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)



18V33CP-PE

PT8

Cypermethrin, penflufen

BC-EL064976-21

FR CA

Date: July 2023

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# CONCLUSION

**Introduction of the application**

France, as e-CA, received an application from V33 for national authorisation for the biocidal product 18V33CP-PE.

The biocidal product 18V33CP-PE containing 0.183% (w/w) (technical content) cypermethrin and 0.027% (w/w) (technical content) penflufen is a PT8 biocidal product intended to be used for preventive and curative treatment of wood.

The biocidal product 18V33CP-PE is a ready to use liquid to be used indoor and outdoor by professional and non-professional users.

**Summary and overall conclusion of the assessment**

**Physico-chemical properties and analytical methods**

The accelerate storage stability at 40°C during 8 weeks shows that the product is stable. The long-term storage stability study of the product 18V33CP-PE demonstrates a 30 months stability. After 36 month the content of active substance cypermethrin decreases by more than 10%. Therefore, as no justification and information about degradation products and efficacy after a storage superior to 36 months are provided, the shelf-life is set at 30 months.

The product is not classified for physical hazard.

The mitigation measure: “Do not store the product at temperature above 40°C should be added on the label”.

**Efficacy**

The product 18V33CP-PE shows a sufficient efficacy for the preservation of wood in the conditions of use detailed in the SPC.

The product is used:

* for the preventive control of wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), wood rotting fungi (brown rot and white rot) and termites (*Reticulitermes spp*), by superficial application, in use class 1 to 3;
* for the curative control of wood in service against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and termites (*Reticulitermes spp.*), indoor and outdoor, by superficial application, completed by injection if need be.

**Resistance**

The applicant must report any inefficiencies of the treatment linked to the uses of the 18V33CP-PE to the Competent Authority.

**Substances of concern (SoCs)**

The co-formulant BIT included in the product was identified as substance of concern for the environment.

Please refer to the confidential annex for further details.

**Risk for Human Health**

For the product 18V33CP-PE, the risk is considered acceptable for professional and non-professional users and the general public, considering a quantitative risk assessment, with the application of risk mitigation measures (RMMs) listed in the SPC.

**Risk for consumer under indirect exposure via food**

Considering the intended uses, food and feed contamination and livestock exposure are not expected. Therefore, the exposure via food or via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed. Wood treated with 18V33CP-PE must contain label restrictions against use in contact with food, feeding stuff and livestock animals.

**Risk for the environment**

The risk assessment for the active substances and their relevant metabolites, as well as for the substance of concern BIT (relevant for the STP only), has been performed for the preventive, curative and injection application.

The emission to the environment is considered negligible for the indoor applications for all application methods. The risks is thus considered acceptable.

For the preventive application (i.e. 200 g/m2):

Unacceptable risks are found for the aquatic compartment during the application phase. Therefore the following risk mitigation measure must be added to the SPC: “Do not apply where the product can reach surface water during outdoor application”

Unacceptable risks are found for the terrestrial compartment during the application phase for the adjacent soil for the application by spray by professionals and non-professionals and for the application by brush for non-professionals only. Therefore the following RMM must be added to the SPC for these uses: “For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”.

Acceptable risks are found for the service-life.

For the curative application (i.e. 300 g/m2):

Unacceptable risks are found for the aquatic compartment during the application phase. Therefore the following RMM must be added to the SPC: “Do not apply where the product can reach surface water during outdoor application”.

Unacceptable risks are found for the terrestrial compartment during the application phase for both professional and non-professional for the application by brush. Therefore the following RMM must be added to the SPC: “For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”.

Unacceptable risks are found for both adjacent and distant soil for the application by spray. No risk mitigation measure can mitigate the risk for the distant soil. Therefore the application by spray for the curative treatment cannot be authorized for outdoor application.

For the injection (i.e. 150 g/m2):

The injection is always carried out in combination with a curative superficial application of 300 g/m2. As the spraying is not acceptable for the curative outdoor application, injection must only be associated with a brushing application for outdoor application. Considering that injection is always associated to a curative treatment, the following risk mitigation measure also applies for this application method “For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment” and “Do not apply where the product can reach surface water during outdoor application”.

As the product is protected by a top-coat, the following RMM must also be added to the SPC: “Use the treated wood outdoors only when it is protected by a top-coat that does not contain any biocidal substance for wood preservation. This top-coat must be classified as stable according to standard EN 927-2, which limits the leaching of the product to the environment throughout the life cycle of the treated wood.”

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the product 18V33CP-PE is reported in the table below, for each use.

|  |  |  |  |
| --- | --- | --- | --- |
| **Target oganisms** | **Doses** | **Conditions of use** | **Conclusions** |
| Wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*),  Wood rotting fungi (brown rot and white rot)  Termites (*Reticulitermes spp*) | 200 g/m² (equivalent to 200 mL/m²) | Preventive treatment in Use-classes 1, 2, 3  Superficial application (spraying, brushing)  Indoor, outdoor | **Acceptable** |
| Wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*)  Termites (*Reticulitermes spp.*) | Superficial application: 300 g/m² (equivalent to 300 mL/m²)  Injection: 150 g/m² (equivalent to 150 mL/m²) | Curative treatment of wood in service  superficial application (spraying, brushing)  Injection (in combination with a superficial application)  Indoor, outdoor | **Not acceptable**  Unacceptable risk for the environment for spraying application outdoor |
| Wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*)  Termites (*Reticulitermes spp.*) | Superficial application: 300 g/m² (equivalent to 300 mL/m²)  Injection: 150 g/m² (equivalent to 150 mL/m²) | Curative treatment of wood in service  superficial application (brushing) indoor and outdoor  superficial application (spraying) indoor only  Injection (in combination with a superficial application) indoor and outdoor | **Acceptable** |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| 18V33CP-PE |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | V33 |
| **Address** | La Muyre 39 210 Domblans, France |
| **Authorisation number** | **FR-2023-0047** | |
| **Date of the authorisation** | **21/08/2023** | |
| **Expiry date of the authorisation** | **20/08/2033** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | V33 |
| **Address of manufacturer** | La Muyre 39 210 Domblans, France |
| **Location of manufacturing sites** | La Muyre 39 210 Domblans, France |

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

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

|  |  |
| --- | --- |
| **Active substance** | Penflufen |
| **Name of manufacturer** | LANXESS Deutschland GmbH Material Protection Products |
| **Address of manufacturer** | Kennedyplatz 1, D-50569 Köln, Germany |
| **Location of manufacturing sites** | Bayer AG – Crop Science Division, Alte Heerstrasse, D 41538 Dormagen, Germany |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Cypermethrin |
| **IUPAC or EC name** | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 607-421-00-4 |
| **Minimum purity / content** | 920 g/kg |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Penflufen |
| **IUPAC or EC name** | 5-fluoro- 1,3-dimethyl-N-{2- [ (2RS) -4-methylpentan-2-yl]phenyl} - lH-pyrazole-4-carboxamide |
| **EC number** | Not allocated |
| **CAS number** | 494793-67-8 |
| **Index number in Annex VI of CLP** | Not allocated |
| **Minimum purity / content** | 980 g/ kg 1:1 (R:S) ratio of enantiomers |
| **Structural formula** |  |

#### Candidate(s) for substitution

Active substances cypermethrin and penflufen are not a candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin (technical) | (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.183 |
| Penflufen  (technical) | 5-fluoro- 1,3-dimethyl N-{2- [ (2RS) -4- methylpentan-2- yl]phenyl} - lH-pyrazole- 4- ca rboxamide | Active substance | 494793-67-8 | / | 0.027 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | / | 0.02 |

#### Information on technical equivalence

For both active substances, the sources are validated in the respective CAR.

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

One co-formulant included in the product, the 1,2-benzisothiazol-3(2H)-one (BIT), was identified as substance of concern for the environment.

Please see the confidential annex for further details.

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

The biocidal product contains the active substances “Cypermerthrin” and “Penflufen” which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| AL: any other liquid |

### Hazard and precautionary statements[[1]](#footnote-2)

**Classification and labelling of the products according 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 | GHS09  Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P103: Read carefully and follow all instructions.  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container according to local regulation |
|  | |
| Note | EUH208 – “Contains 2-methylisothiazolin-3-one and 5-chloro-2-methylisothiazolin-3-one (3:1) (C(M)IT/MIT) and 1,2-benzisothiazol-3(2H)-one (BIT). May produce an allergic reaction.” |

### Authorised use(s)

#### Use description

**Table 1. Use # 1** – Preventive application - Professionals

|  |  |
| --- | --- |
| **Product Type** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) - larvae * Common furniture beetle (*Anobium punctatum*) - larvae * Powder post beetle (*Lyctus brunneus*) - larvae   Subterranean termites (genus *Reticulitermes*)  Wood-rotting basidiomycetes (brown rot, white rot) |
| **Field of use** | Preventive treatment - Use-class 1, Use-class 2, Use-class 3  Softwood and hardwood  Indoor and outdoor use |
| **Application method(s)** | Surface application / spraying  Surface application / brushing |
| **Application rate(s) and frequency** | 200 g of product / m² of wood (equivalent to 200 mL of product / m² of wood) |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L,  - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5 and 6 L, 20, 25, 30,  - Steel drums with internal coating made of phenolic epoxy resins, 60 and 215 L |

#### Use-specific instructions for use[[2]](#footnote-3)

|  |
| --- |
| * For preventive superficial application on wood for use class 3, a top coat has to be applied. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For outdoor in situ treatment by spray, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment * Wear protective chemical resistant gloves and an impermeable protective coverall (material to be specified by the authorisation holder within the product information) during the application of the product by spraying. |

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

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

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

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| - |

#### Use description

**Table 2. Use # 2** – Preventive application – Non professionals

|  |  |
| --- | --- |
| **Product Type** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) - larvae * Common furniture beetle (*Anobium punctatum*) - larvae * Powder post beetle (*Lyctus brunneus*) - larvae   Subterranean termites (genus *Reticulitermes*)  Wood-rotting basidiomycetes (brown rot, white rot) |
| **Field of use** | Preventive treatment - Use-class 1, Use-class 2, Use-class 3  Softwood and hardwood  Indoor and outdoor use |
| **Application method(s)** | Surface application / spraying  Surface application / brushing |
| **Application rate(s) and frequency** | 200 g of product / m² of wood (equivalent to 200 mL of product / m² of wood) |
| **Category(ies) of users** | Non professionals |
| **Pack sizes and packaging material** | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L  - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5 6, 20, 25 and 30 L |

#### Use-specific instructions for use

|  |
| --- |
| * For preventive superficial application on wood for use class 3, a top coat has to be applied. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * For outdoor in situ treatment by spray and by brushing, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment |

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

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

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

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#### Use description

**Table 3. Use # 3 –** Curative application - Professionals

|  |  |
| --- | --- |
| **Product Type** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) - larvae * Common furniture beetle (*Anobium punctatum*) - larvae * Powder post beetle (*Lyctus brunneus*) - larvae   Subterranean termites (genus *Reticulitermes*) |
| **Field of use** | Curative treatment of wood in service  Softwood and hardwood  Indoor and outdoor use |
| **Application method(s)** | Surface application / spraying (indoor only)  Surface application / brushing  Injection (in combination with a superficial application) |
| **Application rate(s) and frequency** | For curative treatment by superficial application:  300 g of product / m² of wood (equivalent to 300 mL of product / m² of wood)  In combination with injection if need be:  150 g of product / m² of wood (equivalent to 150 mL of product / m² of wood) |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L,  - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5 and 6 L, 20, 25, 30  - Steel drums with internal coating made of phenolic epoxy resins 60 and 215 L |

#### Use-specific instructions for use

|  |
| --- |
| * Curative treatment by injection are always performed in combination with a curative treatment by surface application. |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Wear protective chemical resistant gloves (material to be specified by the authorisation holder within the product information) during the application by injection. * Wear protective chemical resistant gloves and an impermeable protective coverall (material to be specified by the authorisation holder within the product information) during the application of the product by spraying. * For outdoor in situ treatment by brushing, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment * Curative application by spraying is authorized indoor only. |

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

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| - |

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

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| - |

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

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| --- |
| - |

#### Use description

**Table 4. Use # 4 –** Curative application – Non professionals

|  |  |
| --- | --- |
| **Product Type** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) - larvae * Common furniture beetle (*Anobium punctatum*) - larvae * Powder post beetle (*Lyctus brunneus*) - larvae   Subterranean termites (genus *Reticulitermes*) |
| **Field of use** | Curative treatment of wood in service  Softwood and hardwood  Indoor and outdoor use |
| **Application method(s)** | Surface application / spraying (indoor only)  Surface application / brushing  Injection (in combination with a superficial application) |
| **Application rate(s) and frequency** | For curative treatment by superficial application:  300 g of product/m² of wood (equivalent to 300 mL of product / m² of wood)  In combination with injection if need be:  150 g of product /m² of wood (equivalent to 150 mL of product / m² of wood) |
| **Category(ies) of users** | Non professional |
| **Pack sizes and packaging material** | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L,  - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5, 6, 20, 25 and 30 L |

#### Use-specific instructions for use

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| * Curative treatement by injection are always performed in combination with a curative treatment by surface application. |

#### Use-specific risk mitigation measures

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| * For outdoor in situ treatment by brushing, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment * Curative application by spraying is authorized indoor only. |

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

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

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| - |

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

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### General directions for use

#### Instructions for use

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| * Inform the registration holder if the treatment is ineffective. * Comply with the instructions for use |

#### Risk mitigation measures

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| * Do not use on wood which may come in direct contact with food, feed and livestock. * Do not apply where the product can reach surface water during outdoor application. * Use the treated wood outdoors only when it is protected by a top-coat that does not contain any biocidal substance for wood preservation. This top-coat must be classified as stable according to standard EN 927-2, which limits the leaching of the product to the environment throughout the life cycle of the treated wood. * Keep uninvolved persons, children and pets away from treated surfaces/areas until dried. |

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

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| * If medical advice is needed, have product container or label at hand. * 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 SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor. * IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. |

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

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

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

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| * Shelf life : 30 months * Do not store the product at temperature above 40°C * Keep out of reach of children and non-target animals/pets. |

### Other information

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### Packaging of the biocidal product

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| --- | --- | --- | --- | --- | --- |
| **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)** |
| Steel cans with internal epoxy varnish | 0.5 L, 0.75 L, 1 L, 2.5L, 5L, 6L | Steel  with internal epoxy varnish | Polyethylene closure systems | Professional and non-professional | Y |
| Steel cans with internal epoxy varnish | 20L, 25L, 30 L | Steel  with internal epoxy varnish | Polyethylene closure systems | Professional Non professional\* | Y |
| Steel barrel with internal epoxy with a lever pump | 60 L, 215 L | Steel  with internal epoxy varnish | Polyethylene closure systems | Professional | Y |

\*Risk assessment allows to grant the same size of packagings for steel cans with internal epoxy varnish for professional and for non professional users.

Considering a French national legislation establishing maximum sizes of packagings accepted in the landfills for individuals, the size of steel cans with internal epoxy varnish is limited to 25L in the French authorisation of the product.

### Documentation

#### Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product 18V33CP-PE were provided by V33 SA.

#### Access to documentation

V33 SA has access to data on the active substances Cypermethrin (0.17%) and Penflufen (0.026%) with a Letter of Access of Arysta LifeScience Benelux SPRL, one applicant of the active substances Cypermethrin and Penflufen.

## Assessment of the biocidal product

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

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.183% of technical active substance cypermethrin and 0.168% of pure active substance and 0.027% of technical active substance penflufen and 0.026% of pure active substance.

The product contains PT6 preservative which are authorized.

The product is ready-to-use.

Formulation type: any other liquids (AL).

Hydrocarbon and H304 co-formulant content: <10%.

Table 2. Intended use # 1 – Preventive

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| --- | --- |
| Product Type(s) | PT08 - Wood preservatives (Preservatives) |
| Where relevant, an exact description of the authorised use | The product 18V33CP-PE is a ready-to-use wood preservative to be used for preventive and curative treatment of wood against wood-boring insects, termites and wood-rotting fungi(brown and white rot). The application rate is 200 g/m² for preventive use and 300 g/m² for curative use. The product can be applied by brushing or spraying. It can also be applied by injection (at the rate of 150 g/m²), in combination with a surface application. |
| Target organism (including development stage) | Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage: not specified Scientific name: Basidiomycetes: Common name: White rot fungi Development stage: not specified Scientific name: Hylotrupes bajulus L. Common name: House longhorn beetle Development stage: Larvae Scientific name: Anobium punctatum De Geer Common name: Common furniture beetle Development stage: Larvae Scientific name: Lyctus brunneus Common name: Powder post beetles Development stage: Larvae Scientific name: Reticulitermes sp. Common name: Subterranean termites Development stage: workers, soldiers, nymphs |
| Field of use | Indoor Outdoor |
| Application method(s) | Method: Spraying Detailed description: The product is a ready-for-use product. It is applied by brushing or spraying. Method: Open system: brush treatment Detailed description: The product is a ready-for-use product. It is applied by brushing or spraying. |
| Application rate(s) and frequency | Application Rate: 200 g/m² Dilution (%): - Number and timing of application: Two layers of the product are applied, with at least 15 minutes in between. However, the product is applied only once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the preventive efficacy is guaranteed for 10 years.  Application Rate: 200 g/m² Dilution (%): - Number and timing of application: Two layers of the product are applied, with at least 15 minutes in between. However, the product is applied only once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the preventive efficacy is guaranteed for 10 years. |
| Category(ies) of user(s) | Professional General public (non-professional) |
| Pack sizes and packaging material | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L, - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5 and 6 L, - Steel drums with internal coating made of phenolic epoxy resins, 20, 25, 30, 60 and 215 L. |

Table 2. Intended use # 1 – Curative

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| Product Type(s) | PT08 - Wood preservatives (Preservatives) |
| Where relevant, an exact description of the authorised use | The product 18V33CP-PE is a ready-to-use wood preservative to be used for preventive and curative treatment of wood against wood-boring insects, termites and wood-rotting fungi(brown and white rot). The application rate is 200 g/m² for preventive use and 300 g/m² for curative use. The product can be applied by brushing or spraying. It can also be applied by injection (at the rate of 150 g/m²), in combination with a surface application. |
| Target organism (including development stage) | Scientific name: Basidiomycetes: Common name: Brown rot fungi Development stage: not specified Scientific name: Basidiomycetes: Common name: White rot fungi Development stage: not specified Scientific name: Hylotrupes bajulus L. Common name: House longhorn beetle Development stage: Larvae Scientific name: Anobium punctatum De Geer Common name: Common furniture beetle Development stage: Larvae Scientific name: Lyctus brunneus Common name: Powder post beetles Development stage: Larvae  Scientific name: Reticulitermes sp. Common name: Subterranean termites Development stage: workers, soldiers, nymphs |
| Field of use | Indoor Outdoor |
| Application method(s) | Method: Spraying Detailed description: The product is a ready-for-use product. It is applied by brushing or spraying.  It can also be applied by injection, before an application by brushing or spraying. Method: Open system: brush treatment Detailed description: The product is a ready-for-use product. It is applied by brushing or spraying. It can also be applied by injection, before an application by brushing or spraying. Method: Open system: injection Detailed description: Injection |
| Application rate(s) and frequency | Application Rate: 300 g/m² Dilution (%): - Number and timing of application: Three layers of the product are applied, with at least 15 minutes in between. However, the product is applied only once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the curative efficacy is guaranteed for 10 years.  Application Rate: 300 g/m² Dilution (%): - Number and timing of application: Three layers of the product are applied, with at least 15 minutes in between. However, the product is applied only once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the curative efficacy is guaranteed for 10 years.  Application Rate: 150 g/m² Dilution (%): - Number and timing of application: Curative injections are always performed in combination with a curative treatment by surface application. |
| Category(ies) of user(s) | Professional General public (non-professional) |
| Pack sizes and packaging material | - Steel bottles with internal coating made of phenolic epoxy resins, 0.5, 0.75 and 1 L, - Steel cans with internal coating made of phenolic epoxy resin, 2.5, 5 and 6 L, - Steel drums with internal coating made of phenolic epoxy resins, 20, 25, 30, 60 and 215 L. |

