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)



TX201 TRAITEMENT MEUBLES PARQUETS

Product type 8

Permethrin

Case Number in R4BP: BC-UH022920-40

Evaluating Competent Authority: FR

Date: May 2018

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# CONCLUSION

**Conclusion for Physico-chemistry:**

The product TX 201 TRAITEMENT MEUBLES PARQUETS is a translucent colourless solvent based formulation. The surface tension is 25.31mN/m. The product is classified H304 Cat 1 Mention Danger according to CLP criteria.

The product is stable after storage 7 days at 0°C, 14 days at 54°C and 50 months at 20°C. Compatibility with tinplate can without varnish has been demonstrated with storage stability studies.

The analytical method for the determination of the active ingredient in the biocidal product has been provided and is validated.

**Conclusion for Efficacy:**

French competent authorities (FR CA) assessed that the product 11LBCEOL03 has shown a sufficient efficacy for the preservation of wood in service used:

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

The application rates validated are the following:

* Preventive treatments: superficial application at 200 mL of product 11LBCEOL03 / m² of wood
* Curative treatment: superficial application at 300 mL of product 11LBCEOL03 / m² of wood (injection 150 mL of product 11LBCEOL03 / m² of wood if need be).

**Conclusion on human health**

For professionals,

* For application by brushing (combined and not combined with injection), the risk is considered acceptable only with gloves.
* For spray application (combined and not combined with injection), the risk is considered unacceptable.

For non-professionals,

* For application by brushing (combined and not combined with injection), the risk is considered acceptable.
* For spray application (combined and not combined with injection), the risk is considered acceptable.

No unacceptable risk has been identified for secondary exposure.

**Conclusion for risk assessment for consumers via residues**

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with TX201 TRAITEMENT MEUBLES ET PARQUETS must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion for Ecotoxicology:**

Considering the intended uses of the product 11LBCEOL03, no direct or indirect contamination of the STP, surface water (including sediment) and soil (including groundwater) is expected. Regarding the air compartment, considering the physical and chemical properties of the active substance permethrin and the intended uses (indoor only), the emissions to the atmosphere will be negligible.

Therefore, the risk for all compartments and the risk for primary and secondary poisoning are considered acceptable under the use conditions provided in the SPC.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| TX201 TRAITEMENT MEUBLES PARQUETS | France |

#### **Other commeciral names :**

* AXTON TRATAMIENTO PLUS MUEBLES Y PARQUES (Spain)
* AXTON TRATAMENTO PLUS MOVEIS E PARQUET (Portugal)
* AXTON TRATTAMENTO ANTITARLO MOBILI INTERNO (Italy)
* AXTON ΘΕΡΑΠΕΙΑ ΓΙΑ ΞΥΛΙΝΑ ΔΑΠΕΔΑ ΚΑΙ ΕΠΙΠΛΑ (Greece)

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | V33 |
| **Address** | La Muyre  39 210 Domblans  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **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** | Permethrin |
| **Name of manufacturer** | LANXESS Deutschland GmbH  Material Protection Products |
| **Address of manufacturer** | Kennedyplatz 1,  D-50569 Köln,  Germany |
| **Location of manufacturing sites** | Bayer Vapi Private Limited  Plot # 306/3 II Phase,  GIDC,  Vapi – 396 195 Gujarat,  India |

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Caldic Denmark A/S (Acting for Tagros Chemicals India Ltd.) |
| **Address of manufacturer** | "Jhaver Centre", Rajah Annamalai Building,IV Floor, 72,  Marshalls Road,  Egmore,  Chennai-600 008,  India |
| **Location of manufacturing sites** | A4/1&2 Sipcot Industrial Complex,  Kudikadu Cuddalore, Tamil Nadu  India |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-  dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | ≥ 93% w/w sum of all isomers |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance permethrin is not a candidate for substitution in accordance with Article 10 of the BPR (Regulation (EU) n°. 528/2012).

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.70 |
| ShellSol D60 | Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics | Non-active substance[[3]](#footnote-3) | 64742-48-9 | 918-481-9 | 99.25 |

#### Information on technical equivalence

Not relevant.

