 g/ml) |
| Concentration of active substance in the product | 0.004 | - |  |
| Concentration of the SoC | 0.0024 | - |  |
| Fraction emitted to soil during application | 0.99 | - |  |
| Number of nests treated per day | 4 | - |  |
| Area exposed to insecticide | 8.5 | m2 | Default |
| Depth of exposed soil | 0.5 | M | Default |
| Volume of exposed soil | 4.5 | m3 | Default |
| Bulk density of soil | 1700 | Kgwwt. m-3 | Default |
| Density of solid phase | 2500 | Kgwwt. m-3 | Default |
| Volume fraction of solids in soil | 0.6 | m3.m-3 | Default |
| Soil-water partition coefficient a.s | 808.1 | m3.m-3 |  |
| Soil-water partition coefficient SoC | 0.299 | m3.m-3 |  |
| Conversion factor for soil concentration wet-dry weight soil | 1.133 | Kgwwt.kgdwt-1 |  |
| Application specific factor, acute exposure for secondary poisoning | 1.15 | - | Default values used in Excel spreadsheet for ESD PT18 |
| Application specific factor, short-term exposure for secondary poisoning | 1.4 | - |
| Effective application rate, for acute exposure of a.s. | 8.4E-05 | Kg.m-2 |  |
| Effective application rate, for short-term of a.s. | 6.9E-05 | Kg.m-2 |  |
| Bioconcentration factor for earthworms | 562.1 | l.kgwwt-1 |  |
| Fraction of gut loading in worm | 0.1 | Kgdwt.kgdwt-1 | default |
| Additional factor to translate Tappl for 1 ha | 1E-04 | Ha.kg-1 | default |

Note: Following OEC ESD No.18 (page 133) a default area of a cube of 0.5 m x 0.5 m (0.25 m2) should be considered in the estimation of product’s quantity to be applied on spot application. However, following eCA indications and according to TAB ENV 154, 8.5 m2 must be considered as exposed area. Hence, taking into account the application rate of the product 15 ml/m2, a total amount of 127.5 mlis considered to be applied for an ant-nest area of 8.5 m2. As 4 applications are deemed for spot and the ant nest is deemed as spot application, 31.875 ml (127.5/4) is deemed as the amount applied per spot.

Following propan-2-ol’s AR, the substance is not considered of concern for secondary poisoning.

Calculations for Scenario 4

| **Resulting local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/campaign]** | | **Remarks** |
| Soil | **Permethrin** | **SoC** |  |
| 5.05E-04 | 3.03E-04 | None |

Other outputs obtained from EUSES 2.2.0 are:

|  |  |  |  |
| --- | --- | --- | --- |
| **PECs** | **Permethrin** | **SoC** | **Units** |
| Local concentration in soil (PECsoil) | 6.99E-08 | 4.19E-08 | Kg.kgwwt-1 |
| Local concentration in porewater (PECgw) | 1.47E-10 | 2.38E-07 | Kg.l-1 |
| Concentration in earthworm | 0.08134 | 0.187 | mg.kgwt earthworm-1 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA: This scenario has been calculated for both professionals and non-professionals. Although, emissions to the terrestrial and aquatic compartment are not expected when the product is applied by professionals, this scenario has been calculated to determine the risk for secondary poisoning.  There have been calculated the emissions for both, paved and unpaved surfaces. Direct emissions on unpaved surfaces is the same for both professional and non-professional users. For paved surfaces, the following scenarios have been calculated: terraces scenario for non-professionals and terraces scenario around buildings for professionals.   | **Input parameters for calculating the local emission** | | | | | --- | --- | --- | --- | | **Input** | **Value** | **Unit** | **Remarks** | | *Scenario 4:* *Outdoor – Spot application into ant’s nest* | | | | | Quantity of commercial product applied | 3 | G | According to efficacy tests (density 1 g/ml) | | Concentration of active substance in the product | 0.004 | - |  | | Concentration of the SoC | 0.0024 | - |  | | Fraction emitted to soil during application | 0.99 | - |  | | Number of nests treated per day (direct application) | 1 | - |  | | Number of nests treated per day (private houses) | 4 | - |  | | Number of nests treated per day (large buildings) | 67 |  |  | | Area exposed to insecticide (terrace) | 8.5 | m2 | Default | | Area exposed to insecticide (nest) | 0.2 | m2 | According to the efficacy test, 3 ml per nest (in 0,2 m2) | | Depth of exposed soil | 0.5 | m | Default | | Bulk density of soil | 1700 | Kgwwt. m-3 | Default | | Density of solid phase | 2500 | Kgwwt. m-3 | Default |   **Direct application:**   |  |  |  |  | | --- | --- | --- | --- | | **PECs** | **Permethrin** | **SoC** | **Units** | | Local concentration in soil (PECsoil) | 6.99E-08 | 3.35E-08 | Kg.kgwwt-1 | | Local concentration in porewater (PECgw) | 1.38E-1 | 1.91E+02 | µ.l-1 |   **Terrace scenario (private houses):**   |  |  |  |  | | --- | --- | --- | --- | | **PECs** | **Permethrin** | **SoC** | **Units** | | Local concentration in soil (PECsoil) | 6.58E-09 | 3.95E-09 | Kg.kgwwt-1 | | Local concentration in porewater (PECgw) | 1.38E-2 | 2.24E+01 | µ.l-1 |   **Large building (terraces around large building):**  As it is stated by the applicant, following endpoints ENV158 and ENV159 from TAB-ENV 2019, no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is intended to be applied outdoor by professional user on paved surfaces (not on bare soil) and in roof-covered areas, which cannot be affected by flooding and protected from rain fall or cleaning wash. This is one of the main intended outdoor applications of INSECTICIDA RTU PER ZNZ against ants so the emission from professional applications outdoors (Scenarios 4) should be considered at safe. ES CA agrees with the applicant about that this is a safe use but, emissions for scenario 4 have been calculated in order to assess the potential risk for secondary poisoning.   | **Resulting local emission to relevant environmental compartments (permethrin)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 4.85E-07 | None |  | **Resulting local emission to relevant environmental compartments (propan-2-ol)** | | | | --- | --- | --- | | **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** | | STP | 2.91E-07 | None | |

Scenario 5 - Outdoor – Spraying into voids/cavities of paved surfaces and roof-covered areas.

The product is intended to be used only on specific paved surfaces (crack and crevice, cavities…), in roof-covered areas and not on bare soil. Hence, the treated area cannot be affected by flooding, and is protected from rain fall or cleaning wash so emissions are unlikely to occur and according to TAB-ENV 158 (v.2.1) no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment when the product is applied by professional users. However, it is considered necessary to assess the environmental risk for general public application.

In addition, as it was done in the risk assessment before, primary/secondary poisoning according to ESD PT18 No.18 needs to be performed. According to new EUSES version (2.2.0), urban areas are not considered relevant for primary secondary poisoning exposure, so taken into account the label statement, no risk exposure should be expected for scenario 5 at urban treated areas which are paved and protected from the weather.

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario 5:* Outdoor – Spraying into voids/cavities of paved surfaces and roof-covered areas. Urban areas treated by general public. | | | |
| Application rate of biocidal product | 15 | mL/m² | Density of 1 g/ml is deemed |
| Concentration of active substance in the product | 0.004 | - |  |
| Concentration of the SoC | 0.0024 |  |  |
| Number of standard houses connected to the same STP | 2500 | - | Default (it should not be considered relevant because releases to STP must be deemed banned. |
| Number of emission days | 365 | d.yr-1 |  |
| Frequency of application in standard houses and large buildings | 1-2 | Times a year |  |
| Simultaneity factor for outdoor use of insecticide in standard houses | 2.042E-03 | - |  |
| Fraction emitted to soil during application on foundation | 0.3 | - |  |
| Fraction emitted to soil due to wash-off by rainfall | 0 | - | This value has been changed from the default value (0.5) due that the treated area must be protected from rainfall |
| Fraction emitted to soil during application on the soil around the house/building:   * emitted to treated area * emitted to untreated area | 0.99  4.2E-03 | -  - |  |
| Values deemed for standard houses: |  | - |  |
| Area of foundation treated per day | 25 | m2.d-1 | default |
| Area of soil treated per day | 26 | m2.d-1 | default |
| Area of untreated zone | 28 | m2.d-1 | default |

Note: Mixing and loading task is considered no covered for general public as the formulation is marketed as RTU for this type of user.