### Physical, chemical and technical properties

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| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | Translucent yellow light liquid at initial time and translucent yellow liquid after 8 weeks at 40 ± 2°C. Translucent yellow green light liquid before and after a low temperature storage procedure for 7 days at 0 ± 2°C | Acceptable | Raphalen E.2019  Report no.  402/17/1256F/adegm-e  Raphalen E.2019  Report no.  402/17/1256F-e |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity | CIPAC MT 75.3 | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | At initial time, the mean pH value of the pure test item 18V33CP-PE was 6.4 at 20 ± 2°C. After 8 weeks at 40 ± 2°C in its packaging (20L plastic can), the mean pH value of the pure test item 18V33CP-PE was 6.0 at 20 ± 2°C. | Acceptable | Raphalen E.2019  Report no.  402/17/1256F-e |
| Relative density / bulk density | EU Method A.3, OECD Guideline No.109 (2012) (pycnometric method) | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | The mean relative density of the test item was 1.001 at 20.0°C. | Acceptable | Raphalen E.2019  Report no.  402/17/1256F-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 method (storage stability) | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin  Analytical methods validated (cf section analytical method) | The test item 18V33CP-PE after 4 weeks and 8 weeks at 40°C in glass flask for physical chemical properties and content of active substance and in 1L metallic (commercial packaging)for the appearance of the packaging.   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T 4 weeks at 40°C | T 8 weeks at 40°C | | Appearance  Glass flask | Translucent yellow light | / | Become darker | | Appearance of commercial packaging | No sign of deformation or degradation | / | No sign of deformation or degradation | | Weight of the test item | 1 123.9 | / | 1123.5 | | AS content: penflufen | 0.0252 | 0.0253 | 0.0251 | | Variation | - | +0.4% | -0.4% | | AS content: cypermethrin | 0.170 | 0.168 | 0.162 | | Variation | / | -1.2% | -4.7% | | pH pure | 6.4 at 20°C | / | 6.0 at 20°C | | Acceptable  The product is stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C.  A mitigation measure : do not store the product at temperature above 40°C should be added on the label | Raphalen E.2019  Report no.  402/17/1256F/adegm-e |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin  Validated Method: Analytical protocol No407-e version 2 | The test item 18V33CP-PE and its commercial packaging (1L steel can with internal coating made of phenolic epoxy resin) after a long-term storage procedure for 36 months at 20 ± 2°C:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | 18 months at RT | 30 months at RT | 36 months at RT | | Appearance | Liquid translucent yellow | Liquid translucent slight yellow | Liquid translucent slight yellow | Liquid translucent slight yellow | | Weight changes | / | -0.04% | -0.03% | -0.02% | | AS content: cypermethrin %w/w | 0.170 | 0.157 | 0.158 | 0.149 | | Variation of Content | / | -7.6% | -7.1% | -12.4% | | AS content:penflufen %w/w | 0.026 | 0.025 | 0.024 | 0.026 | | Variation of Content | / | -3.8% | -7.7% | 0.0% | | pH at RT | 6.4 | / | / | 5.9 | | Acceptable  The preparation is stable 30 months at ambient temperature. After 36 months the loss of cypermethrin is above 10%, as no efficacy data and identification of degradation products were provided, the shelf life is set at 30 months | Raphalen E. 2022  Report no.  402/17/1256F/c-e |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 method (2000) | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | The test item 18V33CP-PE was considered to be stable after a low temperature storage procedure for 7 days at 0 ± 2°C; no change of colour, and no deposit or phase partition was observed.   |  |  | | --- | --- | |  | T 7 days | | Storage stability at 0"C during 7 days | The test item was physically stable after 7 days at 0°C. No deposit or phase partition was observed | | Acceptable  The product is stable 7 days at 0°C. | Raphalen E.2019  Report no.  402/17/1256F-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Not required as the commercial packaging of the product 18V33CP-PE are totally opaque (metal cans). | Acceptable | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | The test item 18V33CP-PE was considered to be stable after 8 weeks at 40 ± 2°C and after 7 days at 0 ± 2°C. The individual commercial packaging are sealed. With this closure system, the packaging are leak-tight. | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | Please see storage stability studies. | - | - |
| Wettability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Wet sieve analysis and dry sieve test | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Disintegration time | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Persistent foaming | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Flowability/Pourability/Dustability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Burning rate — smoke generators | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Burning completeness — smoke generators | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Composition of smoke — smoke generators | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Spraying pattern — aerosols | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Physical compatibility | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Chemical compatibility | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Degree of dissolution and dilution stability | - | - | Not applicable. The product 18V33CP-PE is a ready-to-use liquid. | - | - |
| Surface tension | EU Method A.5, OECD Test Guideline115 (ring method) | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | The mean surface tension of the pure test item 18V33CP-PE was 28.14 mN/m at a temperature of 20.0 ± 2°C. The test item was considered as surface-active in the experimental conditions used. | Acceptable | Raphalen E.2019  Report no.  402/17/1256F-e |
| Viscosity | OECD Test Guideline 114 ISO Standard 2431 (flow cup method) | Product 18V33CP-PE Batch number: 130218V33CP-PE containing 0.026% w/w of penflufen and 0.17% w/w of cypermethrin | The mean kinematic viscosity of the product 18V33CP-PE was found to be < 6.62mm2/s at 20.0 ± 0.2°C and at 40.0 ± 0.2°C. | Acceptable | Raphalen E.2019  Report no.  402/17/1256F-e |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product 18V33CP-PE is an any other liquid (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a translucent yellow light. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 30 months at ambient temperature when stored in steel with internal epoxy varnish packaging material (commercial packaging material).  After 36 month the content of active substance cypermethrin decreases by more than 10%. Therefore, as no justification and information about degradation products and efficacy after a storage superior to 36 months are provided, the shelf-life is set at 30 months.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AL formulation.  A mitigation measure should be added on the label: do not store at temperature above 40°C |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | The product 18V33CP-PE contains 0.026% w/w of penflufen (CAS No.494793-67-8), which is not explosive according to Assessment Report Penflufen Product-type 8 (Wood preservative), March 2017. The product 18V33CP-PE contains 0.168% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8), which is not explosive according to Assessment Report Cypermethrin cis:trans/40:60 Product-type 8 (Wood preservative), July 2013 and to its safety datasheet. The main constituent of the product 18V33CP-PE is water (cf PAR confidential paragraph hazard properties); this ingredient is inert and has no chemical group associated with explosive properties. The other components (cf PAR confidential paragraph hazard properties) are not classified as explosive according to their safety datasheets. In addition, due to their low contents in the product, they are not considered as being able to lead to a classification of the product 18V33CP-PE. Therefore, the product 18V33CP-PE is not expected to present a significant hazard for explosivity and test is considered as unnecessary.  Moreover, a DSC test has been performed, no exothermic reaction was observed up to 600°C under, the preparation is not explosive. | Acceptable  The preparation is not explosive. | IUCLID +  Detrimont H, 2022  Report N° 21-922014-001 |
| Flammable gases | - | - | - | Not relevant as the product is a liquid | - |
| Flammable aerosols | - | - | - | Not relevant as the product is a liquid | - |
| Oxidising gases | - | - | - | Not relevant as the product is a liquid | - |
| Gases under pressure | - | - | - | Not relevant as the product is a liquid | - |
| Flammable liquids | Statement  Method EC A.9. | - | The product 18V33CP-PE contains 0.026% w/w of penflufen (CAS No.494793-67-8), which is not a highly flammable solid according to Assessment Report Penflufen  Product-type 8 (Wood preservative), March 2017.  The product 18V33CP-PE contains 0.168% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8), which has no flammable properties (no flash point up to 110°C) according to Assessment Report Cypermethrin cis:trans/40:60 Product-type 8 (Wood preservative), July 2013 and to its safety datasheet.  The main constituent of the product 18V33CP-PE is water (cf PAR confidential paragraph hazard properties); this ingredient is inert and non-flammable.  The other components (cf PAR confidential paragraph hazard properties), are not classified as flammable according to their safety datasheets, and due to their low contents in the product, they are not considered as being able to lead to a classification of the product 18V33CP-PE*.*  Moreover a flash point has been performed on the product and it is >99°C (see storage stability studies). | Acceptable  The preparation is not a flammable liquid. | IUCLID  Raphalen E.2019  Report no.  402/17/1256F-e |
| Flammable solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-reactive substances and mixtures | Statement  DSC | Batch  20102118V33CPPE  containing 0.026%  w/w of penflufen  and 0.17% w/w of  cypermethrin | The product 18V33CP-PE contains 0.026% w/w of penflufen (CAS No.494793-67-8), which is not self-reactive according to Assessment Report Penflufen Product-type 8 (Wood preservative), March 2017. The product 18V33CP-PE contains 0.168% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8), which is not self-reactive according to Assessment Report Cypermethrin cis:trans/40:60 Product-type 8 (Wood preservative), July 2013 and to its safety datasheet. The main constituent of the product 18V33CP-PE is water (cf PAR confidential paragraph hazard properties); this ingredient is inert and does not present self-reactive properties. The other components (cf PAR confidential paragraph hazard properties), are not classified as self-reactive according to their safety datasheets, and due to their low contents in the product, they are not considered as being able to lead to a classification of the product 18V33CP-PE.  Moreover, a DSC test has been performed. Test conditions :  Crucibles with crimped lids (steel)  Heating procedure : 5°C/min from room temperature to 600°C.  Nitrogen gas  no exothermic reaction was observed up to 600°C | Acceptable  *The DSC was not performed with high pressure crucible, therefore the results of the DSC cannot be taken into account. However, based on the amount of water of the product and the known property to suppress the self-reactive and explosive properties, we can consider that* the preparation is not a self-reactive mixture. | IUCLID +  Detrimont H, 2022  Report N° 21-922014-001 |
| Pyrophoric liquids | Statement | - | Test is not required as the product 18V33CP-PE does not contain any components classified as pyrophoric according to their safety data sheets. Moreover, experience in manufacture and handling shows that the product 18V33CP-PE do not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable | IUCLID |
| Pyrophoric solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-heating substances and mixtures | Statement | - | The product 18V33CP-PE contains 0.026% w/w of penflufen (CAS No.494793-67-8), which is not self-heating according to Assessment Report Penflufen Product-type 8 (Wood preservative), March 2017. The product 18V33CP-PE contains 0.168% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8), which is not classified as self-heating according to Assessment Report Cypermethrin cis:trans/40:60 Product-type 8 (Wood preservative), July 2013. The main constituent of the product 18V33CP-PE is water (cf PAR confidential paragraph hazard properties); this ingredient is inert and does not present self-heating properties. The other components (cf PAR confidential paragraph hazard properties), are not classified as self-heating according to their safety datasheets, and due to their low contents in the product, they are not considered as being able to lead to a classification of the product. Moreover, the product 18V33CP-PE is not expected to present a significant hazard for auto-flammability (please refer to “Auto-ignition temperatures of products (liquids)” properties below) | According to Guidance on the Application of the CLP Criteria, the product has a low melting point (< 160 °C), so it should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is drastically reduced. | IUCLID |
| Substances and mixtures which in contact with water emit flammable gases | - | - | - | Not relevant as the product is a solution with more than 80% of water. | - |
| Oxidising liquids | Statement | - | The product 18V33CP-PE contains 0.026% w/w of penflufen (CAS No.494793-67-8). This substance contains oxygen which is chemically bonded only to carbon. Therefore, the classification procedure for oxidising properties does not apply. Moreover, penflufen is not classified as oxidising solid according to Assessment Report Penflufen Product-type 8 (Wood preservative), March 2017. The product 18V33CP-PE contains 0.168% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8). This substance contains oxygen atoms which are chemically bonded only to carbon. Therefore, the classification procedure for oxidising properties does not apply. Moreover, cypermethrin is not classified as oxidising liquid according to Assessment Report Cypermethrin cis:trans/40:60 Product-type 8 (Wood preservative), July 2013. The main constituent of the product 18V33CP-PE is water (cf PAR confidential paragraph hazard properties); this ingredient is inert and the classification procedure for oxidising properties does not apply as oxygen is chemically bonded only to hydrogen. The other components (cf PAR confidential paragraph hazard properties), are not classified as oxidising according to their safety datasheets and the classification procedure for oxidising properties does not apply to these co-formulants according to their structural formulas (substances containing oxygen atoms which are chemically bonded only to carbon or hydrogen atoms).  In addition, due to their low contents in the product, they are not considered as being able to lead to a classification of the product 18V33CP-PE. Therefore, the product 18V33CP-PE is not expected to have oxidising properties and test is considered as unnecessary. | Acceptable  The preparation has no oxidizing properties. | IUCLID |
| Oxidising solids | - | - | - | Not relevant as the product is a liquid | - |
| Organic peroxides | Statement | - | The product 18V33CP-PE is not concerned by the physical hazard “organic peroxides” as its components are not expected to form or contain organic peroxides. | Acceptable | IUCLID |
| Corrosive to metals | Manual of  Tests and  Criteria,  Method C.1 | Batch  20102118V33CPPE  containing 0.026%  w/w of penflufen  and 0.17% w/w of  cypermethrin | A test UN C1 has been provided: | Acceptable  The preparation was not considered to be corrosive to metals according to the test UN C.1. | RAPHALEN E. 2022, study number No.4021/21/1170F/b-e |
|  |  |  |  |  |  |
| Auto-ignition temperatures of products (liquids and gases) | Method  A.15 (2008) | Batch  20102118V33CPPE  containing 0.026%  w/w of penflufen  and 0.17% w/w of  cypermethrin | A preliminary test was performed: no auto-ignition temperature was observed up to 600°C (corrected value). | Acceptable  The preparation has no auto-ignition temperature. | DETRIMONT H. (2022), study number 21-922014-001 |
| Relative self-ignition temperature for solids | - | - | - | Not relevant as the product is a liquid | - |
| Dust explosion hazard | Statement | - | - | Not relevant as the product is a liquid | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. The product is not classified for physical hazard. |

### Methods for detection and identification

Report: Raphalen E. 2019 Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product 18V33CP-PE before and after an accelerated storage procedure for 14 days at 54 ± 2°C, in compliance with CIPAC MT 46.3 method (Handbook J, 2000)

Report no 402/17/1256F-e

Test facility: XXX

Principle of the method:

The cypermethrin and penflufen contents are determined after extraction from the formulation and quantified by liquid chromatography using a UV detector (210 nm). Quantification is performed using external standard calibration at retention time of about 9.55 min, 9.68 min and 9.75 min for cypermethrin peaks and 3.60 min for penflufen peak.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (acetonitrile) * blank formulation * Reference item of the active substance cypermethrin reference item, the penflufen (all isomers) * Test item of the product   No interference was found: no peak appears in the solvent blank and in the blank formulation, one peak is observed at the same retention time for the reference item and test item. No additional peak appears near the retention times of the active substances peaks in the blank formulation spiked with the reference items and in the test item  All chromatograms were available. | |
| Linearity | Linearity was studied by carrying out five concentrations between 80% and 120% of the cypermethrin (from 40mg/L to 60 mg/L) and for penflufen (from 24 mg/L to 36 mg/L).  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance : penflufen | 80% to 120%  n=5  1st serie: Y = 4.326 \* 104 \* x - 4.307 \* 104  r = 0.99620  2nd serie:  80 – 120% range  y = 3.969 \* 104 \* x + 3.861 \* 104  r = 0.99869 |
| Active substance: cypermethrin | 80% to 120%  n = 5  1st serie:  80 – 120% range  y = 5.131 \* 104 \* x + 9.345 \* 104  r = 0.99944  2nd serie:  80 – 120% range  y = 5.178 \* 104 \* x + 4.226 \* 104  r = 0.99996 |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance : penflufen at C=0.00026% | RSD = 1.56% |
| Active substance : cypermethrin at C = 0.0017% | RSD = 0.56% |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 0.030% penflufen | 96-101.13 | 99.2 | 1.62 | 12 | | 0.050% cypermethrin | 99-101 | 100 | 0.41 | 12 | | |

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

Analytical methods for cypermethrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report of cypermethrin Product-type 08, July 2013.The applicant V33SA has a Letter of Access from Arysta LifeScience Benelux SPRL.

As the active substance cypermethrin is not classified as Toxic or for these data.

Soil (principle of method and LOQ)

GC with MS detection,

LOQ = 0.05 mg/kg (LOQ = 0.5 µg/kg for sediment)

Air (principle of method and LOQ)

GC with MS detection,

LOQ = 0.375 µg/m3

Water (principle of method and LOQ)

GC with electron capture detection,

LOQ = 0.01 µg/L

Body fluids and tissues (principle of method and LOQ)

Not evaluated

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes):

GC with electron capture detection,

LOD = 0.05 mg/kg (oilseed rape)

0.025 mg/kg (wheat).

Analytical methods for penflufen residues in soil, air, water (drinking water) and sediment are available in Assessment Report of penflufen Product-type 08, March 2017.The applicant V33SA has a Letter of Access from LANXESS Deutschland GmbH.France SPRL.

As the active substance penflufen is not classified as Toxic or for these data.

Soil (principle of method and LOQ)

Principle: HPLC-MS/MS

LOQ: 5.0 μg/kg

Air (principle of method and LOQ)

Principle: HPLC-MS/MS

LOQ: 4 μg/m3

Water (principle of method and LOQ)

Principle: HPLC-MS/MS

LOQ: 0.05 μg/L

Body fluids and tissues (principle of method and LOQ)

Not relevant

As the product 18V33CP-PE is not intended to be used on surfaces in contact with food/feed of plant and animal origins, analytical methods for the determination of penflufen residues in food/feed of plant and animal origins are unnecessary.

No analytical methods for penflufen residues in food/feed of plant and animal origins are available in the Assessment Report Penflufen Product-type 8 (Wood preservative), March 2017.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance cypermethrin and penflufen in the product.  The BIT is defined as a SOC. No analytical method has been provided. However, as it is not expected that the concentration of BIT is modified during storage, no further data required.  Analytical methods were provided at EU level for the determination of cypermethrin residue in soil, water and air with respectively LOQ = 0.5 mg/kg, 0.375 µg/m3 and 0.01 µg/L.  Analytical methods were provided at EU level for the determination of penflufen residue in soil, water and air with respectively LOQ = 5.0 µg/kg, 4 µg/m3 and 0.05 µg/L.  Active substances are not toxic (T) or very toxic (T+) active substances. Therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of penflufen in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

Main Group 02: Preservatives

Product Type 08: Wood preservatives

The product 18V33CP-PE is a ready-to-use water-based wood preservative containing cypermethrin and penflufen. It is intended to be used by superficial application for preventive and curative treatment of wood; for curative treatment, superficial application can be completed by application by injection in wood.

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

According to the uses claimed by the applicant, the product 18V33CP-PE is used to kill wood rotting fungi (*Coniophora puteana, Gloephilum trabeum, Poria placenta* and *Coriolus versicolor*), larvae of wood boring insects (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and, termites (*Reticulitermes*spp.).

The product is intended to be used:

* for preventive treatment by superficial application for wood used in use classes 1 to 3 application against wood boring beetles, wood rotting fungi and termites;
* for curative treatment by superficial application (that could be completed by injection), for wood in service, indoor and outdoor, against wood boring insects and termites.

The application rates recommended by the applicant are the following:

* Preventive treatments: superficial application at 200 g of product / m² of wood
* Curative treatment: superficial application at 300 g of product / m² of wood (+ injection 150 g of product / m² of wood if need be).

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

The product 18V33CP-PE kills the insects after ingestion, and acts against fungi. Humaneness is not applicable.

#### Mode of action, including time delay

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon (see Assessment Report Cypermethrin, PT08, 12/07/2013).

Penflufen represents a new class of chemistry from the chemical group Pyrazolecarboxamides of the group of SDHI (succinate dehydrogenase inhibitor). The biochemical mode of action of penflufen has been shown to rely on the inhibition of the enzyme succinate dehydrogenase (complex II) within the fungal mitochondrial respiratory chain, thus blocking electron transport (see Assessment Report penflufen, PT08, March 2017).

There is no time delay between the application of the product and the beginning of the preventive fungicidal and insecticidal activities. The effect is immediate.

Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the product demonstrated a slow action on *Hylotrupes bajulus* and a deferred effect on *Anobium punctatum.*