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

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| AL (other liquid) |

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

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

The active substance is not classified from a physico chemical point of view.

| **Classification** | |
| --- | --- |
| Hazard category | Asp. Tox 1 Aspiration hazard cat. 1  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H304 May be fatal if swallowed and enters airways  H400, Very toxic to aquatic life  H410, Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H304 May be fatal if swallowed and enters airways  H410, Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P102: Keep out of reach of children  P103: Read label before use  P273: Avoid release to the environment  P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/…  P331 Do NOT induce vomiting  P391: Collect spillage  P405 Store locked up  P501: Dispose of contents/container to hazardous waste |
|  | |
| Note | EUH208 Contains permethrin. May produce an allergic reaction.  EUH066 Repeated exposure may cause skin dryness or cracking. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Preventive treatment by brushing for professionals and non-professionals

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood on use class 1 |
| 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 (*Reticulitermes spp., Heterotermes spp. and Coptotermes spp.*) \_ Workers, soldiers and nymphs |
| Field of use | Indoor use, on softwood and hardwood. |
| Application method(s) | Superficial application / brush |
| Application rate(s) and frequency | The product is ready to use  The application is performed by brushing  Application rate is in the analytical zone:  UC1: 200 mL/m² of wood |
| Category(ies) of user(s) | Professionals and non-professionals |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
| For professionals, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during application of the product by brushing. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 2. Use # 2 – Preventive treatment by spraying for non professionals

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood on use class 1 |
| 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 (*Reticulitermes spp., Heterotermes spp. and Coptotermes spp.*) \_ Workers, soldiers and nymphs |
| Field of use | Indoor use, on softwood and hardwood. |
| Application method(s) | Superficial application / spray |
| Application rate(s) and frequency | The product is ready to use  The application is performed by spraying  Application rate is in the analytical zone:  UC1: 200 mL/m² of wood. |
| Category(ies) of user(s) | Non-professionals |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
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|  |

#### Use description

Table 3. Use # 3 – Curative treatment by brushing and brushing combined with injection

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | Curative treatment for wood in service |
| Target organism (including development stage) | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.,* *Coptotermes spp*. and *Heterotermes spp.*) |
| Field of use | Curative treatment for wood in service (indoor) |
| Application method(s) | Superficial application / brush  Injection (combined with a superficial treatment) |
| Application rate(s) and frequency | The product is ready to use.  The application is performed by brushing.  The application rate is :   * 300 mL of product / m² of wood   When the application is performed by injection (combined with a superficial application), the application rate is :  150 mL of product / m² of wood (+ 300 mL of product / m² of wood) |
| Category(ies) of user(s) | Professional and non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

#### Use-specific instructions for use

|  |
| --- |
| * Curative treatments performed by injection must always be combined with curative treatments applied by superficial application. |

#### Use-specific risk mitigation measures

|  |
| --- |
| For professionnals:  - Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during brush application.  - Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during brush application combined with injection application. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 4. Use # 4 – Curative treatment by spraying and spraying combined with injection for non professionals

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | Curative treatment for wood in service |
| Target organism (including development stage) | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.,* *Coptotermes spp*. and *Heterotermes spp.*) |
| Field of use | Curative treatment for wood in service (indoor) |
| Application method(s) | Superficial application / spray  Injection (combined with a superficial treatment) |
| Application rate(s) and frequency | The product is ready to use.  The application is performed by spraying.  The application rate is :   * 300 mL of product / m² of wood   When the application is performed by injection (combined with a superficial application), the application rate is :  150 mL of product / m² of wood (+ 300 mL of product / m² of wood) |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

#### Use-specific instructions for use

|  |
| --- |
| * Curative treatments performed by injection must always be combined with curative treatments applied by superficial application. |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use

#### Instructions for use[[5]](#footnote-5)

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * The users should inform if the treatment is ineffective and report straightforward to the authorisation holder. |

#### Risk mitigation measures

|  |
| --- |
| * Avoid contact with skin. * Wash hands thoroughly after handling. * Do not apply on wood likely to be in contact with food, feed, drinks and livestock. * Keep out of reach of the children. |

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

|  |
| --- |
| * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Keep the container or label available. |

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

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets, ...) or down the drains. * Dispose of unused product, its packaging and any other waste in accordance with local regulations. |

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

|  |
| --- |
| Shelf life: 50 months. |

### Other information

|  |
| --- |
| Treated wood should not be intended for uses involving contact with food, feed or livestock. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Steel cans without internal varnish | 0.5, 0.75, 1, 2.5, 5, 25L | Steel | Polyethylene closure systems | Professional and nonprofessional | Yes (see the results of long term stability study) |

### Documentation

#### Data submitted in relation to product application

**Physico-chemistry:**

The product is not the representative product of the CAR. The applicant has provided studies on the formulation TX201 TRAITEMENT MEUBLES ET PARQUETS (11LBCEOL03).