Calculations for Scenario 5

| **Resulting local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | | **Remarks** |
| **Non-professional use/ Standard houses** | |  |
| Permethrin | SoC |  |
| Wastewater | 0.01 | 6.13E-03 | None |

Other outputs obtained from EUSES 2.2.0 are:

* Derived from application emissions:

|  |  |  |
| --- | --- | --- |
| ***Local emissions*** | **Non-Professional users** | |
| **Standard houses** | |
| ***Permethrin*** | ***SoC*** |
| Local emission due to application on foundations [Kg.d-1] | 4.5E-04 | 2.7E-04 |
| Local emission due to application on soil, treated area [Kg.d-1] | 1.54E-03 | 9.27E-04 |
| Local emission due to application on soil, untreated area [Kg.d-1] | 7.06E-06 | 4.23E-06 |
| Local emission due to wash-off (from foundations) [Kg.d-1] | 0 | 0 |

Note: As it was mentioned before fraction emitted to soil due to wash-off by rainfall is considered 0 according to intended use of the formulation. Hence, the local concentration in soil is due to the application.

|  |
| --- |
| ES CA: this use has not been reviewed since this use has not been supported by efficacy studies. |

Fate and distribution in exposed environmental compartments

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Fresh-water** | **Freshwater sediment** | **Sea-water** | **Seawater sediment** | **STP** | **Air** | **Soil** | **Ground-water** | **Secondary poisoning** |
| Scenario 1 | No\* | No\* | No | No | No\* | No | Yes | Yes | No |
| Scenario 2 | No\* | No\* | No | No | No\* | No | Yes | Yes | No |
| Scenario 3 | No\* | No\* | No | No | No\* | No | Yes | Yes | No |
| Scenario 4 | No | No | No | No | No | No | Yes | Yes | Yes |
| Scenario 5 | No\* | No\* | No | No | No\* | No | Yes | Yes | Yes |

\* Although due to product’s application these compartments should not be deemed of concern, the use of default emission models consider its potential emission so they have been considered in the current assessment as worst and unreal cases.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA does not agree with the fate and distribution in exposed environmental compartments, in the table below ES CA indicates the relevant receiving compartments based on the exposure pathway.  Fate and distribution in exposed environmental compartments   | **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Scenario** | **Fresh-water** | **Freshwater sediment** | **Sea-water** | **Seawater sediment** | **STP** | **Air** | **Soil** | **Ground-water** | **Secondary poisoning** | | Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes | No | | Scenario 2 | Yes | Yes | No | No | Yes | No | Yes | Yes | No | | Scenario 3 | Yes | Yes | No | No | Yes | No | Yes | Yes | No | | Scenario 4 | No | No | No | No | No | No | Yes | Yes | Yes | |

| **Input parameters (only set values) for calculating the fate and distribution in the environment of Permethrin** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 391.29 | g/mol |  |
| Melting point | 35 | °C |  |
| Boiling point | 305 | °C |  |
| Vapour pressure (at XC) | 2.155E-6 | Pa |  |
| Water solubility (at X°C) | 0.18 | mg/l | From TAGROS (0.00495 mg/L is set for another a.s. supplier) |
| Log Octanol/water partition coefficient | 4.67 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 26930 | l/kg | arithmetic mean, n=9 |
| Henry’s Law Constant (at X C)*[if measured data available]* | 4.6E-3 | Pa/m3/mol |  |
| Biodegradability | *Not Ready biodegradable* |  |  |
| DT50 for degradation in soil | 106 | d (at 12ºC) | geometric mean, n=5 |
| DT50 for degradation in air | 0.701 | D | geometric mean, n=5 |

| **Input parameters (only set values) for calculating the fate and distribution in the environment for permethrin’s metabolites** | | | | |
| --- | --- | --- | --- | --- |
| **Input** | **DCVA** | **PBA** | **Unit** | **Remarks** |
| Molecular weight | 267.11\* | 214.22\* | g/mol |  |
| Percentage metabolite in soil | 11.3 | 15 | % |  |
| Percentage metabolite in water | 62.6 | 28.8 | % |  |
| Percentage metabolite in sediment | 21.7 | 16.4 | % |  |

\* Obtained from EPIwin software

In order to estimate potential environmental exposure to the major metabolites, the percentage of each metabolite established in the AR (see table below) has been assumed. These PECs represents an extreme worse-case estimate for surface water’s, sediment’s or soil’s exposure.

PECs have been calculated only for DCVA and PBA, as no data are available for PB alcohol metabolite. The estimation of metabolites concentration in groundwater is based on initial concentration in soil as later by leaching process arrives to groundwater compartment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  **Active substance: Permethrin**   |  |  |  |  | | --- | --- | --- | --- | | **Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)** | | | | | Input | Value | | Unit | | **Permethrin** | | | | | BCF fish | 20700 | L.kg-1 | | | BCF eartworm | 23.8 | L.kg-1 | | | BMF fish | 2 | - | | | **Metabolites** | | | | | **DCVA** | | | | | Molecular weight | 209.07 | | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 175 | | days | | Koc | 93.2 | | L.kg-1 | | **PBA** | | | | | Molecular weight | 214.22 | | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 2.5 | | days | | Koc | 141.2 | | L.kg-1 |  |  |  | | --- | --- | | **Calculated fate and distribution of Permethrin in the STP (EUSES model 2.1)** | | | Compartment | Percentage [%] | |  | | Air | 0 | | Water | 26.19 | | Sludge | 73.81 | | Degraded in STP | 0 |   **Calculation method of metabolites emissions**  To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc value has been considered. Following the releases to STP, concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water was further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic compartment. |

| **Input parameters (only set values) for calculating the fate and distribution in the environment of propan-2-ol as SoC** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 60.09 | g/mol |  |
| Melting point | -89.5 | °C |  |
| Boiling point | 82.5 | °C |  |
| Vapour pressure (at 25ºC) | 5780 | Pa |  |
| Water solubility (at X°C) | Miscible in water | mg/l |  |
| Log Octanol/water partition coefficient | 0.05 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 3.3 | l/kg |  |
| Henry’s Law Constant (at X C) | 0.8 | Pa/m3/mol |  |
| Biodegradability | *Ready biodegradable* |  |  |
| DT50 for degradation in soil | - | d (at 12ºC) |  |
| DT50 for degradation in air | - | D |  |

Seawater and sea sediment are not considered relevant in the assessment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA agrees with the input parameter for propan-2-ol adding the following:   | **Input parameters (only set values) for calculating the fate and distribution in the environment of propan-2-ol as SoC** | | | | | --- | --- | --- | --- | | **Input** | **Value** | **Unit** | **Remarks** | | DT50 for degradation in soil | 30 | d (at 12ºC) |  | |

Calculated PEC values

* Permethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | |
| **Scenarios** | | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/m3] |
| Scenario 1 | Professional | 2.35E-04 | 5.91E-06 | 3.46E-03 | 6.26E-04 | 8.53E-07 | 4.10E-08 |
| Non professional | 1.58E-04 | 3.98E-06 | 2.33E-03 | 4.22E-04 | 5.74E-07 | 3.70E-08 |
| Scenario 2 (Non-professional) | | 1.58E-04 | 3.98E-06 | 2.33E-03 | 4.22E-04 | 5.74E-07 | 3.7E-08 |
| Scenario 3 (Non-professional) | | 3.66E-05 | 3.51E-06 | 2.06E-03 | 3.73E-04 | 5.08E-07 | 5.99E-08 |
| Scenario 4 (direct emission due to a campaign) | | - | - | - | 6.99E-02 | 1.47E-04 | - |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 1.34E-03 | 1.29E-04 | 0.075 | 0.014 | 1.85E-05 | 3.99E-11 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  Permethrin:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | | | | | **Scenarios** | | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** | | [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/m3] | | Scenario 1 (indoor professionals) |  | 5,77E-04 | 5,55E-05 | 3,25E-02 | 6,06E-03 | 8,25E-03 | - | | Scenario 2 (indoor non-professionals) |  | 1,27E-03 | 1,22E-04 | 7,14E-02 | 1,33E-02 | 1,81E-02 | - | | Scenario 3 (non-washable textile) |  | 2,27E-06 | 2,18E-07 | 1,28E-04 | 2,38E-05 | 3,24E-05 | - | | Scenario 4 (Nest) | Direct application |  |  |  | 6.99E-02 | 1.38E-01 |  | | House (terraces) |  |  |  | 6,58E-03 | 1,38E-02 |  | | Large buildings (terraces) | 6,35E-08 | 6,11E-09 | 3,58E-06 | 6,67E-07 | 9,07E-07 | - | |