#### Efficacy data

Laboratory studies were conducted according to the BPR Efficacy Guidance (version 3.0, April 2018), and standards EN 599-1 and EN 14128. The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
| MG 02: preservatives | Wood preservative  Preventive treatment | 17V33CP - concentré (penflufen 0.28% w/w pure + cypermethrin 0.47% w/w pure) | *C. puteana*  *G. trabeum*  *P. placenta*  *C. versicolor* | EN 113 after EN 73  (evaporation) | - On scots pine and beech blocks, targeted concentrations to be tested: 0.0, 8.0, 10.0, 12.5, 15.6, 19.5, 24.3, 30.4 and 38.0 kg of product/m3 of wood.   * Application by vacuum impregnation * ageing according to EN 73 evaporation procedure, during 3 months * 6 test blocks for each treatment and each fungal strain, pine used for *C. puteana, G. trabeum* and *P. placenta*; beech used for *C. versicolor* * untreated controls: one untreated control block included with the treated block in each replicate + untreated virulence control blocks * examination after 4 months exposure of the blocks to the fungal strains. * effect investigated : mass loss of the test blocks, induced by the fungal development * calculation of the mid toxic values and biological reference value. | Virulence control: mean mass loss >20% for the 4 strains. This validates the test.  Mid toxic values of the test product:   * cannot be determined for *C. puteana, P. placenta* and *C. versicolor*, but toxic value lower than 8.0 or 7.8 kg/m3 * *G. trabeum*: 9.0 kg/m3   Thus, biological reference value of the test product for brown and white rot fungi, on softwood and hardwood, after evaporation procedure, is 9.0 kg/m3. | S6.7\_01  Gabille M. and  Le Bayon I., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 17V33CP - concentré (penflufen 0.28% w/w  pure + cypermethrin 0.47% w/w pure) | *C. puteana*  *G. trabeum*  *P. placenta*  *C. versicolor* | EN 113 after  EN 84  (leaching) | - on scots pine and beech blocks, targeted concentrations to be tested: 0.0, 8.0, 10.0, 12.5, 15.6, 19.5, 24.3, 30.4 and 38.0 kg of product/m3 of wood.   * application by vacuum impregnation * ageing according to EN 84 leaching procedure, during 2 weeks * 6 test blocks for each treatment and each fungal strain, pine used for *C. puteana, G. trabeum* and *P. placenta*; beech used for *C. versicolor* * untreated controls: one untreated control block included with the treated block in each replicate + untreated virulence control blocks * examination after 4 months exposure of the blocks to the fungal strains. * effect investigated : mass loss of the test blocks, induced by the fungal development * calculation of the mid toxic values and biological reference value | Virulence control: mean mass loss >20% for the 4 strains. This validates the test.  Mid toxic values of the test product:   * cannot be determined   Toxic value lower than 8 kg/m3 for *C. puteana* and *G. trabeum*, lower than 7.9 kg/m3 for *P. placenta* and lower than 8.1 kg/m3 for *C. versicolor*.  Thus:   * biological reference value of the test product for brown rot fungi, on softwood, after leaching procedure, is 8 kg/m3. * biological reference value of the test product for brown and white rot fungi, on softwood and hardwood, after leaching procedure, is 8.1 kg/m3. | S6.7\_02 Gabille M. and Le Bayon I., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | House longhorn beetle:  *H. bajulus* | EN 46-1 after EN73 (evaporation) | * on scots pine blocks * application by brushing, 200 mL/m² * ageing according to EN 73 evaporation procedure, during 3 months * 6 replicate test blocks * 3 replicate untreated controls * 10 larvae of *H. bajulus* exposed on each test block * examination after 4 weeks exposure * effect investigated : mortality of the insects' larvae * calculation of the mortality percentage | Control: mean percentage of surviving larvae 83%. This validates the test (survival > 70%).  Test blocks:   * dead larvae not having tunneled: 100%. * efficacy criterion (mortality 100%) matched.   The product 18V33CP-PE at 200 mL/m² is effective against *H. bajulus* larvae, after evaporation ageing procedure. | S6.7\_03 Arancon J., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | House longhorn beetle:  *H. bajulus* | EN 46-1 after EN 84 (leaching) | - on scots pine blocks   * application by brushing, 200 mL/m² * ageing according to EN 84 leaching procedure, during 4 weeks * 6 replicate test blocks * 3 replicate untreated controls * 10 larvae of *H. bajulus* exposed on each test block * examination after 4 weeks exposure * effect investigated : mortality of the insects' larvae * calculation of the mortality percentage | Control: mean percentage of surviving larvae 83%. This validates the test (survival > 70%).  Test blocks:   * dead larvae not having tunneled: 100%. * efficacy criterion (100% mortality) matched.   The product 18V33CP-PE at 200 mL/m² is effective against *H. bajulus* larvae, after leaching ageing procedure. | S6.7\_04 Arancon J., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | Common furniture beetle: *A. punctatum* | EN 49-1 after EN 73 (evaporation) | * on *Quercus petraea* sapwood blocks * application by brushing, 200 mL/m² (2 applications) * ageing according to EN 73 evaporation procedure, during 3 months * 5 replicate test blocks * 5 replicate untreated controls * adults of *A. punctatum* exposed on each test block during 5 weeks * number of eggs laid in accordance with EN49-1 (50) * examination after 26 weeks * effect investigated : mortality of the insects' eggs and larvae * calculation of the eggs' mortality percentage | Control: percentage of hatched eggs 91%, 64 alive larvae found before stopping count, and at least 9 living larvae found on each test block. This validates the test (at least 50 alive larvae, and alive larvae on each block).  Test blocks:   * hatched eggs: none * living larvae: none * efficacy criterion (no live larvae) matched.   The product 18V33CP-PE at 200 mL/m² is effective against *A. punctatum*, after evaporation ageing procedure. | S6.7\_05 Schumacher P. and Fennert E.M., 2019  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | Common furniture beetle:  *A. punctatum* | EN 49-1 after  EN 84 (leaching) | * on *Quercus petraea* sapwood blocks * application by brushing, 200 mL/m² (2 applications) * ageing according to EN 84 leaching procedure, during 2 weeks * 5 replicate test blocks * 5 replicate untreated controls * adults of *A. punctatum* exposed on each test block during 6 weeks * number of eggs laid in accordance with EN49-1 (50)examination after 26 weeks * effect investigated : mortality of the insects' eggs and larvae * calculation of the eggs' mortality percentage | Control: percentage of hatched eggs 96%, 58 alive larvae found before stopping count, and at least 8 living larvae found on each test block. This validates the test (at least 50 alive larvae, and alive larvae on each block).  Test blocks:   * hatched eggs: none * living larvae: none * efficacy criterion (no live larvae) matched.   The product 18V33CP-PE at 200 mL/m² is effective against *A. punctatum*, after leaching ageing procedure. | S6.7\_06 Schumacher P. and Fennert E. M., 2019  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | Powder post beetle:  *L. brunneus* | EN 20-1 after EN 73 (evaporation) | * on *Quercus spp.* sapwood blocks * application by brushing: 200 mL/m² * ageing according to EN 73 evaporation procedure, during 3 months * 5 replicate test blocks * 5 replicate untreated controls + 5 replicate solvent controls * minimum 5 couples of *L. brunneus*   exposed on each test block   * examination after 26 weeks * effect investigated : mortality of the insects' larvae/pupae and adults * calculation of the insects' mortality percentage | Control: 101 alive larvae / pupae found before stopping count.  This validates the test (at least 20 larvae retrieved from each block, with at least 85% alive).  Test blocks:   * emerged adults: none * insects retrieved from the blocks: none * efficacy criterion (no live larvae nor emerged adults) matched.   The product 18V33CP-PE at 200 mL/m² is effective against *L. brunneus*, after evaporation ageing procedure. | S6.7\_07 Brunet C. and Paulmier I., 2019  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | European subterranean termite: *R. grassei* | EN 118 after EN 73 (evaporation) | * on scots pine blocks * application by brushing, 200 mL/m² * ageing according to EN 73 evaporation procedure, during 3 months * 6 replicate test devices * 3 replicate untreated test devices * 250 workers, 5-6 nymphs and 2 soldiers exposed on each device * examination after 8 weeks exposure * effect investigated : mortality of the termites and reduction of the damages on the test blocks * calculation of the insects' mortality percentage and mean damage rating | Control: mean 82% surviving workers, and damage rating 4. This validates the test (damage rating 4 for all the blocks and > 50% surviving workers)  Test devices:   * surviving workers: none * damage rating: 1 for all test blocks * efficacy criterion (mean damage rating < 2 and no more than one sample rated 2) matched   The product 18V33CP-PE at 200 mL/m² is effective against *Reticulitermes* spp*.*, after evaporation ageing procedure. | S6.7\_08  Arancon J., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | European subterranean termite: *Reticulitermes grassei* | EN 118 after EN 84 (leaching) | * on scots pine blocks * application by brushing, 200 mL/m² * ageing according to EN 84 leaching procedure, during 4 weeks * 6 replicate test devices * 3 replicate untreated test devices * 250 workers, 5-6 nymphs and 2 soldiers exposed on each device * examination after 8 weeks exposure * effect investigated : mortality of the termites and reduction of the damages on the test blocks * calculation of the insects' mortality percentage and mean damage rating | Control: mean 82% surviving workers, and damage rating 4. This validates the test (damage rating 4 for all the blocks and > 50% surviving workers)  Test devices:   * surviving workers: none * damage rating: 1 for all test blocks * efficacy criterion (mean damage rating < 2 and no more than one sample rated 2)   The product 18V33CP-PE at 200 mL/m² is effective against *Reticulitermes* spp*.*, after leaching ageing procedure. | S6.7\_09 Arancon J., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 18V33CP-PE  (penflufen 0.026% w/w pure + cypermethrin 0.17% w/w pure) | House longhorn beetle:  *H. bajulus* | EN 1390 | * on scots pine blocks * application by brushing, 300 mL/m² * 10 replicate test blocks * 2 replicate untreated test bocks * 6 larvae on each test block * examination after 24 weeks exposure * effect investigated : mortality of the larvae * calculation of the insects' mortality percentage | Control: no mortality. This validates the test (no mortality)  Test blocks:   * 53 dead larvae, i.e. 88% mortality * efficacy criterion (≥ 80% mortality) matched   The product 18V33CP-PE at 300 mL/m² is effective in curative action against *H. bajulus*. | S6.7\_10 Schumacher P. and Fennert E. M., 2018  RI = 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 18V33CP-PE  (penflufen 0.026% w/w pure +  cypermethrin 0.17% w/w pure) | Common furniture beetle:  *A. punctatum* | EN 370 after  EN 73  (evaporation) | According to EN 370 and EN 73 - on scots pine blocks   * application by brushing, 300 mL/m² * ageing according to EN 73 evaporation procedure, during 3 months * 6 replicate test blocks * 6 replicate untreated test bocks * examination after 38 weeks exposure,   7.5 weeks after beginning of hatching in the control blocks  Effect investigated: mortality of the larvae and hatched beetles.  Calculation of the insects' mortality percentage. | Control: 0.1% mortality. This validates the test.  Test blocks:  - no hatched beetles  - 46.5% mortality on total number of insects and 96.9% mortality on adult beetles  - efficacy criterion (max. 3 hatched beetles alive) matched  The product 18V33CP-PE at 300 mL/m² is effective in curative action against *A. punctatum* | S6.7\_11  Schumacher P. and Fennert E.M., 2019  RI = 1 |

**Fungicidal and insecticidal preventive treatment for wood in use classes 1 to 3, at 200 mL/m².**

Regarding the preventive efficacy against wood boring beetles, for superficial application, the product is efficient according to EN 46-1 after (EN 73/84) against house longhorn beetles, after EN 49-1 after (EN 73/EN 84) against common furniture beetles, EN 20-1 after (EN 73) against powder post beetles (EN 20-1 cannot be done after EN 84) at the application rate of 200 g/m² equivalent to 200 mL/m² (density = 1).

Regarding the preventive efficacy against termites, for superficial application, the product 18V33CP-PE is efficient according to EN 118 after (EN 73/EN 84) against subterranean termites (*Reticulitermes* spp.) at the application rate of 200 g/m² equivalent to 200 mL/m².

Regarding the preventive efficacy against wood rotting fungi, according to EN 113 after (EN 73/84) the test product 17V33CP-concentré (penflufen 0.28% w/w + cypermethrin 0.47% w/w, detailed composition is provided in document " A3 6\_Confidential\_composition\_18V33CP-PE\_update20211217) is efficient against wood rotting fungi (brown rot and white rot) for use classes 2 and 3 at the application rate of 9.0 kg/m3 equivalent to 18.0 g/m².

According to the active substances analysed in the product (penflufen analysed 0.29% w/w, cypermethrin analysed 0.50% w/w), this is 18\*0.0029 = 0.0522 g/m² penflufen and 18\*0.0050 = 0.09 g/m² cypermethrin.

The product 18V33CP-PE is an almost exact 9% m/m dilution of 17V33CP-concentré in water, for penflufen and for all the other components, but not for cypermethrin. The ready-for-use product contains 0.183% m/m technical cypermethrin, while 9% of 17V33CP-concentré would be 0.045% m/m. The cypermethrin content has been only increased in the product 18V33CP-PE to have a sufficient insecticidal efficacy. Moreover, cypermethrin has no fungicidal efficacy. Thus, the read-across between 17V33CP-concentré and 18V33CP-PE for fungicidal efficacy has to be considered as acceptable.

The pure active substances' content in the ready-for-use product 18V33CP-PE is 0.026% w/w penflufen and 0.168% w/w cypermethrin. Thus, the equivalent application rates of the product 18V33CP-PE to obtain the effective concentrations of active substances shown with the product 17V33CP-concentré would be 0.0522/0.00026 = 200.8 g/m² for penflufen and 0.09/0.00168 = 53.6 g/m² for cypermethrin.

The maximum ready-for-use product application rate is obtained for penflufen: 200.8 g/m². Thus to ensure that the minimum amount of penflufen is applied, it is necessary to apply 200.8 g/m² of the ready-for-use product. For simplification, 200 g/m² is intended. Since the product has a density of 1, this corresponds to 200 mL/m².

As for use class 3, the demonstration of the efficacy is based on the EN 113 standard. In that case, the use of a top coat is required according to the EN 599[[3]](#footnote-4) (§5.2.17 & §5.2.18). Consequently, it can be concluded that, for preventive superficial application on wood for use class 3, a top coat has to be applied.

The critical value for a preventive use of the ready-for-use 18V33CP-PE product is thus 200 mL/m².

**Insecticidal curative use for wood in service, at 300 mL/m².**

Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product 18V33CP-PE is efficient according to respectively EN 1390 and EN 370 (+ EN 73) against *Hylotrupes bajulus* with a slow action and against *Anobium punctatum* with a differed activity, at the application rate of 300 mL/m².

According to EN 14128[[4]](#footnote-5), if curative treatment against Lyctus brunneus is demanded, a curative wood preservative "for *Hylotrupes* and *Anobium*" should be applied. The curative efficacy against wood boring beetles is then validated.

Regarding the curative claim against termites (*Reticulitermes* spp.), no curative efficacy standard are available against termites. However, the objective of curative products are, as for the preventive treatments against termites (tested following the standard EN 118 + EN73/84), to protect wood against termites and to eliminate termites in the wood. Their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application.

The critical value for a curative use of the ready-for-use 18V33CP-PE product is thus 300 mL/m².

Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection and in combination with a superficial treatment, at the application rate of 150 g of product 18V33CP-PE / m² of wood prior a superficial treatment at 300 mL/m² is validated.

These label claims are in accordance with the efficacy tests conducted. The claimed target organisms and the recommended application rates have been tested.

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| **Conclusion on the efficacy of the product** |
| The efficacy trials have been done according to standards EN 599-1 and EN 14128. They show that the product 18V33CP-PE is effective as preventive treatment, by superficial application, against wood rotting fungi, larvae of wood boring insects (house longhorn beetle, common furniture beetle and powder post beetle) and termites (*Reticulitermes* spp.) for wood in use classes 1 to 3 and as curative treatment, by superficial application and injection if needed, of wood in service, against larvae of wood-boring beetles (house longhorn beetle, common furniture beetle and powder post beetle) and termites (genus *Reticulitermes* spp.). The application rate is 200 mL/m² of wood for preventive treatment and 300 mL/m² for curative treatment. |

#### Occurrence of resistance and resistance management

Resistance to cypermethrin has been reported for a number of pests both in agriculture and public health (German cockroach (Atkinson *et al*., 1991), house fly (Shen and Plapp, 1990), stable fly (Cilek and Greena, 1994), Culex mosquitos (Wan-Norafilack *et al*., 2013), Aedes mosquitos (Saavedra- Rodriguez *et al*., 2008), Anopheles mosquitos (Müller et al., 2008), when cypermethrin has been used as a general insecticide (PT18 use). 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 (see Assessment Report cypermethrin, PT08, July 2013).

However, no specific data has been found in the literature regarding occurrence of resistance to cypermethrin among wood-boring insects and termites. There are no reported cases of development of resistance involving the use of cypermethrin in wood preservation.

Regarding penflufen, in the plant protection area, it has been listed by FRAC (Fungicide Resistance Action Committee) under code No. 7 (SDHI), with medium to high risk of resistance, and resistance management required. As published in the Minutes of the 2020 SDHI working group of FRAC, strains with low resistance to SDHI has been found in field samples of pathogenic fungi.

For biocidal purposes, penflufen is a new active substance. Therefore, information on the occurrence of resistance from the use in wood preservation is not available. No specific data has been found in the literature regarding occurrence of resistance to penflufen among wood-destroying basidiomycetes.

Thus, specific measures in order to prevent the development of resistances to penflufen are regarded to be not necessary, but for cypermethrin resistance, strategies such as alternate with active substances with different modes of action and avoidance of over frequent use, which are efficient standard practices in agriculture, should be applied also to biocide uses of 18V33CP-PE, in order to combat any potential for the onset of resistance.

In case of apparition of resistance phenomena in wood preservative context, active substances with other mode of action should be used.

#### Known limitations

None

#### Evaluation of the label claims

Please refer to Efficacy conclusion section 2.2.5.5.

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

The product 18V33CP-PE is not intended to be used with another biocidal product.

### Risk assessment for human health

#### Assessment of effects on Human Health

No toxicological studies have been submitted for the product 18V33CP-PE.

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

***Skin corrosion and irritation***

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

***Eye irritation***

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

***Respiratory tract irritation***

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

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitizing to skin |
| Justification for the value/conclusion | Both ingredients (C(M)IT/MIT) and 1,2-benzisothiazol-3(2H)-one (BIT) are classified Skin Sens. Cat 1A - H317.  Their concentration in the product is below their respective specific concentration limit (0.0015% and 0.036%) and therefore, the product is not classified H317.  However, both ingredients are present in the product at a concentration above 1/10 of the specific limit. This induces the additional labelling information EUH208 – “Contains C(M)IT/MIT and BIT. May produce an allergic reaction.” |
| Classification of the product according to CLP and DSD | No classification required but the additional labelling information EUH208 – “Contains C(M)IT/MIT and BIT. May product an allergic reaction.” |

***Respiratory sensitization (ADS)***

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

***Acute toxicity***

*Acute toxicity by oral route*

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

*Acute toxicity by inhalation*

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

*Acute toxicity by dermal route*

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

***Information on dermal absorption***

| **Summary table of in vitro studies on dermal absorption** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In-vitro* method for dermal absorption,  OECD 428,  GLP: yes,  Reliability: 1 | Human skin membranes (from 4 donors)  2 cells per donor  8 skin preparations  Thickness: 336-400 µm | Test item: 18V33CP-PE  1.7 g/L corresponding to 0.17% w/w of a.s. pure | Mean recovery: 96.88 + 1.8%  Skin excess: 89.14 + 5.76%  First two layers of the stratum corneum: 2.39 + 1.16%  Strips 3 to 15: 3.04 + 2.47%  Skin = Epidermis + partial dermis = 2.33 + 2.4%  Receptor fluid compartment: 0.35 + 0.11%  Absorption = 2.68 + 2.51% | No deviation | Bernal J. (2019) |

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Penflufen | Cypermethrin |
| Values | 50% | 9.2% |
| Justification for the selected values | Default dermal absorption value for water-based formulation with a concentration in active substance below 5%, according to the EFSA Guidance on dermal absorption (2017) | The mean total recovery was 96.89 + 1.8%, which is between 100 + 5% and validate the results obtained.  At 12h, the mean lower limit of confidence (T0.5) is below 75% (70.95%).  After correction with the k factor and taking into account the standard deviation, a corrected dermal absorption value of 9.2% is calculated for cypermethrin.  For details, please refer to the excel data sheet in Annexe 3.2. |

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

No Substance of Concern (SoC) has been identified.

Please refer to the Confidential annex for further information.

#### Exposure assessment and Risk characterisation

The product 18V33CP-PE is a ready-to-use wood preservative used by professional and non-professional users. It is used for preventive and curative treatment of wood against wood-boring insects, termites and wood-rotting fungi, indoor and outdoor, by brush application, spray application and/or injection.

For preventive treatment, the user applied 2 layers of product (200 ml/m²) by brushing (with a paint brush) or spraying (with a garden spray or a low pressure paint gun) on the surface.

For curative treatment, injections are performed in combination with the surface application (brush or spray application).

First, the product is injected (150 ml/m²) into drilled holes with a syringe or another appropriate device. Then, 3 layers of product are applied (300 ml/m²) on the surface by brushing or spraying. The curative treatment is considered the worst-case in the risk assessment and covers the preventive treatment.

Secondary exposure may occur from adults sanding the treated article (acute and chronic exposure), and toddlers chewing treated wood chip and playing on wooden treated structures. Inhalation of volatilised residues of actives substances after application is also to considered for adults and toddlers.

The product contains two active substances: Penflufen and Cypermethrin.

According to the Assessment Report of Penflufen and Cypermethrin (respectively, United Kingdom, 2017, and Belgium, 2013), they are both characterised by systemic effects observed in toxicity studies. Consequently, a quantitative risk assessment for systemic effects is performed for the biocidal product for dermal, inhalation and oral routes when relevant.

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

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

**Summary table: main paths of human exposure**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: main paths of human exposure** | | | | |  |
| **Exposure path** | **Primary (direct) exposure** | | **Secondary (indirect) exposure** | |  |
| **Professional users** (including industrial users and trained professional users) | **Non-**  **professional users** | **Professional users**  (including industrial users and trained professional users) | **Non-**  **professional bystanders/ General public** | **Via food** |
| Oral | no | no | no | yes | no |
| Dermal | yes | yes | yes | yes | no |
| Inhalation | yes | yes | yes | yes | no |

***List of scenarios***

**Summary table: exposure scenarios**

|  |  |  |
| --- | --- | --- |
| **Summary table: exposure scenarios** | | |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Primary exposure** | | |
| **[Scenario 1]** | ***Surface application/Brushing*** | Professionals |
| **[Scenario 2]** | ***Surface application/Spraying*** |
| Task [2.1] | *Application by spraying* |
| Task [2.2] | *Cleaning of the spraying equipment* |
| **[Scenario 3]** | ***Application by Injection*** |
| Task [3.1] | *Application by injection* |
| Task [3.2] | *Cleaning of the injection equipment* |
| **Combined primary exposure** | | |
| **[Scenarios 1 + 3]** | ***Injection + Brushing*** | |
| **[Scenarios 2 + 3]** | ***Injection + Spraying*** | |
| **Secondary exposure** | | |
| **[Scenario 4]** | ***Professional sanding the treated article (chronic exposure)*** | Professionals |
| **[Scenario 5]** | ***Inhalation of volatilised residues of active substances after the application (chronic exposure)*** |
| **Combined primary and secondary exposure** | | |
| **[Scenarios 1 + 3 + 4]** | ***Injection + Brushing + Sanding*** | |
| **[Scenarios 2 + 3 + 4]** | ***Injection + Spraying + Sanding*** | |
| **Primary exposure** | | |
| **[Scenario 6]** | ***Surface application/Brushing*** | Non-professionals |
| **[Scenario 7]** | ***Surface application/Spraying*** |
| Task [7.1] | *Application by spraying* |
| Task [7.2] | *Cleaning of the spraying equipment* |
| **[Scenario 8]** | ***Application by Injection*** |
| Task [8.1] | *Application by injection* |
| Task [8.2] | *Cleaning of the injection equipment* |
| **Combined primary exposure** | | |
| **[Scenarios 6 + 8]** | ***Injection + Brushing*** | |
| **[Scenarios 7 + 8]** | ***Injection + Spraying*** | |
| **Secondary exposure** | | |
| **[Scenario 9]** | ***Adult sanding the treated article (acute exposure)*** | General public (adult) |
| **[Scenario 10]** | ***Toddler chewing treated wood chip* (acute exposure)** | General public (toddler) |
| **[Scenario 11]** | ***Toddler playing on the playground structure and hand-to-mouth transfer (chronic exposure)*** | General public (toddler) |
| **[Scenario 12]** | ***Inhalation of volatilised residues of active substances after the application (chronic exposure)*** | General public |

Reference values to be used in Risk Characterisation – Penflufen

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Acute neurotoxicity | 50 mg/kg/d | 167 | - | 0.3 mg/kg/d |
| AELmedium-term | 1-year dog | 8 mg/kg/d | 100 | - | 0.077 mg/kg/d |
| AELlong-term | 2-year rat | 4 mg/kg/d | 100 | - | 0.04 mg/kg/d |
| ARfD | Acute neurotoxicity | 50 mg/kg/d | 100 | - | 0.5 mg/kg/d |
| ADI | 2-year rat | 4 mg/kg/d | 100 | - | 0.04 mg/kg/d |

Reference values to be used in Risk Characterisation – Cypermethrin

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute delayed neurotoxicity, oral behavioural effects | 20 mg/kg/d | 100 | 44% | 0.088 mg/kg/d |
| AELmedium-term | Oral, 90-days dog | 12.5 mg/kg/d | 100 | 44% | 0.055 mg/kg/d |
| AELlong-term | Oral, 2-year rat | 5 mg/kg/d | 100 | 44% | 0.022 mg/kg/d |
| ARfD | AR (BE, 2019): At WG-IV 2016, the following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005) | | | | 0.2 mg/kg/d |
| ADI | 0.05 mg/kg/d |

Physico-chemical and toxicological data on active substances:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Active substance** | **Content (% w/w)** | **Molecular weight (g/mol)** | **Vapour pressure (Pa) (20°C)** | **Dermal absorption** | **Inhalation absorption** | **Oral absorption** |
| Penflufen | 0.027% | 317.41 | 4.1x10-7 | 50% | 100% | 100% |
| Cypermethrin | 0.183% | 416.3 | 2.3x10-7 | 9.2% | 100% | 57% |

***Industrial exposure***

Not relevant.