**Efficacy:**

The product 11LBCEOL03 is identical to the product TX201 TRAITEMENT MEUBLES ET PARQUETS.

The following efficacy studies were submitted:

* Laboratory efficacy study conducted according to the standard EN 46-1[[6]](#footnote-6), with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[7]](#footnote-7), with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[8]](#footnote-8), with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 118[[9]](#footnote-9), with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure) against *Reticulitermes grassei*;
* Laboratory efficacy study conducted according to the standard EN 118, with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure) against *Heterotermes tenuis*;
* Laboratory efficacy study conducted according to the standard EN 118, with the product 11LBCEOL03 (0.7 % w/w permethrin), after ageing following EN 73 (evaporating procedure) against *Coptotermes gestroi*;
* Laboratory efficacy study conducted according to the standard EN 370[[10]](#footnote-10), with the product 11LBCEOL03 (0.7 % w/w permethrin) after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy studies conducted according to the standard EN 1390[[11]](#footnote-11), with the product 11LBCEOL03 (0.7 % w/w permethrin).
* Laboratory efficacy study conducted according to the standard EN 48[[12]](#footnote-12), with the product 11LBCEOL03 (0.7 % w/w permethrin).

**Human health:**

The following toxicology studies performed on 11LBCEOL03 were submitted:

- ASSESSMENT OF THE SKIN SENSITISATION POTENTIAL IN THE MOUSE USING THE LOCAL LYMPH NODE ASSAY (LLNA:BrdU); Richeux, F., 2014

- IN-VITRO HUMAN SKIN PENETRATION OF 14C-PERMETHRIN IN 11LBCEOL03 TEST ITEM, IN ACCORDANCE TO THE GUIDANCE OECD No.428; Bernal, J., 2015

**Residue data**

No specific residue data were submitted in the context of this dossier. The product TX201 TRAITEMENT MEUBLES ET PARQUETS is intended to be used as preventive and curative treatment of interior woods. It will not get into contact with food or feed. Residues in food or feed are not expected. Considering the intended uses no data is required.

#### Access to documentation

A letter of access from Lanxess and Tagros to Annex II data of permethrin has been granted to V33.

## Assessment of the biocidal product

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

Table 4. Intended use # 1 – Preventive application[[13]](#footnote-13)

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | ready-to-use solvent-based used for the preventive and curative treatment of interior woods |
| Target organism (including development stage) | Wood boring beetles  House longhorn beetle  Common furniture beetle  Powder post beetle  Subterranean termites (genus *Reticulitermes, Heterotermes and Coptotermes*)  All stages of development |
| Field of use | Indoor use |
| Application method(s) | Spraying and brushing |
| Application rate(s) and frequency | 200 mL/m² (or 158 g/m² with a product density of 0.79) |
| Category(ies) of user(s) | Professional and non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

Table 5. Intended use # 2 – Curative application[[14]](#footnote-14)

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | The product 11LBCEOL03 is a ready-to-use solvent-based used for the  preventive and curative treatment of interior woods |
| Target organism (including development stage) | Wood boring beetles  House longhorn beetle  Common furniture beetle  Powder post beetle  Subterranean termites (genus *Reticulitermes, Heterotermes and Coptotermes*)  All stages of development |
| Field of use | Indoor use |
| Application method(s) | Spraying and brushing  Injection (in combination with a superficial application) |
| Application rate(s) and frequency | Superficial application: 300 mL/m² (or 237 g/m² with a product density of 0.79)  Injection: 150 mL/m² (or 119 g/m² with a product density of 0.79) |
| Category(ies) of user(s) | Professional and non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel without varnish inside  Containers of 2.5-5L made of steel without varnish inside  Barrels of 25L made of steel without varnish inside |