* Permethrin’s metabolites

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for Permethrin’s metabolites** | | | | | | | | | |
|  | | **DCVA** | | | | **PBA** | | | |
| **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] |
| Scenario 1 | (P) | 3.70E-06 | 7.51E-04 | 7.07E-05 | 9.64E-08 | 1.70E-06 | 5.67E-04 | 9.39E-05 | 1.28E-07 |
| (n-P) | 2.49E-06 | 5.06E-04 | 4.77E-05 | 6.49E-08 | 1.15E-06 | 3.82E-04 | 6.33E-05 | 8.61E-08 |
| Scenario 2 (n-P) | | 2.49E-06 | 5.06E-04 | 4.77E-05 | 6.49E-08 | 1.15E-06 | 3.82E-04 | 6.33E-05 | 8.61E-08 |
| Scenario 3 (n-P) | | 2.20E-06 | 4.47E-04 | 4.21E-05 | 5.74E-08 | 1.01E-06 | 3.38E-04 | 5.60E-05 | 7.62E-08 |
| Scenario 4 (direct emission due to a campaign) | | - | - | 7.90E-03 | 1.66E-05 | - | - | 1.05E-02 | 2.21E-05 |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 8.08E-05 | 1.63E-02 | 1.58E-03 | 2.09E-06 | 3.72E-05 | 1.23E-02 | 2.10E-03 | 2.78E-06 |

(P) Professional; (n-P) non-Professional

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| ES CA:  Permethrin metabolites:   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Summary table on calculated PEC values for Permethrin’s metabolites** | | | | | | | | | |  | | **DCVA** | | | | **PBA** | | | | | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [µ  g/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | | Scenario 1 (indoor professionals) | | 1,86E-05 | 3,77E-03 | 3,66E-04 | 1,34E-01 | 8,76E-06 | 2,92E-03 |  |  | | Scenario 2 (indoor non-professionals) | | 4,07E-05 | 8,27E-03 | 8,02E-04 | 2,94E-01 | 1,92E-05 | 6,42E-03 |  |  | | Scenario 3 (non-washable textile) | | 7,29E-08 | 1,48E-05 | 1,44E-06 | 5,28E-04 | 3,44E-08 | 1,15E-05 |  |  | | Scenario 4 (Nest) | Direct application |  |  | 3,37E-03 | 1,91 | 9,64E-10 | 3,22E-07 |  |  | | House (terraces) |  |  | 3,97E-04 | 2,25E-01 | 2,79E-05 | 9,31E-03 |  |  | | Large buildings (terraces) | 2,04E-09 | 4,15E-07 | 4,02E-08 | 1,48E-05 | 4,43E-05 | 1,48E-02 |  |  | |

* SoC

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | |
| **Scenarios** | | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/m3] |
| Scenario 1 | Professional | 1.41E-04 | 1.13E-06 | 9.65E-07 | 1.04E-07 | 1.75E-07 | 2.46E-08 |
| Non professional | 9.48E-05 | 7.60E-07 | 6.50E-07 | 7.12E-08 | 1.23E-07 | 2.22E-08 |
| Scenario 2 (Non-professional) | | 9.48E-05 | 7.60E-07 | 6.50E-07 | 7.12E-08 | 1.23E-07 | 2.22E-08 |
| Scenario 3 (Non-professional) | | 8.38E-05 | 6.72E-07 | 5.74E-07 | 6.56E-08 | 1.24E-07 | 3.60E-08 |
| Scenario 4 (direct emission due to a campaign) | | - | - | - | 4.19E-02 | 2.38E-04 | - |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 2.46E-04 | 2.46E-05 | 2.10E-05 | 2.18E-06 | 3.32E-06 | 1.80E-11 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| ES CA:  Propan-2-ol:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | | | | | **Scenarios** | | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** | | [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/l] | [mg/m3] | | Scenario 1 (indoor professionals) | | 3.46E-04 | 3.46E-05 | 2.96E-05 | 2.15E-03 | 2.95 | - | | Scenario 2 (indoor non-professionals) | | 7.60E-04 | 7.60E-05 | 6.49E-05 | 4.71E-03 | 6.47 | - | | Scenario 3 (non-washable textile) | | 1,36E-06 | 1,36E-07 | 1,16E-07 | 8,43E-06 | 1,16E-02 | - | | Scenario 4 (Nest) | Direct application |  |  |  | 3,35E-02 | 1,91E+02 |  | | House (terraces) |  |  |  | 3,95E-03 | 2,24E+01 |  | | Large buildings (terraces) | 3,81E-08 | 3,81E-09 | 3,26E-09 | 2,36E-07 | 3,24E-04 | - | |

Primary and secondary poisoning

Primary poisoning

According to the ESD for PT 18 primary poisoning is only a matter of concern if insecticides are applied together with food attractants. As this is not the intended use of the product, the assessment in not required.

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| ES CA agrees with the applicant |

Secondary poisoning

The log octanol/water partition coefficient of permethrin (4.67) is above the trigged value of 3 suggesting that the substance may have significant potential for bioconcentration in both aquatic and terrestrial biota. However, as it was mentioned before, aquatic compartment must never be reached by PERMETHRIN 0.4% RTU residues when the label’s claim are followed.

Scenarios 1 and 2 (where the cleaning of mixing/loading by professional users is deemed to be developed by wet cleaning methods) and Scenario 3 (use in non-washable textile) disclose a potential emission to wastewater due to the use of reference scenarios. These scenarios considers by default an emission to wastewater by wet cleaning treatment, which is not the intended use of the product. Therefore, in order to develop a realistic assessment, only secondary poisoning due to soil compartment contamination should be developed for primary and secondary poisoning. On the other hand, the risk derived from outdoor scenarios 4 and 5 are estimated for each potential specie considered in the ESD PT18 by ECHA’s Excel spreadsheet for ESD PT18. Initially, secondary exposure by Scenario 5 should be deemed irrelevant as the product is used in urban areas not connected to STP where the emission of product’s residues should be out of animal’s reach.

As it was mentioned before, propan-2-ol has a low BCF and it is not expected to accumulate in the environment. Therefore, the risk of secondary poisoning by propanol-2-ol is assumed to be negligible via ingestion of contaminated food by birds or mammals. In view of that, no secondary poisoning exposure is estimated for this substance and the potential risk for secondary poisoning is focused in the active substance permethrin.

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| ESCA agrees with the applicant but secondary poisoning has been recalculated with the new PEC values calculated. |

* ***Scenarios 1, 2 and 3***

| **Summary table on secondary poisoning** | | | |
| --- | --- | --- | --- |
| **Scenario** | | **Concentration** | **PEC oral predator** |
| **Scenario: Application, aquatic compartment** | | **PECsw**  **(mg/L)** | **(mg/kg wet fish)** |
| Scenario 1 | (P) | 5.91E-06 | 9.03E-03 |
| (n-P) | 5.69E-06 | 7.40E-03 |
| Scenario 2 (n-P) | | 3.98E-06 | 7.40E-03 |
| Scenario 3 | | 3.51E-06 | 6.54E-03 |
| **Scenario: Application, terrestrial compartment** | | **PECsoil – 180 day (mg/kg wwt)** | **(mg/kg wet earthworm)** |
| Scenario 1 | (P) | 4.05E-04 | 2.36E-04 |
| (n-P) | 2.73E-04 | 1.59E-04 |
| Scenario 2 (n-P) | | 2.73E-04 | 1.59E-04 |
| Scenario 3 | | 2.42E-04 | 1.41E-04 |

(P) Professional; (n-P) non-Professional

* ***Scenario 4:***

The following table summarizes the estimated theoretical exposure (ETE) for secondary poisoning for each indicator species obtained from EUES 2.2.0:

| **Representative specie** | **ETE (mg.kg-1.d-1)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Insectivorous** | | **Herbivorous** | | **Mammals eating worms** | | **Birds eating worms** | |
| Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure | Short-term exposure |
| Small insectivorous mammal 1 (pipistrelle) – 7.6 g \* | 8.05E-04 | 2.41E-04 | - | - | - | - | - | - |
| Small insectivorous mammal 2 (mole) – 85 g | - | - | - | - | 0.234 | 0.234 | - | - |
| Medium insectivorous mammal – 1100 g – hedgehog \* | 1.84E-04 | 5.51E-05 | - | - | 0.111 | 0.111 | - | - |
| Large insectivorous mammal – 10100 g (badger) \* | 9.57E-05 | 2.86E-05 | - | - | 0.058 | 0.058 | - | - |
| Medium herbivorous mammal – 1500 g (rabbit) \* | - | - | 1.89E-03 | 7.13E-04 | - | - | - | - |
| Small Insectivorous bird (Tree sparrow, robin) – 22 g | 3.57E-03 | 1.64E-03 | - | - | - | - | - | - |
| Medium Insectivorous bird – 113 g (blackbird) \* | 9.06E-04 | 2.71E-04 | - | - | - | - | - | - |
| Omnivorous bird – 225 g (Black-billed magpie) \* | 4.83E-04 | 1.45E-04 | - | - | - | - | 0.291 | 0.291 |

\*Indicator species considered as relevant for lawn/garden.