***Professional exposure***

***Scenario [1] – Surface application/Brushing***

For the application of the ready-to-use product by brushing, the user can directly pour the paint brush into the can. Therefore, no mixing and loading task is required.

| **Description of Scenario [1] – Application by brushing** | | | |
| --- | --- | --- | --- |
| The professional user applies 2 or 3 layers of product, depending on a preventive or curative treatment, by brushing with a paint brush on the whole surface of the wood.  The dermal and inhalation exposure during the application has been assessed according to the Recommendation 10 of the Ad Hoc Working Group (*The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling*). This Recommendation can also be used for professional users and its aim is to suggest the most appropriate model for assessing painting with a brush or a roller when using PT8 products.  For dermal exposure, it is recommended to use the Austrian/BfR study results, where distinction between water and solvent-based product is done.  For the inhalation exposure, the volatility of the active substances is taken into account for the assessment. Penflufen and Cypermethrin are considered low volatile substances as their vapour pressure is below 10 mPa at 20°C (respectively 4.1x10-7 Pa and 2.3x10-7). Therefore, exposure to vapour is not assessed and only inhalation exposure to generated aerosols is taken into consideration using the value from the *Consumer Product Painting Model 3*.  The exposure values from the models are as follow:   * 4.07 µl/min (hands, water-based paint); * 1.7 µl/min (body, water-based paint); * 1.63 mg/m3 (inhalation, low volatile substances). | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | HEAd Hoc Recommendation 14 |
| Density of the product | 1 g/ml | Applicant’s data |
| Duration of exposure | 240 min | HEAd Hoc Recommendation 6 |
| Dermal exposure | | | |
|  | Dermal exposure value (hand) | 4.07 µl/min | HEAd Hoc Recommendation 10 |
| Dermal exposure value (body) | 1.7 µl/min | HEAd Hoc Recommendation 10 |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Inhalation exposure | | | |
|  | Inhalation exposure value | 1.63 mg/min | HEAd Hoc Recommendation 10 |
| Inhalation rate | 1.25 m3/h | HEAd Hoc Recommendation 14 |
| Inhalation absorption (Penflufen and Cypermethrin) | 100% | Default value |

**Calculations for Scenario [1]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [1] | 1/ No PPE | 3.67x10-5 | 3.12x10-3 | nr | 3.15x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [1] | 1/ No PPE | 2.49x10-4 | 3.89x10-3 | nr | 4.13x10-3 |

In the HEEG Opinion 11 on Exposure model for the washing out of a brush which has been used to apply paint, it is stated that the exposure scenario developed in this Opinion is usually used for non-water-based paints.

Indeed, “for water-based paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and any contamination from the hands”. Therefore, no post-application task for the cleaning of the brush is required.

***Scenario [2] – Surface application/Spraying***

Before the application of the ready-to-use product by spraying, the user has to load the product into the sprayer (garden spray or low pressure paint gun). Therefore, a loading step has to be assessed. However, the model used to assess the exposure during the application by spraying already includes the mixing and loading step.

* Task [2.1] – Application by spraying;
* Task [2.2] – Post-application – Cleaning of the spray equipment.

*Task [2.1] – Application by spraying*

| **Description of Task [2.1] – Application by spraying** | | | |
| --- | --- | --- | --- |
| The professional user applies 2 or 3 layers of product, depending on a preventive or curative treatment, by spraying on the whole surface of the wood.  To assess the dermal and inhalation exposure during the M&L and application tasks, the *Spraying Model 2*, from BHHEM (p. 284), is used.  The exposure values from the model are as follow:   * 273 mg/min (hands, without protective gloves); * 7.8 mg/min (hands, inside gloves); * 222 mg/min (body); * 76 mg/m3 (inhalation). | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | HEAd hoc Recommendation 14 |
| Duration of exposure | 90 min | HEAd hoc Recommendation 6 |
| Dermal exposure | | | |
|  | Dermal exposure value (hand) | 273 mg/min | Spraying Model 2 |
| Dermal exposure value (body) | 222 mg/min | Spraying Model 2 |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Inhalation exposure | | | |
|  | Inhalation exposure value | 76 mg/min | Spraying Model 2 |
| Inhalation rate | 1.25 m3/h | Ad hoc Recommendation 14 |
| Inhalation absorption (Penflufen and Cypermethrin) | 100% | Default value |
| Tier 2 | Dermal exposure value (hands, inside gloves) | 7.8 mg/min | Spraying Model 2 |
| Protection factor for impermeable coverall | 95% | HEEG Opinion 9 |

**Calculations for Task [2.1]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [2.1] | 1/ No PPE | 6.41x10-4 | 1.00x10-1 | nr | 1.01x10-1 |
| 2/ Gloves + impermeable coverall | 6.41x10-4 | 3.83x10-3 | nr | 4.47x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [2.1] | 1/ No PPE | 4.35x10-3 | 1.25x10-1 | nr | 1.29x10-1 |
| 2/ Gloves + impermeable coverall | 4.35x10-3 | 4.77x10-3 | nr | 9.12x10-3 |

*Task [2.2] – Post-application – Cleaning of the spray equipment*

| **Description of Task [2.2] – Post-application – Cleaning of the spray equipment** | | | |
| --- | --- | --- | --- |
| After the application, the professional user can be exposed to the product during the cleaning of the spray equipment.  Dermal exposure during this task is assessed using the BEATscenario*Cleaning of the spray equipment*, from the TNsG second version of 2007withan exposure duration of 5 min (HEAd hoc Recommendation 6).  The exposure values from the model are as follow:   * 35.87 µl/min (hands); * 19.28 µl/min (body). | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | HEAd hoc Recommendation 14 |
| Duration of exposure | 5 min | HEAd hoc Recommendation 6 |
| Density of the product | 1 g/ml | Applicant’s data |
| Dermal exposure | | | |
| Tier 1 | Dermal exposure value (hand) | 35.87 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal exposure value (body) | 19.28 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |

**Calculations for Task [2.2]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [2.2] | 1/ No PPE | nr | 6.20x10-4 | nr | 6.20x10-4 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [2.2] | 1/ No PPE | nr | 7.74x10-4 | nr | 7.74x10-4 |

As described above, the scenario [2] is the combination of Task [2.1] and [2.2).

**Calculations for Scenario [2]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [2]** | 1/ No PPE | 6.41x10-4 | 1.01x10-1 | nr | 1.01x10-1 |
| Tier 2/ Gloves + impermeable coverall | 6.41x10-4 | 4.45x10-3 | nr | 5.09x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [2]** | 1/ No PPE | 4.35x10-3 | 1.26x10-1 | nr | 1.30x10-1 |
| Tier 2/ Gloves + impermeable coverall | 4.35x10-3 | 5.55x10-3 | nr | 9.89x10-3 |

***Scenario [3] - Injection***

For the curative treatment, injections are performed before the application by brushing or spraying. Holes are drilled into the wood and then are filled with a tight fitting plug which incorporates a one-way valve mechanism so that injection fluid cannot escape after treatment. The product is applied by injection directly through the inserted plug. Exposure to users during the injection would be minimal.

* Task [3.1] – Application by injection;
* Task [3.2] – Post-application – Cleaning of the injection equipment.

| **Description of Task [3.1] – Application by injection** | | | |
| --- | --- | --- | --- |
| There is no specific exposure model available to estimate exposure during the injection of wood preservatives.  As a worst-case approach, it has been considered to take into account the default exposure values from the brush application model used in scenario [1] for the superficial treatment.  Indeed, it has been deemed suitable since an application by injection is assumed to be less contaminant than a brush application due to the specific application mode using a tight fitted plug intended for injection.  Please refer to Scenario [1] for further details. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | HEAd hoc Recommendation 14 |
| Density of the product | 1 g/ml | Applicant’s data |
| Duration of exposure | 240 min | HEAd hoc Recommendation 6 |
| Dermal exposure | | | |
|  | Dermal exposure value (hand) | 4.07 µl/min | HEAd hoc Recommendation 10 |
| Dermal exposure value (body) | 1.7 µl/min | HEAd hoc Recommendation 10 |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Inhalation exposure | | | |
|  | Inhalation exposure value | 1.63 mg/min | HEAd hoc Recommendation 10 |
| Inhalation rate | 1.25 m3/h | HEAd hoc Recommendation 14 |
| Inhalation absorption (Penflufen and Cypermethrin) | 100% | Default value |
| Tier 2 | Protection factor for gloves | 90% | HEEG Opinion 9 |

**Calculations for Task [3.1]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [3.1] | 1/ No PPE | 3.67x10-5 | 3.12x10-3 | nr | 3.15x10-3 |
| 2/ Gloves | 3.67x10-5 | 1.14x10-3 | nr | 1.17x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [3.1] | 1/ No PPE | 2.49x10-4 | 3.89x10-3 | nr | 4.13x10-3 |
| 2/ Gloves | 2.49x10-4 | 1.42x10-3 | nr | 1.67x10-3 |

*Task [3.2] – Post-application – Cleaning of the injection equipment*

| **Description of Task [3.2] – Post-application – Cleaning of the injection equipment** | | | |
| --- | --- | --- | --- |
| After the application, the professional user can be exposed to the product during the cleaning of the injection equipment. The exposure during this task will not be higher than the one determined during the cleaning of the spraying equipment. The cleaning of the spray equipment is considered a worst-case and covers the cleaning of the injection equipment.  Please refer to Task [2.2] for further details. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | HEAd hoc Recommendation 14 |
| Duration of exposure | 5 min | HEAd hoc Recommendation 6 |
| Density of the product | 1 g/ml | Applicant’s data |
| Dermal exposure | | | |
|  | Dermal exposure value (hand) | 35.87 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal exposure value (body) | 19.28 µl/min | BEAT model for Cleaning of spray equipment |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |

**Calculations for Task [3.2]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [3.2] | 1/ No PPE | nr | 6.20x10-4 | nr | 6.20x10-4 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [3.2] | 1/ No PPE | nr | 7.74x10-4 | nr | 7.74x10-4 |

As described above, the scenario [3] is the combination of Task [3.1] and [3.2).

**Calculations for Scenario [3]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [3]** | 1/ No PPE | 3.67x10-5 | 3.74x10-3 | nr | 3.77x10-3 |
| Tier 2/ Gloves | 3.67x10-5 | 1.76x10-3 | nr | 1.79x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [3]** | 1/ No PPE | 2.49x10-4 | 4.66x10-3 | nr | 4.91x10-3 |
| Tier 2/ Gloves | 2.49x10-4 | 2.19x10-3 | nr | 2.44x10-3 |

*Combined scenarios*

The curative treatment is considered the worst-case for exposure during the product application. In this context, the scenario for the injection (Scenario [3]) has to be combined with the scenario for brushing (Scenario [1]) or spraying (Scenario [2]).

Penflufen

| **Summary table: combined systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenarios [1] + [3] | Tier 1/ no PPE | 7.34x10-5 | 6.85x10-3 | nr | 6.93x10-3 |
| Scenarios [2] + [3] | Tier 1/ no PPE | 6.78x10-4 | 1.05x10-1 | nr | 1.05x10-1 |
| Tier 2/ Gloves + impermeable coverall for [2] and Gloves for [3] | 6.78x10-4 | 6.21x10-3 | nr | 6.88x10-3 |

Cypermethrin

| **Summary table: combined systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenarios [1] + [3] | Tier 1/ no PPE | 4.97x10-4 | 8.55x10-3 | nr | 9.04x10-3 |
| Scenarios [2] + [3] | Tier 1/ no PPE | 4.59x10-3 | 1.30x10-1 | nr | 1.35x10-1 |
| Tier 2/ Gloves + impermeable coverall for [2] and Gloves for [3] | 4.59x10-3 | 7.74x10-3 | nr | 1.23x10-2 |

Outcome of systemic exposure and risk characterisation

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

* Penflufen

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.04  mg/kg bw/d |
| Scenario [1] – Brushing | 1/ no PPE | nr | 3.12x10-3 | 3.67x10-5 | 3.15x10-3 | 8% |
| Scenario [2] – Spraying | 1/ no PPE | nr | 1.01x10-1 | 6.41x10-4 | 1.01x10-1 | **254%** |
| 2/ gloves + impermeable coverall during the application | nr | 4.45x10-3 | 6.41x10-4 | 5.09x10-3 | 13% |
| Scenario [3] - Injection | 1/ no PPE | nr | 3.74x10-3 | 3.67x10-5 | 3.77x10-3 | 9% |
| 2/ gloves during the application | nr | 1.76x10-3 | 3.67x10-5 | 1.79x10-3 | 4% |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022  mg/kg bw/d |
| Scenario [1] – Brushing | 1/ no PPE | nr | 3.89x10-3 | 2.49x10-4 | 4.13x10-3 | 19% |
| Scenario [2] – Spraying | 1/ no PPE | nr | 1.26x10-1 | 4.35x10-3 | 1.30x10-1 | **591%** |
| 2/ gloves + impermeable coverall during the application | nr | 5.55x10-3 | 4.35x10-3 | 9.89x10-3 | 45% |
| Scenario [3] - Injection | 1/ no PPE | nr | 4.66x10-3 | 2.49x10-4 | 4.91x10-3 | 22% |
| 2/ gloves during the application | nr | 2.19x10-3 | 2.49x10-4 | 2.44x10-3 | 11% |

**Combined scenarios**

Outcome of combined systemic exposure and risk characterisation for primary exposure

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

* Penflufen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.04  mg/kg bw/d | |
| Scenario [1] + Scenario [3] – Brushing + Injection | 1/no PPE | nr | 6.85x10-3 | 7.34x10-5 | 6.93x10-3 | 17% | |
| Scenario [2] + Scenario [3] – Spraying + Injection | 1/ no PPE | nr | 1.05x10-1 | 6.78x10-4 | 1.05x10-1 | **263%** | |
| 2/ gloves + impermeable coverall during [2] and gloves during [3] | nr | 6.21x10-3 | 6.78x10-4 | 6.88x10-3 | 17% | |

* Cypermethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022  mg/kg bw/d | |
| Scenario [1] + Scenario [3] – Brushing + Injection | 1/no PPE | nr | 8.55x10-3 | 4.97x10-4 | 9.04x10-3 | 41% | |
| Scenario [2] + Scenario [3] – Spraying + Injection | 1/ no PPE | nr | 1.30x10-1 | 4.59x10-3 | 1.35x10-1 | **614%** | |
| 2/ gloves + impermeable coverall during [2] and gloves during [3] | nr | 7.74x10-3 | 4.59x10-3 | 1.23x10-2 | 56% | |

***Secondary exposure of the professional user***

*Scenario [4] – Professional sanding the treated article*

| **Description of Scenario [4] – Professional sanding the treated article** | | | |
| --- | --- | --- | --- |
| The professional user can be expected sanding the treated wooden articles. Exposure to the product *via* dermal and inhalation routes may occur.  As the curative treatment, including the injection (150 g/m²) and brush or spray (300 g/m²) application, is considered the worst-case scenario, an application rate of **45 mg/cm²** is taken into account in the assessment. The product is assumed to be retained in 1cm layer of timber, which results in an application rate of 450 mg/cm3.  In the TNsG 2002, Part 3 (p.50), calculations are proposed to determine the dermal and inhalation exposure during this task.  The dermal exposure to the substances is determined using the following calculation:  **ExpD = AR x DF x SA x AS x DA / BW**  With :  ExpD = Systemic dose to active substance via dermal route (mg/kg bw/d)  AR = application rate (mg/cm²)  DF = Fraction of dislodgeable residues (for painted wood)  SA = Surface area – two palms (cm²)  AS = concentration of active substance in the product  DA = Dermal absorption  BW = Body weight (kg)  For the inhalation route, the volume of wood dust inhaled is calculated first :  **VI = [(DC x Δt x IR) /1000] / WD**  With:  VI = volume of wood inhaled (cm3)  DC = Dust concentration in air while sanding (5 mg/m3)  Δt = Exposure duration, 6 hours for chronic exposure  IR = Inhalation rate (m3/h)  WD = Wood dust density (0.8 g/cm3)  The inhalation exposure to the susbtances is determined using the following calculation:  **ExpI = VI x AR x AS x IA / BW**  With :  ExpI = Systemic dose to active substance via inhalation route (mg/kg bw/d)  VI = volume of wood inhaled (cm3)  AR = application rate (mg/cm3)  AS = concentration of active substance in the product  IA = Inhalation absorption  BW = Body weight (kg) | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | Ad hoc Recommendation 14 |
|  | Density of the product | 1 g/ml | Applicant’s data |
|  | Product application rate | 45 mg/cm² | Applicant’s data |
|  | Layer of timber | 1 cm | Default value |
| Dermal exposure | | | |
|  | Fraction of dislodgeable residues | 3% | BHHEM (p.171), for painted wood – dried fluid |
|  | Surface area (two palms) | 410 cm² | Ad hoc Recommendation 14 |
|  | Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
|  | Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Inhalation exposure | | | |
|  | Dust concentration in air | 5 mg/m3 | Ad hoc Recommendation 10 |
|  | Exposure duration | 6 h | TNsG 2002, Part 3 (p.50), for chronic exposure |
|  | Inhalation rate | 1.25 m3/h | Ad hoc Recommendation 14 |
|  | Wood dust density | 0.8 g/cm3 | TNsG 2002, Part 3 (p.50) |
|  | Inhalation absorption (Penflufen and Cypermethrin) | 100% | Default value |

**Calculations for Scenario [4]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [4] | 1/ No PPE | 9.46x10-6 | 1.25x10-3 | nr | 1.25x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [4] | 1/ No PPE | 6.43x10-5 | 1.55x10-3 | nr | 1.62x10-3 |

*Scenario [5] – Inhalation of volatilised residues of active substances after the application*

| **Description of Scenario [5] – Inhalation of volatilised residues of actives substances after the application** |
| --- |
| Professional users can be exposed to volatilised residues of active substances after the application of the product on wooden surfaces.  In the HEEG Opinion 13 on the Assessment of Inhalation Exposure of Volatilised Biocide Active Substance, a calculation is developed and determines if the risk from inhalation exposure is negligible or should be included in the risk assessment.  This formula is based on the toddler representing the worst-case and covering every age group:  With *mw* being the molecular weight and *vp* the vapour pressure.  If the result is below 1, then the risk from inhalation exposure is considered negligible.  The following parameters are used for the approach:  For Penflufen:   * Mw = 317.41 g/mol * Vp = 4.1x10-7 Pa (20°C) * AELlong-term = 0.04 mg/kg bw/d   For Cypermethrin:   * Mw = 416.3 g/mol * Vp = 2.3x10-7 Pa (20°C) * AELlong-term = 0.022 mg/kg bw/d   For both active substances, the results is < 1, and therefore the inhalation exposure is **negligible** after the application of the product and is not taken into account in the risk assessment. |

Outcome of systemic exposure and risk characterisation – Secondary exposure

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

* Penflufen

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.04  mg/kg bw/d |
| Scenario [4] – Sanding | 1/ no PPE | nr | 1.25x10-3 | 9.49x10-6 | 1.25x10-3 | 3% |
| Scenario [5] – Inhalation of volatilised residues | 1/ no PPE | nr | nr | negligible | | |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022  mg/kg bw/d |
| Scenario [4] – Sanding | 1/ no PPE | nr | 1.55x10-3 | 6.43x10-5 | 1.62x10-3 | 7% |
| Scenario [5] – Inhalation of volatilised residues | 1/ no PPE | nr | nr | negligible | | |

**Combined scenarios for primary and secondary exposure**

Outcome of combined systemic exposure and risk characterisation for primary and secondary exposure

The professional user exposed to the product while sanding the treated articles can be the same that applied the product. In that case, a combined primary and secondary exposure assessment has to be done.

As the inhalation of volatilised residues of active substances during the application (Scenario [5]) is considered negligible, this scenario is not taken into consideration in the combined risk assessment.

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

* Penflufen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.04  mg/kg bw/d | |
| Scenario [1] + Scenario [3] – Brushing + Injection + Scenario [4] | 1/no PPE | nr | 8.10x10-3 | 8.28x10-5 | 8.18x10-3 | 20% | |
| Scenario [2] + Scenario [3] – Spraying + Injection + Scenario [4] | 2/ gloves + impermeable coverall during [2] and gloves during [3] | nr | 7.45x10-3 | 6.87x10-4 | 8.14x10-3 | 20% | |

* Cypermethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELlong-term = 0.022  mg/kg bw/d | |
| Scenario [1] + Scenario [3] – Brushing + Injection + Scenario [4] | 1/no PPE | nr | 1.01x10-2 | 5.61x10-4 | 1.07x10-2 | 48% | |
| Scenario [2] + Scenario [3] – Spraying + Injection + Scenario [4] | 2/ gloves + impermeable coverall during [2] and gloves during [3] | nr | 9.29x10-3 | 4.66x10-3 | 1.40x10-2 | 63% | |

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

The product 18V33CP-PE contains two active substances: Penflufen and Cypermethrin.