### Physical, chemical and technical properties

The product X201 TRAITEMENT MEUBLES ET PARQUETS (11LBCEOL03) is a ready-to-use solvent-based wood preservative (AL) containing 0.70% w/w permethrin. Studies were performed on this formulation.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** |  | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin | Translucent colourless liquid at initial time and after 14 days at 54 ± 2°C. No deposit. No phase partition. | Acceptable | Legay S. 2016  Study 402/15/1172F/abg-e |
| Colour at 20 °C and 101.3 kPa | Visual observation |
| Odour at 20 °C and 101.3 kPa | No guideline required | The product 11LBCEOL03 has a petroleum solvent odour (hydrocarbons). |
| Acidity / alkalinity |  |  | As the product 11LBCEOL03 is a non-aqueous ready-to-use product, it is not intended to be applied as aqueous solutions (see the table of practical use of the product), therefore the determination of pH is not justified | Acceptable. According to Echa guidance for the assessment of biocidal products, pH is only relevant for water based formulations and formulations which are intended to be diluted. In this case, the product is ready to use and is mainly composed of organic solvent. Therefore, pH is not relevant. |  |
| Relative density / bulk density | OECD Guideline No.109 (2012) (pycnometer method) | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin | The mean relative density of the test item 11LBCEOL03 is D (20°C / 4°C) =0.791 ± 0.001. | Acceptable | Legay S. 2015  Study 402/15/1172F/cdef-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 method (storage stability) | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin  Analytical method validated | The test item in its commercial packaging (metal (tin plate) can without internal varnish) and in inert packaging (glass bottles) are considered to be stable after the accelerated storage procedure (14 days at 54 ± 2°C).   |  |  |  | | --- | --- | --- | | Test | At initial time | After 14 days at 54 ± 2°C | | Appearance of the test item (glass bottles) | Translucent colourless liquid No deposit or phase partition | | | Permethrin content (% w/w) (glass bottles) | 0.703 | 0.725 (+ 3.1% *vs.* the value at initial time) | | Appearance of the commercial packaging containing test item | 1L metal (tin plate) can without internal varnish. No sign of corrosion and degradation | | | Weight of the commercial packaging (g) | 929.20 | 928.10  (- 0.12%) | | Acceptable. The product is stable after storage 14 days at 54°C in glass bottles and metal (tin plate) can without varnish. | Legay S. 2016  Study 402/15/1172F/abg-e |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife | Product 11LBCEOL03 Batch number: 09021103 Containing 0.70% w/w of permethrin  Analytical method validated | The test item and its commercial packaging (metal (tin plate) can without internal varnish) are considered to be stable after the long term storage procedure (50 months at 20 ± 2°C).   |  |  |  | | --- | --- | --- | | Test | At initial time | After 50 months at 20 ± 2°C in metal (tin plate) can without internal varnish | | Appearance of the test item | No deposit or phase partition | | | Permethrin content (% w/w) | 0.709 | 0.713 (+ 0.6% *vs.* the value at initial time) | | Appearance of the commercial packaging containing test item | 1L metal (tin plate) can without internal varnish. No sign of corrosion and degradation | | | Weight of the commercial packaging (g) | / | - 0.58% | | Acceptable. The product is stable after storage 50 months at 20°C in metal (tin plate) can without varnish. | Legay S. 2014  Study 402/11/1033F/c/T4A-e  Legay S. 2011  Study 402/11/1033F/ab-fe |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 method (2000) | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin | The product 11LBCEOL03 is considered to be stable after storage for 7 days at 0 ± 2°C: no deposit or phase partition was observed. | Acceptable. The product is stable after storage 7 days at 0°C. | Legay S. 2015  Study 402/15/1172F/cdef-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 11LBCEOL03 are opaque (metal (tin plate) can without internal varnish). | Acceptable. | / |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item 11LBCEOL03 is considered to be stable after 14 days at 54 ± 2°C and after 7 days at 0 ± 2°C  The individual commercial packagings (metal (tin plate) can without internal varnish) are sealed. With this closure system, the packaging is leak-tight. | Acceptable. | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See the storage stability test – accelerated storage and long term storage at ambient temperature | Acceptable. | / |
| Wettability |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Wet sieve analysis and dry sieve test |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Disintegration time |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Persistent foaming |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Flowability/Pourability/Dustability |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Burning rate — smoke generators |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Burning completeness — smoke generators |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Composition of smoke — smoke generators |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Spraying pattern — aerosols |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Physical compatibility |  |  | Not applicable. 11LBCEOL03 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. | Not applicable. | / |
| Chemical compatibility |  |  | Not applicable. 11LBCEOL03 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. | Not applicable. | / |
| Degree of dissolution and dilution stability |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Surface tension | OECD Test Guideline115 EC method A5 (ring method) | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin | The surface tension of the pure test item 11LBCEOL03 was 25.31 mN/m at 19.3 ± 0.5°C. The test item was considered as surface-active in the experimental conditions used. | Acceptable. The preparation is surface active. | Legay S. 2015  Study 402/15/1172F/cdef-e |