* ***Scenario 5:***

No secondary poisoning is foreseen from general public application outdoor against crawling insects at urban areas. In order to assess a worst-case secondary poisoning has been assessed by considering outdoor application against crawling insects at rural areas. The table below shows the estimated theoretical exposure (ETE) for secondary poisoning for each indicator species obtained from EUES 2.2.0 considering default values for the sub-scenario “foundations and soil around the buildings”.

| **Representative specie** | **ETE (mg.kg-1.d-1)** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Insectivorous** | | **Herbivorous** | | **Mammals eating worms** | | **Birds eating worms** | |
| Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure (treated/untreated area) | Short-term exposure | Acute exposure (treated/untreated area) | Short-term exposure |
| Small insectivorous mammal 1 (pipistrelle) – 7.6 g \* | 6.61E-04 | 2.93E-04 | - | - | - | - | - | - |
| Small insectivorous mammal 2 (mole) – 85 g | - | - | - | - | 0.076 / 2.48E-04 | 0.104 | - | - |
| Medium insectivorous mammal – 1100 g – hedgehog \* | 1.51E-04 | 6.7E-05 | - | - | 0.036 / 1.17E-04 | 0.049 | - | - |
| Large insectivorous mammal – 10100 g (badger) \* | 7.86E-05 | 3.49E-05 | - | - | 0.019 / 6.1E-05 | 0.026 | - | - |
| Medium herbivorous mammal – 1500 g (rabbit) \* | - | - | 1.55E-03 | 8.68E-04 | - | - | - | - |
| Small Insectivorous bird (Tree sparrow, robin) – 22 g | 2.94E-03 | 1.99E-03 | - | - | - | - | - | - |
| Medium Insectivorous bird – 113 g (blackbird) \* | 7.45E-04 | 3.3E-04 | - | - | - | - | - | - |
| Omnivorous bird – 225 g (Black-billed magpie) \* | 3.97E-04 | 1.76E-04 | - | - | - | - | 0.094 / 3.08E-04 | 0.129 |

\*Indicator species considered as relevant for lawn/garden.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  Scenarios 1 and Scenario 4 (direct emission) have been chosen as worst cases to calculate the secondary poisoning for calculate the food of fish-eating predators and the concentration of the a.s. in earthworms, respectively.  For secondary poisoning, the concentration in surface water is used as input for calculating the concentration of Permethrin and DCVA in food (fish) of fish-eating predators (PECoral, predator,aquatic) according to equation (95) of the Guidance on BPR IV/B+C (2017). An estimated BCF fish of 20700 L/kgwwt fish and a BMF of 2 (Kow =4.67) are used for calculations.  For the calculation of the concentration of a.s. in earthworms (Cearthworm = PECoral, predator according equation 99 of the Guidance on BPR IV/B+C, 2017), equation 103c of the guidance is used considering PECsoil averaged over a period of 180 days. Therefore, a BCF earthworm of 23.8 L/kgwwt, earthworm and the concentrations in pore water have been used as input parameter to calculate the following PECoral, predator for the terrestrial and aquatic compartment.   |  |  |  | | --- | --- | --- | | **Summary table on secondary poisoning** | | | |  | **Permethrin** | **DCVA** | | **Aquatic food chain** | **PEC oral,predator,aquatic (mg/kg)** | | | Scenario 1 |  |  | |  | 5,04E+00 | 1,69E+00 | | **Terrestrial food chain** | **PEC oral.predator.terrestrial (mg/kg)** | | | Scenario 4 (direct emissions) |  |  | |  | 8,21E-03 | 1,79E-03 | |

#### Risk characterisation

Risk characterisation for environment was conducted by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC) according to the guidance in Technical Guidance Document on Risk Assessment (TGD, 2003, Part II). If the predicted environmental concentration is greater than the predicted no-effect concentration, i.e. the PEC/PNEC ratio is greater than one, the substance is “of concern” and further action has to be taken.

Even if the aquatic metabolites DCVA and PBA are far less toxic to aquatic organism than the parent active ingredient, the risk characterization in water, sediment and soil has been performed for the sake of completeness.

No assessment on PB alcohol can be performed as no data on PNEC value are available.

Atmosphere

Conclusion:

The formulation type of the product (AL), its application mode, the low vapour pressure (Pure) and Henry’s Law constant of the active substance permethrin (K = 4.6E-03 Pa.m3.mol‐1) indicate that there will be negligible loss of permethrin to the atmosphere. On the other hand, the vapour pressure of propan-2-ol at 25°C is 57.8 hPa and direct evaporation is expected, consequently.

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| ESCA agrees with the conclusion of the applicant. |

Sewage treatment plant (STP)

The risk characterization for microorganisms in STPs compartment is carried out by comparing the PECSTP with the PNECmicroorganisms. The PEC/PNEC ratio has been calculated and the results are shown in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | |
| **Scenarios** | | **PEC/PNECSTP** | |
| **Permethrin** | **SoC** |
| Scenario 1 | Professional | 0.047 | 1.41E-05 |
| Non professional | 0.032 | 9.48E-06 |
| Scenario 2 (Non-professional) | | 0.03 | 9.48E-06 |
| Scenario 3 (Non-professional) | | 0.01 | 8.38E-06 |
| Scenario 4 (direct emission due to a campaign) | | - | - |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 0.27 | 2.46E-05 |

Conclusion: According to the obtained PEC/PNEC ratios, the use of PERMETHRIN 0.4% RTU is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between the predicted environmental concentration and the predicted no-effect concentration is lower than 1.

It is important to bear in mind that although this assessment discloses potential emission to STP from Scenarios 1, 2 and 3, the right intended use of the product must not produce any emission to STP because the product is only intended to be used on surfaces not connected to STP and not to be washed with wet methods so any emission to STP and aquatic compartment will be avoided.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA: Values recalculated by ES CA,  Permethrin and propan-2-ol:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table** | | | | | **Scenarios** | | **PEC/PNECSTP** | | | **Permethrin** | **SoC (Propan-2-ol)** | | Scenario 1 (indoor professionals) | | 1,17E-01 | 3,46E-05 | | Scenario 2 (indoor non-professionals) | | 2,56E-01 | 7,60E-05 | | Scenario 3 (non-washable textile) | | 4,59E-04 | 1,36E-07 | | Scenario 4 (Nest) | Direct application |  |  | | House (terraces) |  |  | | Large buildings (terraces) | 1,28E-05 | 3,81E-09 |   Conclusions:  Same conclusions than those indicated by the applicant: According to the obtained PEC/PNEC ratios for the assessed scenarios, the use of INSECTICIDA RTU PER ZNZ is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between PEC/PNEC is lower than 1. |

Aquatic compartment

The risk characterization for aquatic compartment is carried out by comparing the PECsw with the PNECsw.

The risk characterization for sediment compartment is carried out by comparing the PECsed with the PNECsed.

Seawater and sea sediment compartments have not been deemed relevant in the current assessment. The PEC/PNEC ratio has been calculated and the results are shown in the tables below:

* For **Permethrin**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | | |
| **Scenarios** | | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | (P) | **12.574** | **15.965** | Not relevant | Not relevant |
| (n-P) | **8.464** | **10.747** | Not relevant | Not relevant |
| Scenario 2 (n-P) | | **8.464** | **10.747** | Not relevant | Not relevant |
| Scenario 3 | | **7.48** | **9.49** | Not relevant | Not relevant |
| Scenario 4 | | **-** | **-** | Not relevant | Not relevant |
| Scenario 5 (n-P) | | **273.61** | **347.41** | Not relevant | Not relevant |

Values on bold are above the trigger value and that would be deemed of concern in the case the label instructions are not followed. (P) Professional; (n-P) non-Professional.

* For Propan-2-ol as **SoC**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | | |
| **Scenarios** | | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | (P) | 4.01E-07 | 4.00E-07 | Not relevant | Not relevant |
| (n-P) | 2.70E-07 | 2.70E-07 | Not relevant | Not relevant |
| Scenario 2 (n-P) | | 2.70E-07 | 2.70E-07 | Not relevant | Not relevant |
| Scenario 3 | | 2.38E-07 | 2.38E-07 | Not relevant | Not relevant |
| Scenario 4 | | - | - | Not relevant | Not relevant |
| Scenario 5 (n-P) | | 8.72E-06 | 8.71E-06 | Not relevant | Not relevant |

Values on bold are above the trigger value and that would be deemed of concern in the case the label instructions are not followed. (P) Professional; (n-P) non-Professional.