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

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

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

**HQ= Internal Exposure / AEL**

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

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

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

**HI=Σ HQa.s.**

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

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

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

**Tier 1 and Tier 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Primary exposure** | **Penflufen** | **Cypermethrin** | **Conclusions** |
| **INJECTION + BRUSHING + SANDING - Scenarios [1 + 3 + 4]** | | | |
| **Without PPE** | | | |
| Tier 1 | 20% AEL | 48% AEL | Acceptable |
| HQ = 0.2 < 1 | HQ = 0.48 < 1 |
| Tier 2 | 0.2 | 0.48 | Acceptable |
| HI = 0.68 < 1 | |
| **INJECTION + SPRAYING + SANDING - Scenarios 2 + 3 + 4** | | | |
| **With gloves during the injection and gloves + impermeable coverall during the spraying** | | | |
| Tier 1 | 20% AEL | 63% AEL | Acceptable |
| HQ = 0.2 < 1 | HQ = 0.63 < 1 |
| Tier 2 | 0.2 | 0.63 | Acceptable |
| HI = 0.83 < 1 | |

**Overall conclusion for professional users (primary and secondary exposure)**

For the product 18V33CP-PE, the risk for the professional user is acceptable considering the quantitative risk assessment for systemic effects, with the application of the following personal protective equipment (PPE):

For preventive treatment:

* Gloves and impermeable coverall during the application by spraying;

For curative treatment:

* Gloves during the injection;
* Gloves and impermeable coverall during the application by spraying.

***Non-professional exposure***

*Scenario [6] – Surface application/Brushing*

The non-professional user performs the same task as the professional user.

The exposure of the non-professional user during the application of the product by brushing are assumed to be not higher than the exposure of the professional user. Therefore, the dermal and inhalation exposure determine for the professional user in Scenario [1] are similar to the exposure for the non-professional user.

Please refer to Scenario [1] for further information.

**Calculations for Scenario [6]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [6] | 1/ No PPE | 3.67x10-5 | 3.12x10-3 | nr | 3.15x10-3 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [6] | 1/ No PPE | 2.49x10-4 | 3.89x10-3 | nr | 4.13x10-3 |

*Scenario [7] – Surface application/Spraying*

Before the application of the ready-to-use product by spraying, the user has to load the product into the sprayer (garden spray or low pressure paint gun). Therefore, a loading step has to be assessed. However, the model used to assess the exposure during the application by spraying already includes the mixing and loading step.

* Task [7.1] – Application by spraying;
* Task [7.2] – Post-application – Cleaning of the spray equipment.

*Task [7.1] – Application by spraying*

| **Description of Task [7.1] – Application by spraying** | | | |
| --- | --- | --- | --- |
| The non-professional user applies 2 or 3 layers of product, depending on a preventive or curative treatment, by spraying on the whole surface of the wood.  To assess the dermal and inhalation exposure, the **Consumer Product Spraying and Dusting Model 3**, from BHHEM (p. 346), is used.  The exposure values from the model are as follow:   * 176 mg/min (hand and forearm) * 120 mg/min (Legs, feet & face) * 115 mg/m3 (Inhalation)   In the BHHEM (p.50), an exposure duration of 40 minutes is proposed for non-professional low pressure spraying of PT8. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 60 kg | Ad hoc Recommendation 14 |
| Duration of exposure | 40 min | BHHEM (p.50) |
| Dermal exposure | | | |
|  | Dermal exposure value (hand) | 176 mg/min | Consumer Product Spraying and Dusting Model 3 |
| Dermal exposure value (body) | 120 mg/min | Consumer Product Spraying and Dusting Model 3 |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Inhalation exposure | | | |
|  | Inhalation exposure value | 115 mg/min | Consumer Product Spraying and Dusting Model 3 |
| Inhalation rate | 1.25 m3/h | Ad hoc Recommendation 14 |
| Inhalation absorption (Penflufen and Cypermethrin) | 100% | Default value |

**Calculations for Task [7.1]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [7.1] | 1/ No PPE | 4.31x10-4 | 2.66x10-2 | nr | 2.71x10-2 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [7.1] | 1/ No PPE | 2.92x10-3 | 3.32x10-2 | nr | 3.61x10-2 |

*Task [7.2] – Post-application – Cleaning of the spray equipment*

For the cleaning of the spray equipment, no model specific for non-professional user is available. Therefore, the exposure determined for the professional use covers the exposure for non-professional use.

Please refer to Task [2.2] for further information.

**Calculations for Task [7.2]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [7.2] | 1/ No PPE | nr | 6.20x10-4 | nr | 6.20x10-4 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [7.2] | 1/ No PPE | nr | 7.74x10-4 | nr | 7.74x10-4 |

As described above, the scenario [7] is the combination of Task [7.1] and [7.2).

Penflufen

| **Summary table: combined systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [7]** | Tier 1/ no PPE | 4.31x10-4 | 2.73x10-2 | nr | 2.77x10-2 |

Cypermethrin

| **Summary table: combined systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [7]** | Tier 1/ no PPE | 2.92x10-3 | 3.40x10-2 | nr | 3.69x10-2 |

*Scenario [8] - Injection*

The non-professional user performs the same task as the professional user.

It is assumed that exposure during the injection of the product is similar for professional and non-professional users.

Therefore, exposure values determined in Scenario [3] are used for this scenario.

Please refer to Scenario [3] for further information.

* Task [8.1] – Application by injection
* Task [8.2] – Post-application – Cleaning of the injection equipment

**Calculations for Task [8.1]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [8.1] | 1/ No PPE | 3.67x10-5 | 3.12x10-3 | nr | 3.15x10-3 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [8.1] | 1/ No PPE | 2.49x10-4 | 3.89x10-3 | nr | 4.13x10-3 |

**Calculations for Task [8.2]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [8.2] | 1/ No PPE | nr | 6.20x10-4 | nr | 6.20x10-4 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Task [8.2] | 1/ No PPE | nr | 7.74x10-4 | nr | 7.74x10-4 |

As described above, the scenario [8] is the combination of Task [8.1] and [8.2).

**Calculations for Scenario [8]**

Penflufen

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [8]** | 1/ No PPE | 3.67x10-5 | 3.74x10-3 | nr | 3.77x10-3 |

Cypermethrin

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| **Scenario [8]** | 1/ No PPE | 2.49x10-4 | 4.66x10-3 | nr | 4.91x10-3 |

*Combined scenarios*

As the curative treatment is considered a worst-case, the scenario for the infection (Scenario [8]) has to be combined with the scenario for brushing (Scenario [6]) or spraying (Scenario [7]).

Penflufen

| **Summary table: combined systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [6] + Scenario [8] | 1/ No PPE | 7.34x10-5 | 6.85x10-3 | nr | 6.93x10-3 |
| Scenario [7] + Scenario [8] | 1/ No PPE | 4.68x10-4 | 3.10x10-2 | nr | 3.15x10-2 |

Cypermethrin

| **Summary table: combined systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [4] + Scenario [6] | 1/ No PPE | 4.97x10-4 | 8.55x10-3 | nr | 9.04x10-3 |
| Scenario [5] + Scenario [6] | 1/ No PPE | 3.17x10-3 | 3.87x10-2 | nr | 4.18x10-2 |

Outcome of systemic exposure and risk characterisation

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

According to the information provided by the applicant, the product is not intended to be applied on a regular basis Therefore, for the risk characterization of non-professional users, the estimated exposure values are compared to the short-term AEL of each substance.

* Penflufen

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.3  mg/kg bw/d |
| Scenario [6] – Brushing | 1/ no PPE | nr | 3.12x10-3 | 3.67x10-5 | 3.15x10-3 | 1% |
| Scenario [7] – Spraying | 1/ no PPE | nr | 2.73x10-2 | 4.31x10-4 | 2.77x10-2 | 9% |
| Scenario [8] - Injection | 1/ no PPE | nr | 3.74x10-3 | 3.67x10-5 | 3.77x10-3 | 1% |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.088  mg/kg bw/d |
| Scenario [6] – Brushing | 1/ no PPE | nr | 3.89x10-3 | 2.49x10-4 | 4.13x10-3 | 5% |
| Scenario [7] – Spraying | 1/ no PPE | nr | 3.40x10-2 | 2.92x10-3 | 3.69x10-2 | 42% |
| Scenario [8] - Injection | 1/ no PPE | nr | 4.66x10-3 | 2.49x10-4 | 4.91x10-3 | 6% |

**Combined scenarios**

Outcome of combined systemic exposure and risk characterisation for primary exposure

**Summary table: combined systemic exposure and risk characterisation for non-professional users**

* Penflufen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.3  mg/kg bw/d | |
| Scenario [6] + Scenario [8] – Brushing + Injection | 1/no PPE | nr | 6.85x10-3 | 7.34x10-5 | 6.93x10-3 | 2% | |
| Scenario [7] + Scenario [8] – Spraying + Injection | 1/ no PPE | nr | 3.10x10-2 | 4.68x10-4 | 3.15x10-2 | 10% | |

* Cypermethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for non-professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.088  mg/kg bw/d | |
| Scenario [6] + Scenario [8] – Brushing + Injection | 1/no PPE | nr | 8.55x10-3 | 4.97x10-4 | 9.04x10-3 | 10% | |
| Scenario [7] + Scenario [8] – Spraying + Injection | 1/ no PPE | nr | 3.87x10-2 | 3.17x10-3 | 4.18x10-2 | 48% | |

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

*Scenario [9] – Adult sanding the treated article (acute exposure)*

| **Description of Scenario [9] – Adult sanding the treated article (acute exposure)** | | | |
| --- | --- | --- | --- |
| The sanding of the wooden treated articles can be done by a non-professional. He can be exposed to the product *via* dermal and inhalation routes.  The same parameters than those used in scenario [4] have been applied with an exposure duration of 1h.  Please refer to Scenario [4] for further information. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Exposure duration | 1 h | TNsG 2002, Part 3 (p.50), for acute exposure |

**Calculations for Scenario [9]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [9] | 1/ No PPE | 1.58x10-6 | 1.25x10-3 | nr | 1.25x10-3 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [9] | 1/ No PPE | 1.07x10-5 | 1.55x10-3 | nr | 1.56x10-3 |

*Scenario [10] – Toddler chewing treated wood chip (acute exposure)*

| **Description of Scenario [10] – Toddler chewing treated wood chip (acute exposure)** | | | |
| --- | --- | --- | --- |
| The toddler may be exposed to the product *via* oral route when chewing a chip from a wooden article previously treated with the product.  According to the TNsG 2002, Part 3 (p.50), it is assumed that the wood offcut has a volume of 16 cm3 (4 cm x 4 cm x 1 cm) and that the toddler extracts 10% of the product from the chip by chewing it.  As a worst-case, the assessment takes into consideration an application rate of **45 mg/cm3**, with the wooden article treated with both the injection (150 g/m²) and the curative treatment by brushing or spraying (300 g/m²), and a layer of 1 cm of timber in which the product is retained.  The oral exposure to the substances is determined using the following calculation:  **ExpO = AR x V x RF x AS x OA / BW**  With :  ExpO = Systemic dose to active substance via oral route (mg/kg bw/d)  AR = application rate (mg/cm3)  V = Volume of wood cutoff (16 cm3)  RF = Fraction of residues extracted from the cutoff by chewing  AS = concentration of active substance in the product  OA = Oral absorption  BW = Body weight (kg) | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 10 kg | Ad hoc Recommendation 14 |
| Density of the product | 1 g/ml | Applicant’s data |
| Product application rate | 45 mg/cm² | Applicant’s data |
| Layer of timber | 1 cm | Default value |
| Oral exposure | | | |
|  | Volume of the wooden chip | 16 cm3 | TNsG 2002, Part 3 (p.50) |
| Fraction of residues extracted from the wooden chip | 10% | TNsG 2002, Part 3 (p.50) |
| Oral absorption (Penflufen) | 100% | Default value |
| Oral absorption (Cypermethrin) | 57% | CAR of Cypermethrin (2013) |

**Calculations for Scenario [10]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [10] | 1/ No PPE | nr | nr | 1.94x10-3 | 1.94x10-3 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [10] | 1/ No PPE | nr | nr | 7.51x10-3 | 7.51x10-3 |

*Scenario [11] – Toddler playing on the playground structure and hand-to-mouth structure (chronic exposure)*

| **Description of Scenario [11] – Toddler playing on the playground structure and hand-to-mouth structure (chronic exposure)** | | | |
| --- | --- | --- | --- |
| A toddler (representing the worst-case population) may be dermally exposed to the product while playing on the playground wooden structures previously treated with the product.  According to the TNsG 2002, Part 3 (p.50), 20% of the hands can be contaminated.  Also, the toddler can also be orally exposed to the product *via* hand-to-mouth transfer, where 10% of the external dermal exposure is ingested.  As a worst-case, the assessment takes into consideration an application rate of 45 mg/cm2, with the wooden article treated with both the injection (150 g/m²) and the curative treatment by brushing or spraying (300 g/m²).  The dermal exposure to the substances is determined using the following calculation:  **ExpD = AR x DF x SA x HF x AS x DA / BW**  With :  ExpD = Systemic dose to active substance via dermal route (mg/kg bw/d)  AR = application rate (mg/cm²)  DF = Fraction of dislodgeable residues (for painted wood)  SA = Surface area – two hands (cm²)  HF = Faction of the hands contaminated (20%)  AS = concentration of active substance in the product  DA = Dermal absorption  BW = Body weight (kg)  The oral exposure to the susbtances is determined using the following calculation:  **ExpO = AD x AR x AS x IA / BW**  With :  ExpO = Systemic dose to active substance via oral route (mg/kg bw/d)  AD = Amount of product on skin (mg)  OF = Fraction of external dermal exposure ingested (10%)  AS = concentration of active substance in the product  OA = Oral absorption  BW = Body weight (kg) | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of Penflufen | 0.027% w/w | Applicant’s data |
| Concentration of Cypermethrin | 0.183% w/w | Applicant’s data |
| Body weight | 10 kg | Ad hoc Recommendation 14 |
| Density of the product | 1 g/ml | Applicant’s data |
| Product application rate | 45 mg/cm² | Applicant’s data |
| Dermal exposure | | | |
|  | Fraction of dislodgeable residues | 3% | BHHEM (p.171), for painted wood – dried fluid |
| Surface area (two hands) | 230.4 cm² | Ad hoc Recommendation 14 |
| Fraction of the hands contaminated | 20% | TNsG 2002, Part 3 (p.50) |
| Dermal absorption (Penflufen) | 50% | Default value according to EFSA Guidance 2017 |
| Dermal absorption (Cypermethrin) | 9.2% | Dermal absorption study |
| Oral exposure | | | |
|  | Fraction of external dermal exposure ingested | 10% | Consexpo Pest Control Fact Sheet (p.28) |
| Oral absorption (Penflufen) | 100% | Default value |
| Oral absorption (Cypermethrin) | 57% | CAR of Cypermethrin (2013) |

**Calculations for Scenario [11]**

Penflufen

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [11] | 1/ No PPE | nr | 8.40x10-4 | 1.68x10-4 | 1.01x10-3 |

Cypermethrin

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg d/bw)** | **Estimated dermal uptake (mg/kg d/bw)** | **Estimated oral uptake (mg/kg d/bw)** | **Estimated total uptake (mg/kg d/bw)** |
| Scenario [11] | 1/ No PPE | nr | 1.05x10-3 | 6.49x10-4 | 1.70x10-3 |

*Scenario [12] – Inhalation of volatilised residues of active substances after the application*

| **Description of Scenario [12] – Inhalation of volatilised residues of actives substances after the application** |
| --- |
| Adults, children and toddlers can be exposed to volatilised residues of active substances after the application of the product on wooden surfaces.  For both active substances, the inhalation exposure is **negligible** after the application of the product and is not taken into account in the risk assessment.  See Scenario [5] for further details. |

Outcome of systemic exposure and risk characterisation

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

* Penflufen

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.3  mg/kg bw/d  AELlong-term = 0.04  mg/kg bw/d |
| **Scenario 9 – Adult sanding the treated article (acute exposure)** | | | | | | |
| Scenario [9] | 1/ no PPE | nr | 1.25x10-3 | 1.58x10-6 | 1.25x10-3 | 0.4% |
| **Scenario 10 – Toddler chewing treated wood chip (acute exposure)** | | | | | | |
| Scenario [10] | 1/ no PPE | 1.94x10-3 | nr | nr | 1.94x10-3 | 1% |
| **Scenario 11 – Toddler playing on the playground structure and hand-to-mouth transfer (chronic exposure)** | | | | | | |
| Scenario [11] | 1/ no PPE | 1.68x10-4 | 8.40x10-4 | nr | 1.01x10-3 | 3% |
| **Scenario 12 – Inhalation of volatilised residues of active substances after the application (chronic exposure)** | | | | | | |
| Scenario [12] | 1/ no PPE | nr | nr | negligible | | |

* Cypermethrin

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake [mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.088  mg/kg bw/d |
| **Scenario 9 – Adult sanding the treated article (acute exposure)** | | | | | | |
| Scenario [9] | 1/ no PPE | nr | 1.55x10-3 | 1.07x10-5 | 1.56x10-3 | 2% |
| **Scenario 10 – Toddler chewing treated wood chip (acute exposure)** | | | | | | |
| Scenario [10] | 1/ no PPE | 7.51x10-3 | nr | nr | 7.51x10-3 | 9% |
| **Scenario 11 – Toddler playing on the playground structure and hand-to-mouth transfer (chronic exposure)** | | | | | | |
| Scenario [11] | 1/ no PPE | 6.49x10-4 | 1.05x10-3 | nr | 1.70x10-3 | 8% |
| **Scenario 12 – Inhalation of volatilised residues of active substances after the application (chronic exposure)** | | | | | | |
| Scenario [12] | 1/ no PPE | nr | nr | negligible | | |

**Combined scenarios for primary and secondary exposure**

Outcome of combined systemic exposure and risk characterisation for primary and secondary exposure

As the inhalation of volatilised residues of active substances during the application (Scenario [12]) is considered negligible, this scenario is not taken into consideration in the combined risk assessment for non-professionals (IR + IIR) and General public (IIR).

**Summary table: combined systemic exposure and risk characterisation for non-professional users**

* Penflufen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.3  mg/kg bw/d | |
| Scenario [6] + Scenario [8] – Brushing + Injection + Scenario [9] | 1/no PPE | nr | 8.10x10-3 | 7.49x10-5 | 8.17x10-3 | 3% | |
| Scenario [7] + Scenario [8] – Spraying + Injection + Scenario [9] | 1/no PPE | nr | 3.22x10-2 | 4.70x10-4 | 3.27x10-2 | 11% | |

* Cypermethrin

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure and risk characterisation for professional users** | | | | | | |  |
| **Scenarios combined** | **Tier/PPE** | **Estimated oral uptake**  **[mg/kg bw/day]** | **Estimated dermal uptake [mg/kg bw/day]** | **Estimated inhalation uptake [mg/kg bw/day]** | **Estimated total uptake [mg/kg bw/day]** | **Estimated uptake/ AEL**  **(%)**    AELshort-term = 0.088  mg/kg bw/d | |
| Scenario [6] + Scenario [8] – Brushing + Injection + Scenario [9] | 1/no PPE | nr | 1.01x10-2 | 5.08x10-4 | 1.06x10-2 | 10% | |
| Scenario [7] + Scenario [8] – Spraying + Injection + Scenario [9] | 1/no PPE | nr | 4.02x10-2 | 3.18x10-3 | 4.32x10-2 | 49% | |

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

The product 18V33CP-PE contains two active substances: Penflufen and Cypermethrin.

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

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

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

**HQ= Internal Exposure / AEL**

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

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

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

**HI=Σ HQa.s.**

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

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

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

**Tier 1 and Tier 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Primary exposure** | **Penflufen** | **Cypermethrin** | **Conclusions** |
| **INJECTION + BRUSHING + SANDING - Scenarios [6 + 8 + 9]** | | | |
| **Without PPE** | | | |
| Tier 1 | 3% AEL | 12% AEL | Acceptable |
| HQ = 0.03 < 1 | HQ = 0.12 < 1 |
| Tier 2 | 0.03 | 0.12 | Acceptable |
| HI = 0.15 < 1 | |
| **INJECTION + SPRAYING + SANDING - Scenarios [7 + 8 + 9]** | | | |
| **Without PPE** | | | |
| Tier 1 | 11% AEL | 49% AEL | Acceptable |
| HQ = 0.11 < 1 | HQ = 0.49 < 1 |
| Tier 2 | 0.11 | 0.49 | Acceptable |
| HI = 0.6 < 1 | |

**Tier 1 and Tier 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Primary exposure** | **Penflufen** | **Cypermethrin** | **Conclusions** |
| **Scenario [10]** | | | |
| Tier 1 | 1% AEL | 9% AEL | Acceptable |
| HQ = 0.01 < 1 | HQ = 0.09 < 1 |
| Tier 2 | 0.01 | 0.09 | Acceptable |
| HI = 0.1 < 1 | |
| **Scenario [11]** | | | |
| Tier 1 | 3% AEL | 8% AEL | Acceptable |
| HQ = 0.03 < 1 | HQ = 0.08 < 1 |
| Tier 2 | 0.03 | 0.08 | Acceptable |
| HI = 0.11 < 1 | |

**Overall conclusion for non-professional users (primary and secondary exposure) and general public**

For the product 18V33CP-PE, the risk for the non-professional users and general public is acceptable considering the quantitative risk assessment for systemic effects.

**Conclusion**

For the product 18V33CP-PE, the risk for professional and non-professional users is acceptable considering the quantitative risk assessment for systemic effects.