| Viscosity | OECD Test Guideline 114 ISO Standard 2431 (flow cup method) | Product 11LBCEOL03 Batch number: 240815.03 Containing 0.70% w/w of permethrin | < 6.62 mm²/s at 20.0 ± 0.5°C and 40.0 ± 0.5°C | Acceptable. The product is classified H304 Cat1 Mention Danger according to CLP criteria (content of H304 compounds>10% and viscosity<20.5mm2/s). | Legay S. 2015  Study 402/15/1172F/cdef-e |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product 11LBCEOL03 is a translucent colourless liquid with a petroleum solvent odour (hydrocarbons). The relative density is 0.791.  After accelerated storage procedure (14 days at 54 ± 2°C) the appearance of the product 11LBCEOL03 in glass flask and its compatibility with the commercial packaging (metal (tin plate) can without internal varnish) have been provided and found acceptable. The permethrin content is 0.703% w/w at initial time and 0.725% w/w after 14 days at 54 ± 2°C in glass flask. With variation of + 3.1% *vs*. the value at initial time of permethrin, the test item is considered to be stable after the accelerated storage procedure.  After a long term storage procedure (50 months at 20 ± 2°C) the appearance of the product 11LBCEOL03 and its commercial packaging (metal (tin plate) can without internal varnish) are considered to be stable. The permethrin content is 0.709% w/w at initial time and 0.713% w/w after 50 months at 20 ± 2°C. With variation + 0.6% after 50 months *vs.* the value at initial time of permethrin, the test item is considered to be stable after the long term storage procedure in its commercial packaging. The product 11LBCEOL03 is stable after 7 days at 0°C, no deposit or phase partition was observed.  The dynamic viscosity of the product is < 6.62 mm²/s at 20°C and 40°C, and the surface tension of 11LBCEOL03 is 25.31 mN/m (surface active material). The product is classified H304 Cat 1 Mention Danger according to CLP criteria (content of H304 compounds>10% and viscosity<20.5mm2/s).  Shelf life: 50 months.  Labelling Mention: H304 Cat 1 Danger |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives |  |  | Not required as the product 11LBCEOL03 contains more than 99% w/w of compounds which are not classified as explosive. | Acceptable. The product is not explosive. | / |
| Flammable gases |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Flammable aerosols |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Oxidising gases |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Gases under pressure |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Flammable liquids | ASTM D-93 | ShellSol D60 | According to the SDS, the solvent used is not considered flammable (flash point: 61 – 66°C).  As the product 11LBCEOL03 contains more than 99% of this solvent, it is not expected to be flammable. | Acceptable. Regarding the composition of the product and the available SDS, the product is not considered to be flammable according to CLP criteria. | / |
| Flammable solids |  |  | Not required as the product is a ready-to-use liquid | Not applicable. | / |
| Self-reactive substances and mixtures |  |  | The product 11LBCEOL03 is not a self-reactive mixture. Not required as the product 11LBCEOL03 contains more than 99% w/w of solvent which is not classified as self-reactive mixture. | Acceptable. | / |
| Pyrophoric liquids |  |  | The product 11LBCEOL03 is not a pyrophoric liquid. Test is not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable. | / |
| Pyrophoric solids |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Self-heating substances and mixtures |  |  | Not required as the product is a ready-to-use liquid. | Regarding the composition of the product, it is not expected to be a self heating mixture. | / |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The product 11LBCEOL03 does not emit flammable gases when in contact with water. Test is not required as the product 11LBCEOL03 contains more than 99% w/w of solvent which does not emit flammable gases in contact with water. | Acceptable. | / |
| Oxidising liquids |  |  | The product 11LBCEOL03 is not oxidising. Test is not required as the product 11LBCEOL03 contains more than 99% w/w of solvent which is not classified as oxidising. | Acceptable. The product has no oxidizing properties. | / |
| Oxidising solids |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Organic peroxides |  |  | Not required as the product does not contain organic peroxides. | Not applicable. | / |
| Corrosive to metals |  |  | The product 11LBCEOL03 is not corrosive to metal. Test is not required as the product 11LBCEOL03 contains more than 99% w/w of compounds which are not classified as corrosive to metal. Moreover, no corrosion effect and no significant loss of weight of the packaging has been noticed during the accelerated and long term storage stability study. | Acceptable. According to CLP, the test recommended should be performed at 55°C for at least 7 days and the loss of weight is determined. Regarding the results after accelerated storage at 54°C, no loss of weight of the packaging and no sign of corrosion have been noticed. Therefore, the test can be avoided and the product is not considered corrosive. | / |
| Auto-ignition temperatures of products (liquids and gases) | ASTM E-659 | ShellSol D60 | The solvent used has an auto-ignition temperature of 235-315°C. As the product 11LBCEOL03 contains more than 99% w/w of this solvent, it is expected that the product has an auto-ignition temperature of 235-315°C. | Acceptable. The product is expected to have an auto-ignition temperature of 235-315°C. | / |
| Relative self-ignition temperature for solids |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |
| Dust explosion hazard |  |  | Not required as the product is a ready-to-use liquid. | Not applicable. | / |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on its composition, the product 11LBCEOL03 is not expected to present a significant hazard for explosive properties, flammability, self-reactivity, oxidising properties and auto-flammability. The product is not corrosive. |