Conclusion for aquatic compartment:

According to the intended use of PERMETHRIN 0.4% RTU, no potential emission from any scenario to aquatic compartment should be foreseen. However, the assessment of scenarios 1, 2 and 3 considers a potential emission from application and cleaning areas of treated premises by default. Under this default-assumption, taking into account permethrin’s outputs, all scenarios 1, 2, 3 and 5 would be unacceptable risk for aquatic compartment. On the other hand, no risk is expected from Propan-2-ol as SoC for the aquatic compartment.

The following risk mitigation measure is proposed in order to avoid any emission to wastewater during application:

*- Do not apply in areas connected or suspected to be connected to STP*

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  Permethrin and propan-2-ol:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table** | | | | | | | **Scenarios** | | **Permethrin** | | **Propan-2-ol** | | | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECwater** | **PEC/PNECsed** | | Scenario 1 (indoor professionals) | | **1,18E+02** | **1,50E+02** | 3,46E-05 | 1,24E-05 | | Scenario 2 (indoor non-professionals) | | **2,59E+02** | **3,29E+02** | 7,60E-05 | 2,72E-05 | | Scenario 3 (non-washable textile) | | 4,64E-01 | 5,89E-01 | 1,36E-07 | 4,86E-08 | | Scenario 4 (Nest) | Direct application |  |  |  |  | | House (terraces) |  |  |  |  | | Large buildings (terraces) | 1,30E-02 | 1,65E-02 | 1,36E-09 |  |   Permethrin metabolites:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table** | | | | | | | **Scenarios** | | **DCVA** | | **PBA** | | | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECwater** | **PEC/PNECsed** | | Scenario 1 (indoor professionals) | | 1,24E-03 | 3,14E-01 | 8,76E-04 | 3,25E-01 | | Scenario 2 (indoor non-professionals) | | 2,71E-03 | 6,89E-01 | 1,92E-03 | 7,13E-01 | | Scenario 3 (non-washable textile) | | 4,86E-06 | 1,23E-03 | 3,44E-06 | 1,28E-03 | | Scenario 4 (Nest) | Direct application |  |  |  |  | | House (terraces) |  |  |  |  | | Large buildings (terraces) | 1,36E-07 | 3,46E-05 | 9,64E-08 | 9,31E-03 |   Conclusion for aquatic compartment:  The assessment of scenarios 1 and 2 (indoor use, professional and non-professional) showed an unacceptable risk for surface water and sediment compartments. However, this risk can be reduced to acceptable levels or prevented by imposing the following RMM: The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects. Therefore, these uses are acceptable.  Following the label instruction for Use 3 (non-washable textile surfaces non-professionals user): “The excess of the product on non-treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste“ no risk for the aquatic compartment is expected. |

Terrestrial compartment

The risk characterization for terrestrial compartment was carried out by comparing the PECsoil with the PNECsoil.

The PEC/PNEC ratio has been calculated and the results are shown in the table below.

| **Calculated PEC/PNEC values for soil** | | | |
| --- | --- | --- | --- |
| **Scenarios** | | **PECsoil/PNECsoil** | |
| **Permethrin** | **SoC** |
| Scenario 1 | Professional | 3.58E-03 | 2.10E-07 |
| Non professional | 2.41E-03 | 1.44E-07 |
| Scenario 2 (Non-professional) | | 2.41E-03 | 1.44E-07 |
| Scenario 3 (Non-professional) | | 2.13E-03 | 1.32E-07 |
| Scenario 4 (direct emission due to a campaign) | | 0.4 | 0.14 |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 0.08 | 4.40E-06 |

(P) Professional; (n-P) non-Professional.

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERMETHRIN 0.4% RTU is safe for the soil compartment at all scenarios, since the PECsoil/PNECsoil ratio is lower than 1.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table** | | | | | **Scenarios** | | **PEC/PNECSOIL** | | | **Permethrin** | **SoC (Propan-2-ol)** | | Scenario 1 (indoor professionals) | | 3,46E-02 | 4,29E-03 | | Scenario 2 (indoor non-professionals) | | 7,59E-02 | 9,41E-03 | | Scenario 3 (non-washable textile) | | 1,36E-04 | 1,69E-05 | | Scenario 4 (Nest) | Direct application | 3,99E-01 | 6,71E-02 | | House (terraces) | 3,76E-02 | 7,89E-03 | | Large buildings (terraces) | 3,81E-06 | 4,72E-07 |  |  |  |  |  | | --- | --- | --- | --- | | **Summary table** | | | | | **Scenarios** | | **PEC/PNECSOIL** | | | **DCVA** | **PBA** | | Scenario 1 (indoor professionals) | | 3,66E-04 |  | | Scenario 2 (indoor non-professionals) | | 8,02E-04 |  | | Scenario 3 (non-washable textile) | | 1,44E-06 |  | | Scenario 4 (Nest) | Direct application | 3,37E-03 |  | | House (terraces) | 3,97E-04 |  | | Large buildings (terraces) | 4,02E-08 |  | |  |  |  |   Conclusion: ESCA agrees with the conclusion on the applicant. The use of INSECTICIDA RTU PER ZNZ is safe for the soil compartment at all scenarios, since the PECsoil/PNECsoil ratio is lower than 1. |

Groundwater

| **Calculated PEC/PNEC values for groundwater** | | | |
| --- | --- | --- | --- |
| **Scenarios** | | **PECgw/trigger value** | |
| **Permethrin** | **SoC** |
| Scenario 1 | Professional | 9E-03 | 0.002 |
| Non professional | 6E-03 | 0.001 |
| Scenario 2 (Non-professional) | | 6E-03 | 0.001 |
| Scenario 3 (Non-professional) | | 5.08E-03 | 1.24E-03 |
| Scenario 4 (direct emission due to a campaign) | | **1.47** | **2.38** |
| Scenario 5 (crack/crevice outdoor cover to weather by non-professional) | | 0.19 | 0.03 |

Values on bold are above the trigger value (1E-04 mg/l) and deemed of concern. (P) Professional; (n-P) non-Professional.

Conclusion: According to the obtained PECgw, the use of PERMETHRIN 0.4% RTU is safe for the groundwater compartment at scenarios 1, 2, 3 and 5, since the PECgw is lower than the trigger value for drinking water of 0.1 µ/L.

Scenario 4 discloses values above the trigger value for permethrin and propan-2-ol, but this values must be deemed as an overestimation because the application is only local concentration and the treated soil must not be used for arable land and should not be exposed to water.

PECgw was calculated using FOCUS PEARL 4.4.4. and considering TAB ENV 157 with the following assumptions:

- Number of houses treated per hectare: 16 houses without considering Fsim (since already taken into account by the number of applications within a period of time). As 127.5 ml of product is applied per nest, 2.04 kg/ha (127.5 ml/house x 16house/ha) is considered emitted over the year as worst case.

- Dates of application: those included in the ESD for PT 8 – Supplement to Appendix 4 (paragraph 594 c, p.178); The application scheme considers that 10 applications takes place over the year (10.01, 15.02, 24.03, 29.04, 05.06, 11.07, 17.08, 22.09, 29.10 and 04.12), and amount of 0.204 kg/ha is deemed in each application.

- Crops to be used: grass/alfalfa.

Only private houses in rural areas should be looked at

Taking into account the concentration of each substance and potential metabolite, the following application rates have been considered in the Tier 2 groundwater exposure assessment:

App\_rate\_Permethrin: 8.04E-04 kg application /ha

App\_rate\_SoC: 4.896E-04 kg application /ha

The appl\_rates before and the following chemical parameters are used for FOCUS PEARL simulations:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Parameter** | **Value** | | | | **Unit** | **Origin** |
| **Permethrin** | **DCVA\*** | **PBA\*** | **SoC** |
| Molar mass | 391.29 | 267.11 | 214.22 | 60.09 | [g.mol-1] | S |
| Solubility in water (at test temperature) | 0.18 | 0.18(1) | 0.18(1) | 1E+05(3) | [mg.L-1] | S |
| Molar enthalpy of dissolution | 27 | 27 | 27 | 27 | [kJ.mol-1] | D |
| Vapour pressure (at test temperature) | 2.15E-06 | 2.15E-06(1) | 2.15E-06(1) | 5780 | [Pa] | S |
| Molar enthalpy of vaporisation | 95 | 95 | 95 | 95 | [kJ.mol-1] | D |
| Diffusion coefficient in water | 4.3E-05 | 4.3E-05 | 4.3E-05 | 4.3E-05 | [m2.d-1] | D |
| Gas diffusion coefficient | 0.43 | 0.43 | 0.43 | 0.43 | [m2.d-1] | D |
| Reference temperature to degradation, vaporization and dissolution | 20 | 20 | 20 | 20 | [ºC] | D |
| Exponent for the effect of liquid (degradation moisture relationship) | 0.7 | 0.7 | 0.7 | 0.7 | [-] | D |
| Sorption to soil organic carbon (Koc or Kom) (Kom = Koc / 1.724) | 73,441 | 93.2 | 141.2 | 3.3 | [dm3.kg-1] | S |
| Exponent of the Freundlich-Isotherm (1/n) | 0.9 | 0.9 | 0.9 | 0.9 | [-] | D/S |
| DT50 (20°C) | 106 | 175(2) | 2(2) | 15 (4) | [d] | S |
| Arrhenius activation energy | 65.4 | 65.4 | 65.4 | 65.4 | [kJ.mol-1] | D |
| Plant uptake factor | 0 | 0 | 0 | 0 | [-] | D |

\* 11.3% and 15% are the percentage of DCAV and PBA metabolites considered from parent permethrin concentration for soil compartment and used in FOCUS.