For the professional users, the following personal protective equipment (PPE) applied:

For the preventive treatment:

* Gloves and impermeable coverall during the application of the product by spraying.

For the curative treatment:

* Gloves during the application of the product by injection;
* Gloves and impermeable coverall during the application of the product by spraying.

The risk is also acceptable for the general public.

***Dietary exposure***

The product 18V33CP-PE is a ready-to-use water-based wood preservative intended to be used for the preventive and curative treatment of interior woods against wood-boring insects and termites. These preventive and curative treatments are done by professionals and non-professionals by brush application, spray application or injection, indoors.

The product shall not be used in areas where food/feed, food utensils or food processing surfaces may come into contact with or be contaminated by it.

The following risk mitigation measure is proposed:

“Do not use on wood which may come in direct contact with food, feed and livestock”.

Therefore, an investigation of residues in food does not appear to be justified.

*List of scenarios*

Not relevant.

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

According to Regulation (EU) No 2021/2049 of 24 November 2021, cypermethrin is approved for use as active substance in plant protection products. Cypermethrin is also used as an antiparasitic active ingredient in veterinary medicine products applied to livestock.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection products | Insecticide for use on crops | MRL of 0.05\* – 30 mg/kg dependent upon commodity (Regulation (EU) No 2017/626) (1) |
| 2. | Veterinary medicine | Antiparasitic agent for use against ectoparasites | MRL (all ruminants) (2):  20 µg/kg muscle, liver, kidney, milk  200 µg/kg fat  MRL (*Salmonidae*) (2):  50 µg/kg muscle/skin |

(1) <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=65&product_ids=&v=1&e=search.pr>

(2) As listed in Annex I to commission Regulation (EU) No 37/2010.

According to regulation (EU) No 1031/2013 of 24 October 2013, penflufen is approved for use as active substance in plant protection products.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection products | Insecticide for use on crops | MRL of 0.01\* – 0.05\* mg/kg dependent upon commodity (Regulation (EU) No 2021/644) (1) |

(1) <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=2594&product_ids=&v=1&e=search.pr>

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

Not relevant.

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

Not relevant.

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

Not relevant.

**Specific reference value for groundwater**

*[If it is proposed to derive a value according to BPR Annex VI point 68, other than the maximum permissible concentration laid down by Directive 98/83/EC, please include the argumentation and the calculations here. Otherwise, please delete this chapter.]*

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

Not relevant (see § dietary exposure).

### Risk assessment for animal health

In the human health section, no unacceptable risk has been identified for toddlers in contact with the treated surfaces. Therefore, the risk is also considered acceptable for animal health.

### Risk assessment for the environment

#### Effects assessment on the environment

The product 18V33CP-PE is a ready-to-use water-based wood preservative containing 0.183% w/w cypermethrin and 0.027% w/w penflufen as active substances (technical concentrations).

A summary of the ecotoxicity values on the active substances cypermethrin and penflufen and on relevant metabolites of penflufen (M01 and M02) are presented below. Data are coming from the Competent Authority Report (CAR), Doc IIA, effect assessment for the active substance, cypermethrin 2019 and the Assessment Report of penflufen, PT08, March 2017.

**Summary of PNECs of Cypermethrin**

|  |  |  |
| --- | --- | --- |
| **PNEC** | | **Remarks** |
| PNECSTP | 1.63 mg/L | - |
| PNECwater | 4.00E-06 mg/L | - |
| PNECsediment,EPM | 0.005 mg/kg wwt | Equilibrium partitioning method. This value already considers the additional factor of 10 needed in case of high Koc value |
| PNECsoil | 0.07 mg/kg wwt | - |
| PNECoral bird | 33.3 mg/kg food | - |
| PNECoral mammal | 3.3 mg/kg food | - |

**Summary of PNECs of Penflufen and its relevant metabolites**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PNEC** | **Substances** | | | **Remarks** |
|  | Penflufen | M01 | M02 | - |
| PNECSTP | 1.09 mg/L | not relevant | not relevant | - |
| PNECwater | 2.34E-03 mg/L | 0.0157 mg/L | not relevant | - |
| PNECsediment,EPM | 0.016 mg/kg wwt | not relevant | not relevant | Equilibrium partitioning method. Low Koc, no additional factor needed |
| PNECsoil | 0.377 mg/kg wwt | 0.390 mg/kg wwt | 0.322 mg/kg wwt | - |
| PNECoral bird | 31.5 | not relevant | not relevant | - |
| PNECoral mammal | 33.3 | not relevant | not relevant | - |

The product 18V33CP-PE contains one substance of concern for the environment (see section 2.1.2.6 above). The PNEC for the microorganisms in the STP, the only relevant compartment for which the substance is of concern, is presented below and comes from the CAR of the substance approved in PT06:

**Summary of PNECs of 1,2-benzisothiazol-3-(2H)-one (BIT):**

|  |  |  |
| --- | --- | --- |
| **PNEC** | | **Remarks** |
| PNECSTP | 5.50E-02 mg/L | - |

The risk assessment is therefore performed based on the active substances, the relevant metabolites and the substance of concern.

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

The product 18V33CP-PE is classified for the environment Aquatic toxicity category 1 (acute and chronic), H400, H410, according to Regulation (EC) No.1272/2008 (CLP) based on active substance and co-formulants data. No further aquatic ecotoxicity data on the product are deemed necessary.

***Further Ecotoxicological studies***

No additional data available.

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

No data available.

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

No data available.

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

No data available.

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

No data available.

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

The product 18V33CP-PE is a ready-to-use water-based wood preservative. It is intended to be used for the preventive and curative treatment of woods against wood-boring insects, termites and wood destroying fungi, indoor and outdoor. These preventive and curative treatments are done by professionals and non-professionals by brush application, spray application or injection.

According to the revised ESD for PT08, the emissions to the environment following indoor treatments by spraying, brushing and injection are considered negligible. Therefore, when the product 18V33CPPE is used indoor an exposure of environmental compartments is unlikely.

For treatment of exterior woods, emissions to the environment may occur during the application phase and during the service life of the treated wood.

- Application phase: When the product is applied outdoor by brushing, spraying or injection, spills, drips and spray-drift may end-up directly in the adjacent soil if it is not protected. Also, if the treated structure is located near a surface water body, emission into the surface water may occur.

- Service life: During the service life of the treated structure, leaching of active substances out of the wood may occur due to rainfall. Then, the adjacent soil and the surface water near to the treated area may be exposed. If the treated structure is located in urban area, the releases will be washed with rain to the rain water/sewer system and the STP will be considered as the main receiving compartment.

Exposure of the atmosphere can be expected considering the mode of application by spraying of the product 18V33CP-PE resulting in a direct emission to air. However, the volatilisation of cypermethrin and penflufen is considered to be negligible based on the vapour pressure (6.00E-07 at 25°C and 4.10E-07 Pa at 20°C respectively) and Henry constant values (0.024 at 20°C and 1.19E-05 Pa.m3/mol respectively). The vapour pressure of the SoC is also low (1.10E-04 Pa), and therefore its volatilization is also considered to be negligible. In addition, as cypermethrin and penflulen are rapidly degraded in the air (DT50 = 18 hours and 0.27 days respectively), they would not be transported over large distances in the atmosphere. Therefore the risk of contamination of air can be considered as negligible and this foreseeable route of entry in the environment is not of concern.

Please see section 2.2.8.2.2 "Fate and distribution in exposed environmental compartments" for more information regarding cypermethrin fate and distribution in the environment.

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

No data available.

***Leaching behaviour (ADS)***

The leaching values used in the calculation of emissions are derived from the leaching study results. The semi-field study has been carried out with the product 18V33CP-PE during 743 days and from a surface application at 200 g product/m2. The results of the semi-field study were recalculated by expressing the leaching in losses per mm rain incident on the panels for the standard rain year, instead of time, as the variability with time is of secondary interest due to the natural variability of rainfall. The results are presented over calendar years and over standard rain years (700 mm rain, in 365 days, i.e. 1.92 mm rain per day).

The applicant performed a leaching test for 18V33CP-PE using the product with and without topcoat. Only results from leaching study with topcoat are presented below, i.e results used for the environmental risk assessment.

For Cypermethrin to estimate the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rainfall plot using a linear regression:

Q\*leach,time = a\*mm + b

For Penflufen, to estimate the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rainfall plot using a Ln regression:

Q\*leach,time = a\*Ln(mm) + b

Q\*leach, time values are calculated for:

* TIME1 = 30 days, equivalent to 30 \* 1.92 = 57.53 mm of accumulated rain;
* TIME2 = 365 days, equivalent to 365 \* 1.92 = 700 mm of accumulated rain;
* TIME3 = 5 years, equivalent to 1825 \* 1.92 = 3504 mm of accumulated rain.

The leaching values obtained from an application by brushing at 200 g.m-² with topcoat have been normalized d to 700 mm of rainfall per year for each active substance are summarized in the following table:

Leaching values obtained from surface application at 200 g/m² with topcoat

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Equations used for calculations** |  | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME 2 (365d)** | **TIME 3 (5y)** |
| Cypermethrin | Q\*leach = 7.00E-06 \* mm + 0.001  **(r² = 0.8741)** | 1.40E-03 | 5.90E-03 | *2.55E-02* |
| Penflufen | Q\*leach = 0.1552 \* Ln(mm) – 0.5774  **(r² = 0.98)** | 5.15E-02 | 4.39E-01 | *6.89E-01* |

**As the above results are from a leaching study with a topcoat, an assessment factor of 2 has been applied on leaching values used in the emissions estimation, only for Time 3 (as realistic leaching rates are available until 365 days)**

Leaching values considering the assessment factor of 2 (TIME 3):

|  |  |
| --- | --- |
|  | **Q\*leach [mg.m-2]** |
| **TIME 3 (5y)**  ***In situ*** |
| Cypermethrin | 5.10E-02 |
| Penflufen | 1.38 |

The leaching values for application with topcoat at 450 g/m² were considered as a worst case for estimating releases due to the outdoor injection treatment (150 g/m²) followed by a curative surface treatment (300 g/m²). Q\*leach values for treatment at 450 g/m² are extrapolated from data obtained at the dose of 200 g/m² using a linear extrapolation without taking into account an additional assessment factor of 10, in order to not unrealistically overestimate leaching values. In fact, the leaching from injection can be considered to be much lower than from a surface treatment.

Leaching values obtained from surface application at 450 g/m² with topcoat

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Q\*leach [mg.m-2]** | | |
| **TIME 1 (30d)** | **TIME 2 (365d)** | **TIME 3 (5y) (including AF 2)** | |
| Cypermethrin | 3.16E-03 | 1.33E-02 | | 1.15E-01 |
| Penflufen | 1.16E-01 | 9.88E-01 | | 3.1 |

The degradation of Penflufen in soil and in the aquatic systems leads to formation of two main metabolites M01 (surface water and soil only) and M02 (soil only). In this risk assessment, those metabolites have been taken into account considering the molar ratio. The formation fractions are added for each scenarios according to the relevant compartment of formation. The results presented below are only with the molar ratio.

Relevant metabolites - Leaching values obtained from surface application at 450 g/m² with topcoat

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Q\*leach [mg.m-2]** | | |
| **TIME 1**  **(30d)** | **TIME 2 (365d)** | **TIME3**  **(5y)** |
| **Equations:**  Q\*leach, time1  = ( Q\*leach time 1/time2/time 3 \* Molar mass metabolite/Molar mass parent) | | | |
| M01 | 1.22E-01 | 1.038 | 3.26 |
| M02 | 1.01E-01 | 8.57E-01 | 2.69 |

The product used in the semi-field study does not allow to calculate leaching rates for the substance of concern BIT, therefore according to the TAB v2.1 ENV 187, the leaching rates will be:

Time 1 (30days): 50% of the applied substance leaches out

Time 2 (365 days): 75% of the applied substance leaches out

Time 3 (service life): 100% of the substance leaches out

As BIT is only relevant for the STP (see confidential PAR for more details), the calculations will be performed only for the noise barrier scenario. As a worst-case, the surface application at 450 g/m2 is taken into account:

BIT - Leaching values obtained from surface application at 450 g/m² (considering a concentration of this substance in the product of 0.02% w/w, product density around 1)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Q\*leach [mg.m-2]** | |
| **TIME 1**  **(30d)** | **TIME 2 (365d)** | **TIME3**  **(5y)** |
| BIT | 45 | 67.5 | 90 |

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

No data available.

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

No data available.

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

No data available.

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

No data available.

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

No data available.

#### Exposure assessment

The environmental exposure assessment has been performed in accordance with the revised Emission Scenario Document for wood preservatives (revised ESD for PT08, 24/09/2013).

The product 18V33CP-PE is a ready-to-use water-based wood preservative containing 0.183% w/w cypermethrin and 0.027% w/w penflufen (technical concentration). It is intended to be used for the preventive (at 200 g/m2) and curative (at 300 g/m2) treatment of woods against wood-boring insects, termites and wood-destroying fungi, indoor and outdoor. These preventive and curative treatments are done by professionals and non-professionals by brush application, spray application or injection. Outdoor injection application is only performed as curative treatment. The treatment by injection is performed at 150 g/m2 of product and is always followed by a curative surface application by brushing or spraying at 300 g/m2 of product.

According to the revised ESD for PT08, the emissions to the environment following indoor treatments (UC1 and UC2 woods) by spraying, brushing and injection are considered negligible. Therefore, the exposure assessment presented below regards outdoor uses only.

For treatment of exterior woods (UC3 class), emissions to the environment may occur during the application phase and during the service life of the treated wood.

The applicant confirmed that no treatment for UC4 is foreseen for this product.

**- Application phase:**

When the product is applied outdoor by brushing, spraying or injection, spills, drips and spray-drift may end-up directly in the adjacent soil if it is not protected. Also, if the treated structure is located near a surface water body, emission into the surface water may occur.

For applications by brushing, the emissions to soil and surface water have been estimated by applying the scenarios described in the ESD-PT08 (2013) “house” and “bridge over pond” respectively.

For applications by spraying, the emissions to soil have been estimated using the scenario “*in situ* spraying”, according to the ESD-PT08, section 4.4.5. No scenario is currently available for estimatingdirect release to surface water from outdoor spraying application. Therefore, the scenario “bridge overpond” was adapted by considering the fraction of product lost to water during application as the sum ofreleases due to run-off (Frunoff = 0.2) and drift (Fdrift = 0.1) described in the section 4.4.5 of the ESDPT08(2013).

No scenario is currently described in the ESD-PT08 for estimating releases during outdoor application by injection. A worst case approach was considered for estimating releases by applying the scenarios used for brushing application (house and bridge over pond) by non-professional with an application rate of 150 g/m2. As the injection is always followed by a curative surface application by brushing or spraying at 300 g/m2 of product, emissions have been aggregated, accordingly. When relevant, emissions have been calculated for both professionals and non-professionals.

**- Service life:**

During the service life of the treated structure, leaching of active substances out of the wood may occur due to rainfall. Then, the adjacent soil and the surface water body located near to the treated area may be exposed. Also, if the treated structure is located in urban area, the releases will be washed with rain to the rain water/sewer system and the STP will be considered as the main receiving compartment.

Emissions into the soil, the surface water and the STP are calculated using the scenarios house, bridge over pond and noise barrier respectively, using the worst-case application rate (450 g/m2).

General information

|  |  |
| --- | --- |
| Assessed PT | PT08 |
| Assessed scenarios | House, Bridge over the pond, Noise barrier |
| ESD(s) used | Revised Emission Scenario Document for wood preservatives, 2013 |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on Volume IV Guidance (2017) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | All scenarios  Production: No  Formulation No  Use: Yes  Service life: Yes |

***Emission estimation***

For the application phase, the technical active substance contents have to be considered.

|  |  |  |
| --- | --- | --- |
| Expression of the active substance’s content | Cypermethrin | Penflufen |
| Technical (%w/w) | 0.183 | 0.027 |

Regarding the metabolites of penflufen, M01 and M02, the formation fraction for the relevant compartments are used in the calculations as presented below:

|  |  |  |
| --- | --- | --- |
|  | M01 | M02 |
| Formation fraction in soil | 0.17 | 0.115 |
| Formation fraction in surface water | 0.128 | Not relevant |

For service-life, the leaching rates calculated in section 2.2.8.5.2 have been applied. Leaching rates have been derived for Time 1 (30 days), 2 (365 days) and 3 (1825 days).

According to the technical Agreements for Biocides (June 2016), the house-scenario is the worst case scenario for soil and is therefore be sufficient. Consequently, the fence scenario has not been presented.

According to the ESD-PT08, no scenario is currently available for estimating direct release to surface water from outdoor spraying application. Therefore, the ESD-TP08 scenario “bridge over pond” was adapted by considering the fraction of product lost to water during application as the sum of releases due to run-off (Frunoff= 0.2) and drift (Fdrift = 0.1) described in the section 4.4.5 of the ESD-PT08 (2013).

As explained in the “Leaching behaviour” section, the BIT is only relevant in the STP (see confidential PAR for more details), therefore the calculations will be performed only for the noise barrier scenario. Only the service-life is assessed for this substance.

For the calculations, the application rates at 200 g/m2 and 300 g/m2, corresponding to the preventive and curative application are presented. The injection is assessed separately (more details below).

**Emissions estimation during the application phase**

**Emissions from in-situ brushing application (Bridge – House)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Inputs – in situ application by brush (Bridge – House)** | | | |
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Treated wood area | AREAbridge | 10 | [m².d-1] |
| Treated wood area | AREAhouse | 125 | [m².d-1] |
| Application rate of the product | Qapplic.product Preventive  Curative | 0.2  0.3 | [l.m-2] |
| Content of the active substances | fai | See above | [-] |
| Density of the product | RHOproduct | 1000 | [kg.m-3] |
| Fraction of product lost to water during application | Fwater,brush | 0.03 | [-] |
| 0.05 |

|  |  |  |
| --- | --- | --- |
| **Outputs – *in situ* application by brush - Bridge scenario - 200 g/m2** | | |
| **Emission of substance to water – E water [kg.d-1]** | | |
|  | Professional | Non professional |
| Cypermethrin | 1.10E-04 | 1.83E-04 |
| Penflufen | 1.62E-05 | 2.70E-05 |
| M01 | 2.18E-06 | 3.63E-06 |

|  |  |  |
| --- | --- | --- |
| **Outputs – *in situ* application by brush - Bridge scenario - 300 g/m2** | | |
| **Emission of substance to water – E water [kg.d-1]** | | |
|  | Professional | Non professional |
| Cypermethrin | 1.65E-04 | 2.75E-04 |
| Penflufen | 2.43E-05 | 4.05E-05 |
| M01 | 3.27E-06 | 5.45E-06 |

|  |  |  |
| --- | --- | --- |
| **Outputs – *in situ* application by brush - House scenario - 200 g/m2** | | |
|  | Professional | Non professional |
| **Emission of substance to soil – E soil [kg.d-1]** | | |
| Cypermethrin | 1.37E-03 | 2.29E-03 |
| Penflufen | 2.03E-04 | 3.38E-04 |
| M01 | 3.62E-05 | 6.03E-05 |
| M02 | 2.02E-05 | 3.37E-05 |

|  |  |  |
| --- | --- | --- |
| **Outputs – *in situ* application by brush - House scenario - 300 g/m2** | | |
|  | Professional | Non professional |
| **Emission of substance to soil – E soil [kg.d-1]** | | |
| Cypermethrin | 2.06E-03 | 3.43E-03 |
| Penflufen | 3.04E-04 | 5.06E-04 |
| M01 | 5.42E-05 | 9.04E-05 |
| M02 | 3.03E-05 | 5.05E-05 |

**Emissions from *in-situ* spraying application - Bridge**

|  |  |  |  |
| --- | --- | --- | --- |
| **Inputs – in situ application by spray - Bridge scenario** | | | |
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Treated wood area | AREAbridge | 10 | [m².d-1] |
| Application rate of the product | Qapplic.product  Preventive  Curative | 0.2  0.3 | [l.m-2] |
| Content of the active substances | fai | See above | [-] |
| Density of the product | RHOproduct | 1000 | [kg.m-3] |
| Fraction of product lost to water during application by drift and by run-off | Fwater,spray | 0.3 | [-] |
| Water volume under bridge | Vwater | 1000 | [m²] |

|  |  |
| --- | --- |
| **Outputs - in situ application by spray - Bridge scenario – 200 g/m2** | |
| **Emission of substance to water after application – E water [kg.d-1]** | |
| Cypermethrin | 1.10E-03 |
| Penflufen | 1.62E-04 |
| M01 | 2.18E-05 |
| **Outputs - in situ application by spray - Bridge scenario – 300 g/m2** | |
| **Emission of substance to water after application – E water [kg.d-1]** | |
| Cypermethrin | 1.65E-03 |
| Penflufen | 2.43E-04 |
| M01 | 3.27E-05 |

**Emissions from *in-situ* spraying application - House**

|  |  |  |  |
| --- | --- | --- | --- |
| **Inputs – in situ application by spray - House scenario** | | | |
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Treated wood area | AREAbridge | 125 | [m².d-1] |
| Application rate of the product | Qapplic.product  Preventive  Curative | 0.2  0.3 | [l.m-2] |
| Content of the active substances | fai | See above | [-] |
| Density of the product | RHOproduct | 1000 | [kg.m-3] |
| Fraction of product lost to soil during application by run-off | Frun-off | 0.2 | [-] |
| Fraction of product lost to soil during application by drift (Tier I) | Fdrift | 0.1 | [-] |
| Fraction of spray drift depositing to a 0.5 m wide soil band 1-1.5 m distant from the house (Tier II) | Fdep | 0.33 | [-] |

|  |  |
| --- | --- |
| **Outputs – in situ application by spray - House scenario – 200 g/m2** | |
| **Emission of substance to soil after application (run-off) – E soil [kg.d-1]** | |
| Cypermethrin | 9.15E-03 |
| Penflufen | 1.35E-03 |
| M01 | 2.41E-04 |
| M02 | 1.35E-04 |
| **Emission of substance to soil after application (drift Tier 1) – E soil [kg.d-1]** | |
| Cypermethrin | 4.58E-03 |
| Penflufen | 6.75E-04 |
| M01 | 1.21E-04 |
| M02 | 6.73E-05 |
| **Emission of substance to soil after application (drift Tier 2) – E soil [kg.d-1]** | |
| Cypermethrin | 1.51E-03 |
| Penflufen | 2.23E-04 |
| M01 | 3.98E-05 |
| M02 | 2.22E-05 |

|  |  |
| --- | --- |
| **Outputs – in situ application by spray - House scenario – 300 g/m2** | |
| **Emission of substance to soil after application (run-off) – E soil [kg.d-1]** | |
| Cypermethrin | 1.37E-02 |
| Penflufen | 2.03E-03 |
| M01 | 3.62E-04 |
| M02 | 2.02E-04 |
| **Emission of substance to soil after application (drift Tier 1) – E soil [kg.d-1]** | |
| Cypermethrin | 6.86E-03 |
| Penflufen | 1.01E-03 |
| M01 | 1.81E-03 |
| M02 | 1.01E-04 |
| **Emission of substance to soil after application (drift Tier 2) – E soil [kg.d-1]** | |
| Cypermethrin | 2.26E-03 |
| Penflufen | 3.34E-04 |
| M01 | 5.97E-05 |
| M02 | 3.33E-05 |

**Emissions from *in-situ* injection application**

According to the applicant’s intended uses, outdoor injection application is only performed as curative treatment. The treatment by injection at 150 g/m2 of product is always followed by a curative surface application by brushing or spraying at 300 g/m2 of product.