(1) values considered from the parent compound as worst-case.

(2) values considered as worse cases according to permethrin’s CAR.

(3) As the substance in deemed miscible with water, this value has been chosen as worst case.

(4) no data is available in propan-2-ol’s CAR. Due of that, following Guidance on the BPR:Volume IV Part B Risk Assessment (active substances) Version 1.0 April 2015, a value <16 days should be considered as DT50 for substances considered as “readily biodegradable”. As worst case 15 d was used in FOCUS to estimate the PECgw.

Outputs below show the predicted 80th concentrations for Permethrin in groundwater:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FOCUS Scenarios** | | | | |
| ***Location*** | **Concentration closest to the 80th percentile [µg.L-1]** | | | |
| **Permethrin** | **DCVA** | **PBA** | **SoC** |
| **Châteaudun** | <0.01 | 0.000069 | <0.01 | 0.05545 |
| **Hamburg** | <0.01 | 0.000328 | <0.01 | **0.177225** |
| **Jokioinen** | <0.01 | 0.000027 | <0.01 | <0.01 |
| **Kremsmünster** | <0.01 | 0.000138 | <0.01 | 0.070222 |
| **Okehampton** | <0.01 | 0.000292 | <0.01 | **0.111604** |
| **Piacenza** | <0.01 | 0.000282 | <0.01 | 0.071421 |
| **Porto** | <0.01 | 0.000115 | <0.01 | 0.059932 |
| **Sevilla** | <0.01 | 0.000002 | <0.01 | 0.029432 |
| **Thiva** | <0.01 | 0.000021 | <0.01 | 0.020826 |

\* Values on bold are above the trigger value

From the results it can be seen that the average concentration of Permethrin and its metabolites is closest to the 80th percentile is 0.00 µg·L-1 and thus the predicted concentrations in groundwater are significantly below the threshold criteria of 0.1 µg·L-1 for all locations. Concentrations of Propan-2-ol in groundwater are above the trigger value at two locations Hamburg and Okehampton but these amounts must be taken with caution because as it was mentioned before according to propan-2-ol’s CAR no DT50 value is available in soil so the used DT50 value (15 days) may be deemed an overestimation. In addition, following its classification and labelling according to Regulation (EC) No 1272/2008, this substance is not classified of concern for the environment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ESCA:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | **Scenarios** | | **PECGW (µg/L)** | | | **Permethrin** | **SoC** | | Scenario 1 (indoor professionals) | | 8,25E-03 | **2,95E+00** | | Scenario 2 (indoor non-professionals) | | 1,81E-02 | **6,47E+00** | | Scenario 3 (non-washable textile) | | 3,24E-05 | **1,16E-02** | | Scenario 4 (Nest) | Direct application | **1,18E-01** | **1,91E+02** | | House (terraces) | 1,38E-02 | **2,24E+01** | | Large buildings (terraces) | 9,07E-07 | **3,24E-04** |   Permethrin: Predicted environmental concentration in pore water for Scenario 4 (direct application) is > 0.1 µg/L. According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L. The calculated pore water concentration for Permethrin does not comply with this criterion. Therefore, an exposure refinement should be conducted using FOCUS PEARL 4.4.4.  IPA: Regards Propan-2-ol, the concentration is greater than the drinking water threshold trigger value of 0.1 µg/ L for all of scenarios assessed. Following discussions at WG-VII-2018 it was agreed that the following argument forms an acceptable weight of evidence approach to support FOCUS PEARL not offering an appropriate tier 2 refinement for these proposed uses of propan-2-ol.  The FOCUS PEARL model was developed for the determination of groundwater concentrations related to the application of plant protection products (PPP) on agricultural land. Accordingly, the model assumptions for the nine locations rely on e.g. soil properties that are representative for agriculturally used areas in Europe. The unlimited applicability of the model for the very diverse field of biocidal applications is thus questionable. For biocidal applications where the release of active substances to the environment is related to the application of sewage sludge or manure/slurry to agricultural land, the applicability of FOCUS PEARL might be given. In the present case, where the products is used in urban areas where a direct exposure to the urban environment is assumed, the model assumptions of FOCUS PEARL may not be accurate and the results of such a refinement should be evaluated with caution. The same applies, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, for which the model is might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.  This discussion is supported by the conclusion at the 21st BPC meeting that if not all nine scenarios show a safe use and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach.  An acceptable risk of propan-2-ol to groundwater is therefore expected  Permethrin metabolites:  the two major metabolites (DCVA and PBA) are expected to be more mobile in soil with mean Koc for DCVA of 93.2 L/kg (n = 5) and for PBA of 141.2 L/kg, which may result in leaching to the groundwater. Therefore, the risk for the groundwater is quantitatively assessed for the major metabolite DCVA (worst case DT50 soil [12°C]: 175 d) covering for the significantly more rapidly degrading PBA (DT50 soil [12°C]: 2.5 d). The risk for the soil compartment is presented for completeness.  The maximum observed DCVA in soil compared to the parent was 0.113 and the formation fraction to be used in the groundwater modelling is 1. The environmental behaviour of DCVA was described with a worst-case sorption coefficient Koc of 93.2 L.kg-1. The degradation in soil was described with a worst-case half-life of 175 days at 12°C.   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | **Scenarios** | | **PECGW (µg/L)** | | | **DCVA** | **PBA** | | Scenario 1 (indoor professionals) | | **1,34E-01** |  | | Scenario 2 (indoor non-professionals) | | **2,94E-01** |  | | Scenario 3 (non-washable textile) | | 5,28E-04 |  | | Scenario 4 (Nest) | Direct application | **1,91E+00** |  | | House (terraces) | 2,25E-01 |  | | Large buildings (terraces) | 1,48E-05 |  |   Predicted environmental concentrations for DCVA in pore water for Scenarios 1, 2 and 4 (direct application) are > 0.1 µg/L. According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L. The calculated pore water concentration does not comply with this criterion. Therefore, a more realistic exposure assessment is conducted using FOCUS PEARL 4.4.4. The application scheme and the calculation of the application rates for grassland are presented below.  A refinement is done by FOCUS PEARL 4.4. The following parameters were used in the estimation of the application rate to be used in FOCUS program for the estimation of PECGW:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Parameter** | **substance** | **Value** | **Unit** | **Origin** | | Molar mass | Permethrin | 391.29 | [g.mol-1] | S | | DCVA | 209.07 | | Solubility in water (at 20 ºC) | Permethrin | 0.18 | [mg.L-1] | S | | DCVA | 127.6 | | Molar enthalpy of dissolution |  | 27 | [kJ.mol-1] | D | | Vapour pressure (at 20 ºC) | Permethrin | 2.155E-06 | [Pa] | S | | DCVA | 2.60E-01 | | Molar enthalpy of vaporisation |  | 95 | [kJ.mol-1] | D | | Diffusion coefficient in water |  | 4.3E-05 | [m2.d-1] | D | | Gas diffusion coefficient |  | 0.43 | [m2.d-1] | D | | Reference temperature to degradation, vaporization and dissolution |  | 20 | [ºC] | D | | Exponent for the effect of liquid (degradation moisture relationship) |  | 0.7 | [-] | D | | Sorption to soil organic carbon (Koc) | Permethrin | 73441 | [dm3.kg-1] | S | | DCVA | 93.2 | | Exponent of the Freundlich-Isotherm (1/n) |  | 0.9 | [-] | D/S | | DT50 soil(12°C) | Permethrin | 106 | [d] | S | | DCVA | 175 | | Plant uptake factor |  | 0 | [-] | D |   According to TAB ENV 157, only grassland (alfalfa) was considered. Outputs below show the predicted 80th concentrations for each substance in groundwater:   |  |  |  | | --- | --- | --- | | **FOCUS Scenarios for Permethrin and DCVA (grassland)** | | | | **Ground land Scenarios** | **Concentration closest to the 80th percentile [μg·L-1]** | | | **Permethrin** | **DVCA** | | **Châteaudun** | <0.01 | <0.01 | | **Hamburg** | <0.01 | <0.01 | | **Jokioinen** | <0.01 | <0.01 | | **Kremsmünster** | <0.01 | <0.01 | | **Okehampton** | <0.01 | <0.01 | | **Piacenza** | <0.01 | <0.01 | | **Porto** | <0.01 | <0.01 | | **Sevilla** | <0.01 | <0.01 | | **Thiva** | <0.01 | <0.01 |   Conclusion:  Taking into account the outputs above, no risk for groundwater compartment is expected. |

Primary and secondary poisoning

Primary poisoning

Not relevant

|  |
| --- |
| ES CA agrees with the applicant. |

Secondary poisoning

The exposure due to secondary poisoning via the terrestrial and aquatic food chain has been evaluated according to the TGD Part II (2003).

The risk to the fish-eating birds and mammals is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake (PNECoral, fish food chain). The concentration of permethrin in fish has been calculated only for Scenarios 1, 2 and 3 from the potential PEC in surface water and the estimated bioconcentration factor for fish.

The risk to the predators for Scenarios 1, 2 and 3 is calculated as the ratio between the concentration in their food and the predicted no-effect concentration for oral intake (PNECoral, terrestrial food chain). The concentration of permethrin in earthworm has been calculated from the PEC in soil averaged over 180 days and the estimated bioconcentration factor for earthworm.

The PEC/PNEC ratio has been calculated and the results are shown in tables below:

| **Summary table on secondary poisoning for permethrin** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | | **Concentration** | **PEC oral predator** | **PEC/PNEC birds** | **PEC/PNEC mammals** |
| **Scenario: Application, aquatic compartment** | | **PECsw (mg/L)** | **mg/kg wet fish** |  | |
| Scenario 1 | Professional | 5.91E-06 | 9.03E-03 | 5.41E-04 | 7.53E-05 |
| Non professional | 3.98E-06 | 7.40E-03 | 4.43E-04 | 6.17E-05 |
| Scenario 2 (Non-professional) | | 3.98E-06 | 7.40E-03 | 4.43E-04 | 6.17E-05 |
| Scenario 3 (Non-professional) | | 3.51E-06 | 6.54E-03 | 3.92E-04 | 5.45E-05 |
| **Scenario: Application, terrestrial compartment** | | **PECsoil – 180 day (mg/L)** | **mg/kg wet earthworm** |  | |
| Scenario 1 | Professional | 4.05E-04 | 2.36E-04 | 1.41E-05 | 1.97E-06 |
| Non professional | 2.73E-04 | 1.59E-04 | 9.52E-06 | 1.33E-06 |
| Scenario 2 (Non-professional) | | 2.73E-04 | 1.59E-04 | 9.52E-06 | 1.33E-06 |
| Scenario 3 (Non-professional) | | 2.42E-04 | 1.41E-04 | 8.44E-06 | 1.18E-06 |

The risk assessment for specific species by secondary poisoning considered in scenarios 4, and 5 are considered by splitting the ETE with the correspondent PNEC (i.e. bird or mammal value). These quotients are showed in the following tables:

*ETE/PNEC for terrestrial species of secondary poisoning at Scenario 4:*

| **Representative specie** | **ETE / PNEC** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **gInsectivorous** | | **Herbivorous** | | **Mammals eating worms** | | **Birds eating worms** | |
| Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure | Short-term exposure |
| Small insectivorous mammal 1 (pipistrelle) – 7.6 g \* | 6.71E-06 | 2.01E-06 | **-** | **-** | **-** | **-** | **-** | **-** |
| Small insectivorous mammal 2 (mole) – 85 g | **-** | **-** | **-** | **-** | 1.95E-03 | 1.95E-03 | **-** | **-** |
| Medium insectivorous mammal – 1100 g – hedgehog \* | 1.53E-06 | 4.59E-07 | **-** | **-** | 9.25E-04 | 9.25E-04 | **-** | **-** |
| Large insectivorous mammal – 10100 g (badger) \* | 7.98E-07 | 2.38E-07 | **-** | **-** | 4.83E-04 | 4.83E-04 | **-** | **-** |
| Medium herbivorous mammal – 1500 g (rabbit) \* | **-** | **-** | 1.58E-05 | 5.94E-06 | **-** | **-** | **-** | **-** |
| Small Insectivorous bird (Tree sparrow, robin) – 22 g | 2.14E-04 | 9.82E-05 | **-** | **-** | **-** | **-** | **-** | **-** |
| Medium Insectivorous bird – 113 g (blackbird) \* | 5.43E-05 | 1.62E-05 | **-** | **-** | **-** | **-** | **-** | **-** |
| Omnivorous bird – 225 g (Black-billed magpie) \* | 2.89E-05 | 8.68E-06 | **-** | **-** | **-** | **-** | 1.74E-02 | 1.74E-02 |

\*Indicator species considered as relevant for lawn/garden.

*ETE/PNEC for terrestrial species of secondary poisoning at Scenario 5:*

| **Representative specie** | **ETE / PNEC** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Insectivorous** | | **Herbivorous** | | **Mammals eating worms** | | **Birds eating worms** | |
| Acute exposure | Short-term exposure | Acute exposure | Short-term exposure | Acute exposure (treated/ untreated area) | Short-term exposure | Acute exposure (treated/ untreated area) | Short-term exposure |
| Small insectivorous mammal 1 (pipistrelle) – 7.6 g \* | 5.51E-06 | 2.44E-06 | **-** | **-** | **-** | **-** | **-** | **-** |
| Small insectivorous mammal 2 (mole) – 85 g | **-** | **-** | **-** | **-** | 5.56E-03 / 2.067E-06 | 8.67E-04 | **-** | **-** |
| Medium insectivorous mammal – 1100 g – hedgehog \* | 1.26E-06 | 5.58E-07 | **-** | **-** | 3E-04 / 9.75E-07 | 4.08E-04 | **-** | **-** |
| Large insectivorous mammal – 10100 g (badger) \* | 6.55E-07 | 2.91E-07 | **-** | **-** | 1.583E-04 / 5.125E-07- | 2.17E-04 | **-** | **-** |
| Medium herbivorous mammal – 1500 g (rabbit) \* | **-** | **-** | 1.29E-05 | 7.23E-06 | **-** | **-** | **-** | **-** |
| Small Insectivorous bird (Tree sparrow, robin) – 22 g | 1.76E-04 | 1.19E-04 | **-** | **-** | **-** | **-** | **-** | **-** |
| Medium Insectivorous bird – 113 g (blackbird) \* | 4.46E-05 | 1.98E-05 | **-** | **-** | **-** | **-** | **-** | **-** |
| Omnivorous bird – 225 g (Black-billed magpie) \* | 2.38E-05 | 1.05E-05 | **-** | **-** | **-** | **-** | 5.63E-03 / 1.84E-05 | 7.72E-03 |

\*Indicator species considered as relevant for lawn/garden.

Conclusion: As it can be observed, the PEC/PNEC ratio is lower than 1 for all the use/scenario, indicating acceptable risk of secondary poisoning trough the terrestrial food-chain via earthworm and aquatic food chain via unlikely fish.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ESCA agrees with the conclusion of the applicant. With the new calculations, taking into account only the worst case an acceptable risk is showed.   |  |  |  | | --- | --- | --- | | **Summary table on secondary poisoning** | | | |  | **Permethrin** | **DCVA** | | **Aquatic food chain** | **PEC/PNEC** | | | Scenario 1 |  |  | |  | 3,02E-01 | 1,01E-01 | | **Terrestrial food chain** | **PEC/PNEC** | | | Scenario 4 (direct emissions) |  |  | |  | 4,91E-04 | 1,07E-04 | |

**Risk characterization for metabolites**

The risk characterization for surface water, sediment and soil compartments were carried out by comparing the PECs with the PNEC of metabolites.