No scenario is currently described in the PT08-ESD for estimating releases during outdoor application by injection in use class 3. As outdoor injection application is always followed by a curative surface application by brushing or spraying, the emissions from injection and surface application has to be cumulated.

However, as presented in the section 2.2.8.3 “Risk characterisation”, unacceptable risks are found at 300 g/m2 at the application phase for brushing and spraying. Therefore, only the Elocal are presented in the assessment, but no PEC and PEC/PNEC are presented as the RCR for a combined application by injection and by spray/brush (150 g/m2 + 200 or 300 g/m2) would always be higher than the ones already presented and therefore the conclusions remain unchanged.

|  |  |  |  |
| --- | --- | --- | --- |
| **Inputs – in situ application by injection -(Bridge – House)** | | | |
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Treated wood area | AREAbridge | 10 | [m².d-1] |
| Treated wood area | AREAhouse | 125 | [m².d-1] |
| Application rate of the product | Qapplic.product | 0.15 | [l.m-2] |
| Content of the active substances | fai | See above | [-] |
| Density of the product | RHOproduct | 1000 | [kg.m-3] |
| Fraction of product lost to water during application | Fwater,injection | 0.05 | [-] |

|  |  |
| --- | --- |
| **Outputs – *in situ* application by injection - Bridge scenario - 150 g/m2** | |
| **Emission of substance to water – E water [kg.d-1]** | |
| Cypermethrin | 1.37E-04 |
| Penflufen | 2.03E-05 |
| M01 | 2.72E-06 |

|  |  |
| --- | --- |
| **Outputs – *in situ* application by injection - House scenario - 150 g/m2** | |
| **Emission of substance to soil – E soil [kg.d-1]** | |
| Cypermethrin | 1.72E-03 |
| Penflufen | 2.53E-04 |
| M01 | 4.52E-05 |
| M02 | 2.52E-05 |

**Emissions estimation of service-life**

The leaching values for application with topcoat at **450 g/m²** are considered as a worst case to estimate the releases due to the outdoor injection treatment (150 g/m²) followed by a curative surface treatment (300 g/m²). Q\*leach values for treatment at 450 g/m² are extrapolated from data obtained at the dose of 200 g/m² using a linear extrapolation without taking into account an additional assessment factor of 10, in order to not unrealistically overestimate leaching values. The reasoning is presented in the section 2.2.8.1 “Leaching behavior”.

**Treated wood in-service – brushing and spraying**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Symbol** | | | **Value** | **Unit** | |
|  | **Inputs** | | | | |
| Application | | | *In situ surface application* | [-] | |
| AREA noise-barrier | | | 3000 | [m²] | |
| AREA bridge | | | 10 | [m²] | |
| AREA house | | | 125 | [m²] | |
| TIME1 | | | 30 | [d] | |
| TIME3 | | | 1825 | [d] | |
| Q\*leach,TIME1 | | | See leaching values above | [mg.m-2] | |
| Q\*leach,TIME2 | | |
| Q\*leach,TIME3 | | |
| DT50 soil | | | See table in section 2.2.8.1 | [d-1] | |
| V soil (noise-barrier) | | | 250 | [m3] | |
| V water (bridge) | | | 1000 | [m3] | |
| V soil (house) | | | 13 | [m3] | |
| RHO soil | | | 1700 | [kgwwt.m-3] | |
| F SOIL | | | 0.3 | [-] | |
| F STP | | | 0.7 | [-] | |
|  | **Outputs – NOISE BARRIER** | | | | |
|  | ***Direct emissions to soil*** | | | | |
|  | | | **Qleach, TIME1 (30d)**  **[kg]** | **Qleach, TIME2 (365d)**  **[kg]** | **Qleach, TIME3 (5y)  [kg]** |
| Cypermethrin | | | 2.84E-06 | 1.20E-05 | 1.04E-04 |
| Penflufen | | | 1.04E-04 | 8.89E-04 | 2.79E-03 |
| M01 | | | 1.10E-04 | 9.34E-04 | 2.93E-03 |
| M02 | | | 9.05E-05 | 7.71E-04 | 2.42E-03 |
| BIT | | | 4.05E-02 | 6.08E-02 | 8.10E-02 |
|  | ***Emissions to STP*** | | | | |
|  | | | **ESTP TIME1 (30d)**  **[kg.d-1]** | **ESTP TIME2 (365d)**  **[kg.d-1]** | **ESTP TIME3 (5y)  [kg.d-1]** |
| Cypermethrin | | | 2.21E-07 | 7.65E-08 | 1.32E-07 |
| Penflufen | | | 8.12E-06 | 5.68E-06 | 3.57E-06 |
| M01 | | | 8.53E-06 | 5.97E-06 | 3.75E-06 |
| M02 | | | 7.04E-06 | 4.93E-06 | 3.09E-06 |
| BIT | | | 3.15E-03 | 3.88E-04 | 1.04E-04 |
|  | **Outputs - BRIDGE** | | | | |
|  | ***Direct emissions to water*** | | | | |
|  | | | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (365d)**  **[kg]** | **Qleach, TIME3 (5y)  [kg]** |
| Cypermethrin | | | 3.16E-08 | 1.33E-07 | 1.15E-06 |
| Penflufen | | | 1.16E-06 | 9.88E-06 | 3.10E-05 |
| M01 | | | 1.56E-07 | 1.33E-06 | 4.17E-06 |
|  | **Outputs - HOUSE** | | | | |
|  | | **Qleach, TIME1(30d)**  **[kg]** | | **Qleach, TIME2 (365d)**  **[kg]** | **Qleach, TIME3 (5y)  [kg]** |
|  | ***Direct emissions to soil*** | | | | |
| Cypermethrin | | 3.95E-07 | | 1.66E-06 | 1.44E-05 |
| Penflufen | | 1.45E-05 | | 1.24E-04 | 3.88E-04 |
| M01 | | 2.59E-06 | | 2.21E-05 | 6.92E-05 |
| M02 | | 1.45E-06 | | 1.23E-05 | 3.87E-05 |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Freshwater | Freshwater sediment | STP | Air | Soil | Groundwater |
| Indoor use | No | No | No | No | No | No |
| Outdoor use- Application phase | Yes | Yes | No | No | Yes | Yes |
| Outdoor use- service life | Yes | Yes | Yes | No | Yes | Yes |

Available data on the fate and the behaviour of cypermethrin and penflufen (and its relevant metabolites) are summarized in the following table. These data are coming from the CAR of cypermethrin, 2019 and the CAR of penflufen, PT08, March 2017.Relevant data for the substance of concern BIT are also presented (CAR for PT06).

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | | | | |
| Input | | Value | | | | | Unit |
|  | | **Cypermethrin** | **Penflufen** | **M01** | **M02** | **BIT** |  |
| Molecular weight | | 416.3 | 317.41 | 333.4 | 275.4 | 151.19 | g/mol |
| Vapour pressure | | 6.00E-07  at 25°C | 4.10E-07  at 20°C | 1.30E-09  at 20°C | 2.30E-06  at 20°C | 1.10E-04 at 20°C | Pa |
| Water solubility (at 20°C) | | 4.00E-03 | 10.9 | 95 | 3.6 | 1150 at 20°C | mg/l |
| Log Octanol/water partition coefficient | | 5.45 | 3.30 | 1.70 | 2.10 | 0.7 | Log 10 |
| Organic carbon/water partition coefficient (Koc) | | 575000 | 280 | 38.2 | 1006 | 197 | l/kg |
| Henry’s Law Constant (at 20°C) | | 0.024 | calculated | calculated | calculated | 1.45E-05 | Pa/m3/mol |
| Biodegradability | | Not readily biodegradable | Not readily biodegradable | Not readily biodegradable | Not readily biodegradable | Not readily biodegradable |  |
| DT50 for degradation in soil | | 17.2 | 214 | 180 | 311 | 0.54 | d (at 12ºC) |
| DT50 water | | 0.95  (dissipation) | 419  (whole system) | 1000  (whole system) | 1000  (whole system) | 1.24 (whole system) | d(at 12ºC) |
| DT50 for degradation in sediment | | 18.5 | 1000 | 1000 | 1000 |  | d(at 12ºC) |
| k bio soil (as a worst case) | | 4.03E-02 | 3.24E-03 | 3.85E-03 | 2.23E-03 | 1.28 | d-1 |
| BCF fish | | 417 | not relevant | not relevant | not relevant | not relevant | L/kgwwt, measured |
| BCF earthworm | | 3383 | not relevant | not relevant | not relevant | not relevant | L/kgwwt, calculated |
| BMF fish | | 1 | not relevant | not relevant | not relevant | not relevant | [-] |

For the noise barrier scenario, there are releases to the STP. TAB (2021) ENV 9 was considered when using SimpleTreat 4.0. The distribution of the different substances in the STP are shown in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | | Remarks |
| Cypermethrin | Penflufen | BIT |  |
| Air | 6.734E-04 | 4.725E-05 | 1.45E-05 | SimpleTreat 4.0 |
| Water | 8.356 | 96.51 | 30.88 |
| Sludge | 91.65 | 3.495 | 1.973 |
| Degraded in STP | 0 | 0 | 67.17 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | Remarks |
| M01 | M02 |
| Water | 99.51 | 88.50 | SimpleTreat 4.0 |
| Sludge | 0.49 | 11.46 |
| Degraded in STP | 0 | 0 |

***Calculated PEC values***

The emissions to local water (bridge over pond) were calculated for the outdoor application phase at the application rate of 200 and 300 g product/m² of wood, and with the leaching rates values at 450 g product/m² of wood (considering a top coat) for the service life of treated wood as a worst case covering injection and curative treatment.

For the injection at 150 g/m2 associated with a curative treatment of 300 g/m², PECs for the application phase are not presented as there are already unacceptable risks found for the curative application (300 g/m2) and risk mitigation measures are needed to prevent releases during application.

The initial concentrations in soil (house) and water (bridge over pond) were defined on the day of application for the application phase (PT08-ESD eq. 4.42). For service-life, concentrations were calculated at the end of the assessment periods (*i.e.* at the end of 30 days for TIME1, 365 days for TIME2 and 1825 days for the TIME3), with the worst case half-life of each active substance (DT50sediment for the aquatic system, DT50bio soil for the terrestrial compartment).

Application and service-life were calculated separately (as the application phase led to non-acceptable risks). Following the environmental risk assessment performed for the application phase, releases to the environment must be prevented. Then, no emission occurs during the application and only emissions into the soil during the service-life of the treated wood due to leaching are relevant.

For the metabolites M01 and M02, the specific values of DT50 have been used after the application of the formation fractions in each compartment.

**Application Phase**

**200 g/m2:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Cypermethrin - 200 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 6.21E-01 |
| Tier 2 (distant soil) | / | / | 5.92E-02 |
| House - brushing | Professional | / | / | 6.21E-02 |
| Non-professional | / | / | 1.04E-01 |
| Bridge over pond - spraying |  | 1.10 | 1.37E+01 | / |
| Bridge over pond -brushing | Professional | 1.10E-01 | 1.37 | / |
| Non-professional | 1.83E-01 | 2.29 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Penflufen - 200 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 9.16E-02 |
| Tier 2 (distant soil) | / | / | 8.74E-03 |
| House - brushing | Professional | / | / | 9.16E-03 |
| Non-professional | / | / | 1.53E-02 |
| Bridge over pond - spraying |  | 1.62E-01 | 1.11E-03 | / |
| Bridge over pond -brushing | Professional | 1.62E-02 | 1.11E-04 | / |
|  | Non-professional | 2.70E-02 | 1.85E-04 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M01 - 200 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 1.64E-02 |
| Tier 2 (distant soil) | / | / | 1.56E-03 |
| House - brushing | Professional | / | / | 1.64E-03 |
| Non-professional | / | / | 2.73E-03 |
| Bridge over pond - spraying |  | 2.18E-02 | 3.51E-05 | / |
| Bridge over pond -brushing | Professional | 2.18E-03 | 3.51E-06 | / |
|  | Non-professional | 3.63E-03 | 5.86E-06 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M02 - 200 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 9.14E-03 |
| Tier 2 (distant soil) | / | / | 8.71E-04 |
| House - brushing | Professional | / | / | 9.14E-04 |
| Non-professional | / | / | 1.52E-03 |

**300 g/m2:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Cypermethrin - 300 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 9.32E-01 |
| Tier 2 (distant soil) | / | / | 8.88E-02 |
| House - brushing | Professional | / | / | 9.32E-02 |
| Non-professional | / | / | 1.55E-01 |
| Bridge over pond - spraying |  | 1.65 | 2.06E+01 | / |
| Bridge over pond -brushing | Professional | 1.65E-01 | 2.06 | / |
| Non-professional | 2.75E-01 | 3.43 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Penflufen- 300 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 1.37E-01 |
| Tier 2 (distant soil) | / | / | 1.31E-02 |
| House - brushing | Professional | / | / | 1.37E-02 |
| Non-professional | / | / | 2.29E-02 |
| Bridge over pond - spraying |  | 2.43E-01 | 1.67E-03 | / |
| Bridge over pond -brushing | Professional | 2.43E-02 | 1.67E-04 | / |
|  | Non-professional | 4.05E-02 | 2.78E-04 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M01 - 300 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 2.45E-02 |
| Tier 2 (distant soil) | / | / | 2.34E-03 |
| House - brushing | Professional | / | / | 2.45E-03 |
| Non-professional | / | / | 4.09E-03 |
| Bridge over pond - spraying |  | 3.27E-02 | 5.27E-5 | / |
| Bridge over pond -brushing | Professional | 3.27E-03 | 5.27E-06 | / |
|  | Non-professional | 5.45E-03 | 8.78E-06 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M02 - 300 g/m2** | | **PECsurface water** | **PECsediment** | **PECsoil** |
| **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 1.37E-02 |
| Tier 2 (distant soil) | / | / | 1.31E-03 |
| House - brushing | Professional | / | / | 1.37E-03 |
| Non-professional | / | / | 2.28E-03 |

**Service life**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **Cypermethrin – 450 g/m2** | | **PECSTP** | **PECsurface water** | **PECsediment** | **PECsoil direct release** | **PECsoil indirect release** | **PECGW direct release** |
| **(mg/L)** | **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.04E-05 | / | / |
| Time 2 | / | / | / | 5.11E-06 | / | / |
| Time 3 | / | / | / | 8.84E-06 | / | 8.72E-07 |
| Service life- Noise barrier | Time 1 | 9.24E-09 | 4.96E-07 | 6.20E-06 | 3.88E-06 | 2.19E-07 | / |
| Time 2 | 3.20E-09 | 1.72E-07 | 2.15E-06 | 1.91E-06 | 7.57E-08 | / |
| Time 3 | 5.53E-09 | 2.97E-07 | 3.71E-06 | 3.31E-06 | 1.31E-07 | 3.26E-07 |
| Service life- Bridge over pond | Time 1 | / | 4.22E-07 | 5.27E-06 | / | / | / |
| Time 2 |  | 2.16E-07 | 2.70E-06 | / | / | / |
| Time 3 | / | 3.74E-07 | 4.67E-06 | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **Penflufen – 450 g/m2** | | **PECSTP** | **PECsurface water** | **PECsediment** | **PECsoil direct release** | **PECsoil indirect release** | **PECGW direct release** |
| **(mg/L)** | **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 6.25E-04 | / | / |
| Time 2 | / | / | / | 3.28E-03 | / | / |
| Time 3 | / | / | / | 2.96E-03 | / | **5.85E-01** |
| Service life- Noise barrier | Time 1 | 3.92E-06 | 3.92E-04 | 2.69E-06 | 2.34E-04 | 6.94E-07 | / |
| Time 2 | 2.74E-06 | 2.74E-04 | 1.88E-06 | 1.23E-03 | 4.86E-07 | / |
| Time 3 | 1.72E-06 | 1.72E-04 | 1.18E-06 | 1.11E-03 | 3.05E-07 | **2.19E-01** |
| Service life- Bridge over pond | Time 1 | / | 1.12E-03 | 7.70E-06 | / | / | / |
| Time 2 | / | 8.52E-03 | 5.85E-05 | / | / | / |
| Time 3 | / | 1.72E-02 | 1.18E-04 | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **M01 – 450 g/m2** | | **PECSTP** | **PECsurface water** | **PECsediment** | **PECsoil direct release** | **PECsoil indirect release** | **PECGW direct release** |
| **(mg/L)** | **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.11E-04 | / | / |
| Time 2 | / | / | / | 5.36E-04 | / | / |
| Time 3 | / | / | / | 4.45E-04 | / | **5.62E-01** |
| Service life- Noise barrier | Time 1 | / | 5.43E-05 | / | 4.14E-05 | 1.40E-08 | / |
| Time 2 | / | 3.80E-05 |  | 2.01E-04 | 9.77E-09 |  |
| Time 3 | / | 2.39E-05 | / | 1.67E-04 | 6.13E-09 | **2.10E-01** |
| Service life- Bridge over pond | Time 1 | / | 1.53E-04 | / | / | / | / |
| Time 2 | / | 1.17E-03 | / | / | / | / |
| Time 3 | / | 2.35E-03 | / | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **M02 – 450 g/m2** | | **PECSTP** | **PECsurface water** | **PECsediment** | **PECsoil direct release** | **PECsoil indirect release** | **PECGW direct release** |
| **(mg/L)** | **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 6.33E-05 | / | / |
| Time 2 | / | / | / | 3.81E-04 | / | / |
| Time 3 | / | / | / | 4.23E-04 | / | 2.36E-02 |
| Service life- Noise barrier | Time 1 | / | / | / | 2.37E-05 | 2.93E-07 | / |
| Time 2 | / | / | / | 1.43E-04 | 2.05E-07 | / |
| Time 3 | / | / | / | 1.58E-04 | 1.29E-07 | 8.85E-03 |
| Service life- Bridge over pond | Time 1 | / | / | / | / | / | / |
| Time 2 | / | / | / | / | / | / |
| Time 3 | / | / | / | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **BIT – 450 g/m2** | | **PECSTP** | **PECsurface water** | **PECsediment** | **PECsoil direct release** | **PECsoil indirect release** | **PECGW direct release** |
| **(mg/L)** | **(µg/L)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(mg/kgwwt)** | **(µg/L)** |
| Service life- Noise barrier | Time 1 | 4.86E-04 | 1.22E-01 | 6.15E-04 | 6.19E-03 | 7.51E-06 |  |
| Time 2 | 6.00E-05 | 1.50E-02 | 7.59E-05 | 7.63E-04 | 9.26E-07 |  |
| Time 3 | 1.60E-05 | 4.00E-03 | 2.02E-05 | 2.02E-04 | 4.34E-07 |  |

***Primary and secondary poisoning***

Primary poisoning

The product is a wood preservative (Product Type 8). The product is ready to use and is applied in liquid form by brushing or spraying. A direct uptake of the product is unlikely.

Secondary poisoning

According to Vol IV, Part B the calculation of a possible risk to man via the food chain (PECoral,predator) should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log Kow value >3.

Secondary poisoning is relevant for the aquatic food chain and for the terrestrial food chain for both active substances whose Log Kow is above the trigger value of 3 (log Kow = 5.45 and 3.3 for cypermethrin and penflufen respectively). Secondary poisoning concerns toxic effects in organisms at high trophic levels based on ingestion of organisms from lower trophic levels. Measured or predicted concentrations of residues in top predators are compared to no effect concentrations for the predators. The key components of the assessment of secondary poisoning are the assessment of potential bioaccumulation and potential toxicity of the substance following exposure to residues of the active substance.

Secondary poisoning is not relevant for both penflufen metabolite M01 and M02 and for the BIT (log Kow < 3).

**Via the consumption of worms from contaminated soil**

Only the worst case scenario is presented here which is the house scenario. The values presented here are from the service life only. Indeed, as unacceptable risks are found for the application phase and thus emission during application should be prevented, the results regarding service life does not include the application phase. .

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Cearthworm values** | | | | | | |
| **Scenario** | **Clocalsoil time 3**  **[mg/kg wwt]** | | **PECporewater time 3**  **[mg/l]** | | **PECoral predator (Cearthworm)**  **[mg/kgwet worm]** | |
| House scenario | Cypermethrin | Penflufen | Cypermethrin | Penflufen | Cypermethrin | Penflufen |
| 8.84E-06 | 2.96E-03 | 8.72E-10 | 5.85E-04 | 1.77E-06 | 6.66E-03 |

These values have then been compared to the worst case PNEC value derived for predatory birds as the worst-case.