The PEC/PNEC ratio has been calculated and the results are shown in the table below.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated RCR for Permethrin’s metabolites** | | | | | | | | | |
|  | | **DCAV** | | | | **PBA** | | | |
| **PECwater/ PNECwater** | **PECsed/ PNECsed** | **PECsoil/ PNECsoil** | **PECGW /trigger value** | **PECwater/ PNECwater** | **PECsed/ PNECsed** | **PECsoil/ PNECsoil** | **PECGW /trigger value** |
| Scenario 1 | (P) | 2.47E-04 | 6.26E-02 | 1.54E-05 | 9.64E-04 | 1.70E-04 | 6.30E-02 | 6.52E-05 | 1.28E-03 |
| (n-P) | 1.66E-04 | 4.21E-02 | 1.04E-05 | 6.49E-04 | 1.15E-04 | 4.25E-02 | 4.40E-05 | 8.61E-04 |
| Scenario 2 (n-P) | | 1.66E-04 | 4.21E-02 | 1.04E-05 | 6.49E-04 | 1.15E-04 | 4.25E-02 | 4.40E-05 | 8.61E-04 |
| Scenario 3 (n-P) | | 1.46E-04 | 3.73E-02 | 9.16E-06 | 5.74E-04 | 1.01E-04 | 3.75E-02 | 3.89E-05 | 7.62E-04 |
| Scenario 4 | | - | - | 1.72E-03 | 1.66E-01 | - | - | 7.28E-03 | 2.21E-01 |
| Scenario 5 (n-P) | | 5.38E-03 | **1.36** | 3.44E-04 | 2.09E-02 | 3.72E-03 | **1.37** | 1.46E-03 | 2.78E-02 |

(P) Professional; (n-P) non-Professional

The potential risk of secondary poisoning derived from metabolites is deemed covered by the parent compound because its concentration and toxicity is higher than any metabolite.

Conclusion: According to the obtained PEC/PNEC ratio, the use of PERMETHRIN 0.4% RTU is safe for all scenarios with the exception of Scenario 5 where unacceptable risk is expected for sediment compartment.

|  |
| --- |
| ESCA: please see section for every compartment, both parent and metabolites has been recalculated by the ES CA. |

Mixture toxicity

As the biocidal product consists of one active substance and one substance of concern, the environmental risk should be based on the combined risk. It is found that the model of concentration addition can be recommended as the best reference model when evaluating combined risk of chemical mixtures.

In the first tier a PEC/PNEC summation based on effect data (most sensitive organism) for the individual substances is performed for each environmental compartment of concern. [(PEC/PNEC)product = Σ (PEC/PNEC)individual substances] for each environmental compartment.

(PEC/PNEC)product values for each environmental compartment of concern are summarized below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated RCR for the product** | | | | | | |
| ***∑PEC/PNEC*** | | **PEC/ PNECSTP** | **PEC/ PNECsurface water** | **PEC/ PNECsed** | **PEC/ PNECsoil** | **PECGW/ trigger value** |
| Scenario 1 | (P) | 0.047 | **12.57** | **16.09** | 3.66E-03 | 1.32E-02 |
| (n-P) | 0.032 | **8.46** | **10.83** | 2.46E-03 | 8.51E-03 |
| Scenario 2 (n-P) | | 0.030 | **8.46** | **10.83** | 2.46E-03 | 8.51E-03 |
| Scenario 3 (n-P) | | 0.010 | **7.48** | **9.56** | 2.18E-03 | 7.66E-03 |
| Scenario 4 | | - | - | - | 0.55 | **4.24\*** |
| Scenario 5 (n-P) | | 0.270 | **273.62** | **350.14** | 8.18E-02 | 2.69E-01 |

\* refined in the table below by FOCUS PEARL 4.4.4:

|  |  |
| --- | --- |
| **FOCUS Scenarios** | |
| ***Location*** | **∑PEC/PNEC groundwater** |
| **Châteaudun** | 0.055519 |
| **Hamburg** | **0.177553** |
| **Jokioinen** | **0.282403** |
| **Kremsmünster** | 0.07036 |
| **Okehampton** | **0.111896** |
| **Piacenza** | 0.071703 |
| **Porto** | 0.060047 |
| **Sevilla** | 0.029434 |
| **Thiva** | 0.020847 |

Due that the estimated concentration of Propan-2-ol in groundwater was already above the trigger value, the derived mixture toxicity of the product to groundwater is consequently above the trigger value and unacceptable risk is foreseen in three locations: Hamburg, Jokioinen and Okehampton. However, as it was mentioned before, the estimated concentration of propan-2-ol in groundwater by FOCUS PEARL 4.4.4 must be taken with caution as it could be considered as overestimation.

In the rest of European locations and scenarios, an acceptable risk for groundwater is foreseen.

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| ESCA:  Permethrin is the only substance classified for the aquatic environment, and it also has a factor M = 1000. Propan-2-ol has no significant effects. The PEC/PNECs values of Propan-2-ol (for all the environmental compartments, direct application and via STP), are much lower than those of permethrin, in most of the cases several orders of magnitude.  In addition to this, it does not present synergistic effects with permethrin since it does not affect the effectiveness of the product. The exposure analysis is performed only because it is a substance that has biocidal properties and has been approved for various uses in accordance with the BPR. It meets the criteria to be considered as a substance of concern. However, based on the results of the evaluation, the overall toxicity of the product is due to the permethrin.  ESCA considers that mixture toxicity is not needed |

Overall conclusion

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| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| An acceptable risk should be foreseen for all scenarios at the assessed environmental compartments, when the use instructions given in the product’s label and the proposed risk mitigations measures are followed for each scenario.  Indoor scenarios 1, 2 (spraying into voids/cavities and spot surfaces against crawling and flying insects respectively) and scenario 3 (spraying over non washable textile surfaces), when consider a default emission to STP, shows an unacceptable risk for aquatic compartment. However, as it was mentioned before the emission to STP should not be considered because the product cannot be applied on washable surfaces nor surfaces connected (or suspected to be connected) to waste water.  When the product is applied outdoors, into ant nests (Scenario 4) no directly emission to aquatic compartment is foreseen and only soil and groundwater compartments are deemed of concern. Soil compartment is considered at safe whilst in groundwater the concentration of propan-2-ol discloses values slightly above the trigger value in specific localities (tier 2). However this output must be taken with caution as no real DT50 value is available for soil and a risk overestimation could be occur.  Outdoor application in voids/crevices of paved terraces not connected to STP and protected to rainfall and wash (Scenario 5), shows an unacceptable risk for the aquatic compartment. However, for all outdoor intended uses, the use of a trap over the adjacent soil of walls, ceilings,… (where the product could be applied) is proposed as efficient risk mitigation measure in order to reduce the fraction emitted to environment during product’s application.  The main statement is that the product must be applied on surfaces not connected to wastewater, treated surfaces must not be washed nor cleaned by wet method and in the case of outdoor, treated areas must be protected from rain fall and flooding. Under these assumptions a safe use of the product for the environment must be obtained. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ES CA:  Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Summary table for the risk assessment of this product. | | | | | | | |  | Use | PEC/PNECstp | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PECGW | | Scenario 1: indoor, spot to a surface, professional | 1 | Acceptable | Unacceptable | Unacceptable | Acceptable | Acceptable | | Scenario 2: indoor use, spot treatment to a surface, non-professionals | 2 | Acceptable | Unacceptable | Unacceptable | Acceptable | Acceptable | | Scenario 3: indoor use, non-washable textiles, non-professionals (TIER II) | 3 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario 4: Outdoor – Ant nests | 4 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | 5 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |   For Uses 1 and 2, the assessment of scenarios 1 and 2 (indoor use, professional and non-professional) showed an unacceptable risk for surface water and sediment compartments. However, this risk can be reduced to acceptable levels or prevented by imposing the following RMM: The product must be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects. Therefore, these uses are acceptable.  For Use 3, following the label instruction for Use 3 (non-washable textile surfaces non-professionals user) and the RMM (calculated in tier II)“The exceed of the product on not treated surfaces contaminated during the application must be remove with a damp paper and dispose as solid waste” no risk for the aquatic compartment is expected.  Uses 4 and 5 are safe, since the PEC/PNEC ratios for all environmental compartments are lower than 1.    In conclusion, acceptable risk should be foreseen for all the uses at the assessed environmental compartments when the use instructions given in the product’s label and the proposed risk mitigations measures are followed for each scenario, the same conclusion can be extrapolated to the higher dose for controlling silverfish. |

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

Not applicable as the product is only intended to be used as PT18.

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

Please refer to summary of the product assessment (SPC) and to the relevant sections of the assessment report.

### Assessment of a combination of biocidal products

Not relevant as the biocidal products are not intended to be authorised for the use with other biocidal products.

### Comparative assessment

Not relevant.

# Annexes

## List of studies for the biocidal product

Please, see confidential PAR.

## Model used and exposure calculations

### Human expousere model

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### Emission Environmental expousere calculation

Outputs from EUSES 2.2.0 are attached in the excel datasheet below:

|  |  |
| --- | --- |
| Permethrin: | Propan-2-ol as SoC: |

## New information on the active substance

Not available

## Residue behaviour

Not available

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

See summary table of efficacy tests. Section 2.2.5.5.

## Confidential annex

See PAR confidential.

## Other

No other information required.