**Via the aquatic food chain**

Only the worst-case scenario has been presented (bridge over pond), considering service-life only as risks has been identified for the application phase and emission during application should be prevented.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PECoral predator using PECsurface water** | | | | |
| **Scenario** | **PECsurface water TIME 3**  **[µg/l]** | | **PECoral predator**  **[mg/kgwet fish]** | |
|  | Cypermethrin | Penflufen | Cypermethrin | Penflufen |
| Bridge over the pond | 3.74E-07 | 1.72E-02 | 7.79E-08 | 1.22E-03 |

These values have then been compared to the worst case PNEC value derived for predatory birds as the worst-case.

***Groundwater***

Concentrations in groundwater are non-acceptable for penflufen and its metabolites. A refinement has been conducted with FOCUS Pearl 4.4.4.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD was applied for injection followed by a curative surface application treatment (eq. to 450 g.m-2) as a worst case, based on leaching values calculated in the section 2.2.8.1 “Leaching Behaviour” and summarized below:

|  |  |
| --- | --- |
| **Extrapolated leaching values for a surface application at 450 g/m² with topcoat** | |
| Active substance | Q\*leach, TIME3 (5y) [kg.m-2] |
| Penflufen | 3.10E-06 |

Other inputs are:

|  |
| --- |
| ***Inputs:*** |

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | **Origin** |
| Total leachable area per hectare [m².ha-1] | 2000 (corresponding to 16 houses) | D – PT08-ESD, appendix 4 |
| Fraction of house surface exposed to weather – Fweatherside [-] | 0.5 | D – PT08-ESD, appendix 4 |
| Service life for surface applicaton [d] | 1825 | D – PT08-ESD |
| Fraction of house surface exposed to weather (Fweatherside) | 0.5 | D – PT08-ESD, appendix 4 |
| Number of equal applications per annum | 10 | D – PT08-ESD, appendix 4 |
| Application scheme | 10.01  15.02  24.03  29.04  05.06  11.07  17.08  22.09  29.10  04.12 | D – PT08-ESD, appendix 4 |
| Scenarios to be calculated | All 9 scenarios | D – PT08-ESD, appendix 4 |
| Crop setting | “grassland” scenario | D – PT08-ESD, appendix 4 |
| Freundlich exponent | Penflufen : 0.92  M01 : 0.93  M02 : 0.747 | CAR Penflufen |
| Formation fraction | M01: 0.58 from parent  M02: 0.08 from parent; 1 from M01 | CAR Penflufen |
| Application rate (kg/ha/event) | 6.20E-05 | O |

The results are listed in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Model** | **Scenario** | **Penflufen [µg.L-1]** | **M01 [µg.L-1]** | **M02 [µg.L-1]** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PEARL 4.4.4 | CHATEAUDUN | 0.00002 | 0.019966 | 0.000074 |
|  | HAMBURG | 0.000111 | 0.031988 | 0.000764 |
| JOIKIONEN | 0.000003 | 0.028698 | 0.000081 |
| KREMSMUENSTER | 0.000044 | 0.019081 | 0.000070 |
| OKEHAMPTON | 0.000103 | 0.022441 | 0.000127 |
| PIACENZA | 0.000095 | 0.018551 | 0.000724 |
| PORTO | 0.000033 | 0.013086 | 0.000024 |
| SEVILLA | 0.000000 | 0.011575 | 0.000026 |
| THIVA | 0.000006 | 0.015209 | 0.000082 |

For all locations, the values are below the threshold value of 0.1 µg/L*.* No unacceptable are thus foreseen for penflufen in the groundwater.

#### Risk characterisation

**Application Phase - 200 g/m2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Cypermethrin - 200 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | **8.87** |
| Tier 2 (distant soil) | / | / | 8.46E-01 |
| House - brushing | Professional | / | / | 8.87E-01 |
| Non-professional | / | / | **1.48** |
| Bridge over pond - spraying | / | **2.75E+02** | **2.75E+03** | / |
| Bridge over pond -brushing | Professional | **2.75E+01** | **2.75E+02** | / |
|  | Non-professional | **4.58E+01** | **4.58E+02** | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Penflufen - 200 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 2.43E-01 |
| Tier 2 (distant soil) | / | / | 2.32E-02 |
| House - brushing | Professional | / | / | 2.43E-02 |
| Non-professional | / | / | 4.05E-02 |
| Bridge over pond - spraying | / | 6.92E-02 | 6.95E-02 | / |
| Bridge over pond -brushing | Professional | 6.92E-03 | 6.95E-03 | / |
|  | Non-professional | 1.15E-02 | 1.16E-02 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M01- 200 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 4.20E-02 |
| Tier 2 (distant soil) | / | / | 4.00E-03 |
| House - brushing | Professional | / | / | 4.20E-03 |
| Non-professional | / | / | 6.99E-03 |
| Bridge over pond - spraying | Not relevant | 1.39E-03 | / | / |
| Bridge over pond -brushing | Professional | 1.39E-04 | / | / |
|  | Non-professional | 2.31E-04 | / | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M02 - 200 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 2.84E-02 |
| Tier 2 (distant soil) | / | / | 2.71E-03 |
| House - brushing | Professional | / | / | 2.84E-03 |
| Non-professional | / | / | 4.73E-03 |

**Application Phase - 300 g/m2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Cypermethrin - 300 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | **1.33E+01** |
| Tier 2 (distant soil) | / | / | **1.27** |
| House - brushing | Professional | / | / | **1.33** |
| Non-professional | / | / | **2.22** |
| Bridge over pond - spraying |  | **4.12E+02** | **4.12E+03** | / |
| Bridge over pond -brushing | Professional | **4.12E+01** | **4.12E+02** | / |
|  | Non-professional | **6.86E+01** | **6.86E+02** | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Penflufen - 300 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 3.65E-01 |
| Tier 2 (distant soil) | / | / | 3.48E-02 |
| House - brushing | Professional | / | / | 3.65E-02 |
| Non-professional | / | / | 6.08E-02 |
| Bridge over pond - spraying |  | 1.04E-01 | 1.04E-01 | / |
| Bridge over pond -brushing | Professional | 1.04E-02 | 1.04E-02 | / |
|  | Non-professional | 1.73E-02 | 1.74E-02 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M01 - 300 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 6.29E-02 |
| Tier 2 (distant soil) | / | / | 6.00E-03 |
| House - brushing | Professional | / | / | 6.29E-03 |
| Non-professional | / | / | 1.05E-02 |
| Bridge over pond - spraying | Not relevant | 2.08E-03 | / | / |
| Bridge over pond -brushing | Professional | 2.08E-04 | / | / |
|  | Non-professional | 3.47E-04 | / | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **M02 - 300 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | 4.26E-02 |
| Tier 2 (distant soil) | / | / | 4.06E-03 |
| House - brushing | Professional | / | / | 4.26E-03 |
| Non-professional | / | / | 7.10E-03 |

**Service life**

As there are unacceptable risks found for the application, only PEC/PNEC ratios for service-life (without application) are presented hereafter.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **Cypermethrin – 450 g/m2** | | **PEC/PNECSTP** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.48E-04 | / | / |
| Time 2 | / | / | / | 7.31E-05 | / | / |
| Time 3 | / | / | / | 1.26E-04 | / | 8.72E-07 |
| Service life- Noise barrier | Time 1 | 5.67E-09 | 1.24E-04 | 1.24E-03 | 5.55E-05 | 3.13E-06 | / |
| Time 2 | 1.96E-09 | 4.29E-05 | 4.29E-04 | 2.74E-05 | 1.08E-06 | / |
| Time 3 | 3.39E-09 | 7.42E-05 | 7.42E-04 | 4.73E-05 | 1.87E-06 | 3.26E-07 |
| Service life- Bridge over pond | Time 1 | / | 1.05E-04 | 1.05E-03 | / | / | / |
| Time 2 | / | 5.40E-05 | 5.40E-04 | / | / | / |
| Time 3 | / | 9.35E-05 | 9.35E-04 | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **Penflufen – 450 g/m2** | | **PEC/PNECSTP** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.66E-03 | / | / |
| Time 2 | / | / | / | 8.69E-03 | / | / |
| Time 3 | / | / | / | 7.85E-03 | / | < 0.1\* |
| Service life- Noise barrier | Time 1 | 3.59E-06 | 1.67E-04 | 1.68E-04 | 6.21E-04 | 1.84E-06 | / |
| Time 2 | 2.52E-06 | 1.17E-04 | 1.18E-04 | 3.26E-03 | 1.29E-06 | / |
| Time 3 | 1.58E-06 | 7.35E-05 | 7.38E-05 | 2.94E-03 | 8.09E-07 | < 0.1\* |
| Service life- Bridge over pond | Time 1 | / | 4.79E-04 | 4.81E-04 | / | / | / |
| Time 2 | / | 3.64E-03 | 3.66E-03 | / | / | / |
| Time 3 | / | 7.34E-03 | 7.37E-03 | / | / | / |

\* with a FOCUS Pearl refinement

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **M01 – 450 g/m2** | | **PEC/PNECSTP** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 2.84E-04 | / | / |
| Time 2 | / | / | / | 1.37E-03 | / | / |
| Time 3 | / | / | / | 1.14E-03 | / | < 0.1\* |
| Service life- Noise barrier | Time 1 | / | 3.46E-06 | / | 1.06E-04 | 3.12E-08 | / |
| Time 2 | / | 2.42E-06 | / | 5.14E-04 | 2.50E-08 | / |
| Time 3 | / | 1.52E-06 | / | 4.27E-04 | 1.57E-08 | < 0.1\* |
| Service life- Bridge over pond | Time 1 | / | 9.78E-06 | / | / | / | / |
| Time 2 | / | 7.43E-05 | / | / | / | / |
| Time 3 | / | 1.50E-04 | / | / | / | / |

\* with a FOCUS Pearl refinement

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **M02 – 450 g/m2** | | **PEC/PNECSTP** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.97E-04 | / | / |
| Time 2 | / | / | / | 1.18E-03 | / | / |
| Time 3 | / | / | / | 1.31E-03 | / | 2.36E-02 |
| Service life- Noise barrier | Time 1 | / | / | / | 7.36E-05 | 9.10E-07 | / |
| Time 2 | / | / | / | 4.44E-04 | 6.37E-07 | / |
| Time 3 | / | / | / | 4.91E-04 | 4.00E-07 | 8.85E-03 |
| Service life- Bridge over pond | Time 1 | / | / | / | / | / | / |
| Time 2 | / | / | / | / | / | / |
| Time 3 | / | / | / | / | / | / |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE-LIFE**  **BIT – 450 g/m2** | | **PEC/PNECSTP** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- Noise barrier | Time 1 | 8.84E-03 | / | / | / | / | / |
| Time 2 | 1.09E-03 | / | / | / | / | / |
| Time 3 | 2.91E-04 | / | / | / | / | / |

**MIXTURE TOXICITY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Mixture (Cypermethrin + Penflufen) - 200 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | **9.12** |
| Tier 2 (distant soil) | / | / | 8.69E-01\* |
| House - brushing | Professional | / | / | 9.19E-01\* |
| Non-professional | / | / | **1.52** |
| Bridge over pond - spraying |  | **2.75E+02** | **2.75E+03** | / |
| Bridge over pond -brushing | Professional | **2.75E+01** | **2.75E+02** | / |
|  | Non-professional | **4.58E+01** | **4.58E+02** | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **APPLICATION**  **Mixture (Cypermethrin + Penflufen) - 300 g/m2** | | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil direct release** |
| House - spraying | Tier 1 (adjacent soil) | / | / | **1.37E+01** |
| Tier 2 (distant soil) | / | / | **1.30** |
| House - brushing | Professional | / | / | **1.37** |
| Non-professional | / | / | **2.28** |
| Bridge over pond - spraying |  | **4.12E+02** | **4.12E+03** | / |
| Bridge over pond -brushing | Professional | **4.12E+01** | **4.12E+02** | / |
|  | Non-professional | **6.86E+01** | **6.86E+02** | / |

\* risks remains acceptable even with the addition of risk ratios from M01 and M02

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SERVICE LIFE**  **Mixture (Cypermethrin + Penflufen) – 450 g/m2** | | **PEC/PNECSTP\*** | **PEC/PNECsurface water** | **PEC/PNECsediment** | **PEC/PNECsoil (direct release)** | **PEC/PNECsoil (indirect release)** | **PECGW**  **(direct release)**  **(µg/L)** |
| Service life- House | Time 1 | / | / | / | 1.81E-03 | / | / |
| Time 2 | / | / | / | 8.77E-03 | / | / |
| Time 3 | / | / | / | 7.97E-03 | / | <0.5 |
| Service life- Noise barrier | Time 1 | 8.85E-03 | 2.92E-04 | 1.41E-03 | 6.76E-04 | 4.97E-06 | / |
| Time 2 | 1.09E-03 | 1.60E-04 | 5.47E-04 | 3.28E-03 | 2.37E-06 | / |
| Time 3 | 2.92E-04 | 1.48E-04 | 8.16E-04 | 2.99E-03 | 2.68E-06 | <0.5 |
| Service life- Bridge over pond | Time 1 | / | 5.85E-04 | 1.54E-03 | / | / | / |
| Time 2 | / | 3.70E-03 | 4.20E-03 | / | / | / |
| Time 3 | / | 7.43E-03 | 8.31E-03 | / | / | <0.5 |

\*Cypermethrin + Penflufen + BIT

**All the conclusions presented below refer directly to the mixture:**

***Atmosphere***

Only negligible exposure to the atmosphere is expected therefore risk to the atmosphere is not relevant.

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

No unacceptable risks are foreseen for the noise barrier scenario for all the compartments and all the assessed substances.

***Aquatic compartment***

**Regarding the application phase:**

For surface water and sediment, unacceptable risks are foreseen at 200 g/m2, 300 g/m2 and consequently also at 450 g/m2 for both professionals and non-professionals by brushing, and also with spraying application. Therefore, the following risk mitigation measure is added to SPC to mitigate the risk: “**Do not apply where the product can reach surface water during outdoor application”**

**Regarding the service-life:**

No unacceptable risks are foreseen.

***Terrestrial compartment***

**Regarding the application phase:**

At 200 g/m2, unacceptable risks are foreseen with the spraying application in Tier 1 (adjacent soil) for both professionals and non-professionals. The Tier 2 assessment (for distant soil) leads to acceptable risks. Moreover, unacceptable risks are foreseen with the brushing application by non-professionals. Acceptable risks are foreseen for brushing applications by professionals (and it was verified that combined emissions from application and service-life still lead to acceptable risks).

For brush (non-professionals) and spray (professionals and non-professionals) applications at the application rate of 200 g/m2, the following RMM must be added to the SPC in order to mitigate the risks for the other in situ applications: **“For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”.**

At 300 g/m2, unacceptable risks are foreseen with the spraying application for both Tier 1 (adjacent soil) and Tier 2 (distant soil). No RMM can mitigate a risk in Tier 2 and therefore, the curative use by spraying cannot be authorized. The injection (always followed by a curative treatment) can thus only be authorized if it is followed by a brushing application only.

For brush (professionals and non-professionals) applications at the application rate of 300 g/m2, the following RMM must be added to the SPC in order to mitigate the risks for the other in situ applications: **“For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”.** Considering that injection is always associated to a curative treatment, the same risk mitigation measure applies for this application method.

**Regarding the service-life:**

No unacceptable risks are foreseen.

***Groundwater***

As presented in the section 2.2.8.2, the values are all below the threshold value of 0.1 µg/L and therefore the risk for groundwater is considered acceptable.

***Primary and secondary poisoning***

Primary poisoning

The product is a wood preservative (Product Type 8). The product is ready to use and is applied in liquid form by brushing or spraying. A direct uptake of the product is unlikely.

Secondary poisoning

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| **Scenario** | **PECoral predator** | | **PEC/PNECoral** | |
|  | Cypermethrin | Penflufen | Cypermethrin\* | Penflufen\*\* |
| House scenario | 1.77E-06 | 6.66E-03 | 5.38E-07 | 2.11E-04 |
| Bridge over the pond | 7.79E-08 | 1.22E-03 | 2.36E-08 | 3.87E-05 |

\* PNEC oral mammals as a worst case

\*\* PNEC oral birds as a worst case

Conclusion: All PEC/PNEC ratios are lower than 1, therefore the risks of secondary poisoning are acceptable for both the active substances.

***Mixture toxicity***

As the biocidal product consists of more than one active substance, the environmental risk should be based on the combined risk. The previous conclusions already consider mixture toxicity.

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

The aggregated exposure is not relevant.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The risk assessment for the active substances and their relevant metabolites, as well as for the substance of concern BIT (relevant for the STP only), has been performed for the preventive, curative and injection application.  For the preventive application (i.e. 200 g/m2):   * Unacceptable risks are found for the aquatic compartment during the application phase. Therefore the following risk mitigation measure must be added to the SPC: “**Do not apply where the product can reach surface water during outdoor application”** * Unacceptable risks are found for the terrestrial compartment during the application phase for the adjacent soil for the application by spray by professionals and no-professionals and for the application by brush for non-professionals only. Therefore the following RMM must be added to the SPC for these uses: “**For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”** * Acceptable risks are found for the service-life   For the curative application (i.e. 300 g/m2):   * Unacceptable risks are found for the aquatic compartment during the application phase. Therefore the following RMM must be added to the SPC: “**Do not apply where the product can reach surface water during outdoor application”.** * Unacceptable risks are found for the terrestrial compartment during the application phase for both professional and non-professional for the application by brush. Therefore the following RMM must be added to the SPC: “**For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”** * Unacceptable risks are found for both adjacent and distant soil for the application by spray. No risk mitigation measure can mitigate the risk for the distant soil. Therefore the application by spray for the curative treatment cannot be authorized.   For the injection (i.e. 150 g/m2):  The injection is always carried out in combination with a curative superficial application of 300 g/m2. As the spraying is not authorized for the curative application, injection must only be associated with a brushing application. Considering that injection is always associated to a curative treatment, the following risk mitigation measure also applies for this application method “**For outdoor in situ treatment, cover the ground with an appropriate impermeable sheet to prevent any emission to the terrestrial compartment”**  As the product is protected by a top-coat, the following RMM must also be added to the SPC: “**Use the treated wood outdoors only when it is protected by a top-coat that does not contain any biocidal substance for wood preservation. This top-coat must be classified as stable according to standard EN 927-2, which limits the leaching of the product to the environment throughout the life cycle of the treated wood.***”* |

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

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

### Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

### Comparative assessment

*Not relevant*

# Annexes[[5]](#footnote-6)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Gabille M. and Le Bayon I. | 2018 | 17V33CP-concentré. EN 113. Test method for determining the protective effectiveness of a wood preservative against wood-destroying basidiomycetes. Determination of the toxic valued.  Accelerated ageing prior to biological testing: evaporation (EN 73).  FCBA Biology Laboratory  Report n°401/17/006F/b-e | Y | Groupe V33 |
| Gabille M. and Le Bayon I. | 2018 | 17V33CP-concentré. EN 113. Test method for determining the protective effectiveness of a wood preservative against wood-destroying basidiomycetes. Determination of the toxic valued.  Accelerated ageing prior to biological testing: leaching (EN 84).  FCBA Biology Laboratory  Report n°401/17/006F/a-e | Y | Groupe V33 |
| Arancon J. | 2018 | Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus) - Part 1: application by surface treatment (laboratory method). EN 46-1: 2016 (+ EN 73)  Tecnalia  Report n°071946-1-a | Y | Groupe V33 |
| Arancon J. | 2018 | Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus) - Part 1: application by surface treatment (laboratory method). EN 46-1: 2016 (+ EN 84)  Tecnalia  Report n°071946-2-a | Y | Groupe V33 |
| Schumacher P. and Fennert EM. | 2019 | Determination of the protective effectiveness against *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 1 (2016) after evaporative ageing procedure according to EN 73 (2014)  MPA Eberswalde  Report n°32/18/10147/07 | Y | Cecil Division professionnelle  Groupe V33 |
| Schumacher P. and Fennert EM. | 2019 | Determination of the protective effectiveness against *Anobium punctatum* (de Geer) by egg-laying and larval survival according to EN 49 part 1 (2016) after evaporative ageing procedure according to EN 84 (1997)  MPA Eberswalde  Report n°32/18/10147/06 | Y | Cecil Division professionnelle  Groupe V33 |
| Brunet C. and Paulmier I. | 2019 | 18V33CP-PE. Protective efficacy against *Lyctus brunneus* according to NF EN 20-1.  FCBA Biology Laboratory  Report n°401/18/003F/a-e | Y | Groupe V33 |
| Arancon J. | 2018 | Determination of preventive action against *Reticulitermes* species according to NF EN 118:2013. + EN 73  Tecnalia  Report n°071946-3-a | Y | Groupe V33 |
| Arancon J. | 2018 | Determination of preventive action against *Reticulitermes* species according to NF EN 118:2013. + EN 84  Tecnalia  Report n°071946-4-a | Y | Groupe V33 |
| Schumacher P. and Fennert EM. | 2018 | Determination of the eradicant action against larvae of *Hylotrupes bajulus* (L.) according to EN 1390 (2006).  MPA Eberswalde  Report n°32/18/10147/03 | Y | Cecil Division professionnelle  Groupe V33 |
| Schumacher P. and Fennert EM. | 2019 | Determination of the eradicant efficacy in preventing hatching of *Anobium punctatum* (De Geer) according to EN 370 (1993) in combination with evaporative ageing procedure according to EN 73 (2014).  MPA Eberswalde  Report n°32/18/10147/05 | Y | Cecil Division professionnelle  Groupe V33 |

## Output tables from exposure assessment tools

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## New information on the active substance

Not relevant.

## Residue behaviour

Not relevant

## Summaries of the efficacy studies (B.5.10.1-xx)[[6]](#footnote-7)

## Confidential annex

See separated annex.

1. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
2. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-3)
3. Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class. [↑](#footnote-ref-4)
4. Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-5)
5. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-6)
6. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-7)