### 

### Methods for detection and identification

**Analytical method for the determination of the active ingredient in the biocidal product**

|  |  |
| --- | --- |
| Study report | Validation of analytical method and chemical analysis of active ingredient declared in wood preservative11LBCEOL03, Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France) Legay S., 2011 |
| *Report* | 402/11/1033F/ab-fe |
| *GLP* | *Y* |

Test item: 11LBCEOL03, batch 09021103

Blank formulation: 090211010203M

**Principle of the method**

An analytical method for the determination of Permethrin in 11LBCEOL03 was validated during these studies by definition of the specificity, the linearity, the accuracy and the precision of the method. For these validation parameters, the criteria of SANCO 3030/99 rev.4, from 11/07/00 were fulfilled. Permethrin is analysed after dissolution of the formulation of 11LBCEOL03 in acetone and quantified by Liquid Chromatography using a UV detector (210nm) using a PINNACLE II C18 column.

**Specificity**  
Specificity was studied by analysis of the matrix without any active substance (formulation blank), the permethrin reference item (permethrin standard), and the test item (11LBCEOL03). The specificity was assessed by checking for any interference in HPLC-UV (210 nm) at the retention time of the active substance. No peak appears in the formulation blank. In the solutions of permethrin reference item and test item, the peak at the retention time around 9.6 min represents permethrin I and the peak at the retention time around 10.9 min represents permethrin II. No additional peak appears near the retention times of the permethrin I peak and the permethrin II peak in the reference item and in the test item. Therefore, the analytical method showed a good specificity for analysis of permethrin in formulation 11LBCEOL03.

**Linearity**  
To define the linearity of the detector answer of permethrin, five concentrations taken between 80% and 120% (eq 16.00 mg/L to 24.00 mg/L of permethrin reference standard in acetonitrile) were analysed.

The response of the detector during the analysis of permethrin was linear within the range of 16.00 mg/L to 24.00 mg/L (y = 1.75 \* 104 \* x + 5.44 \* 104 (y = sum of the two peaks areas (permethrin I + permethrin II), x = permethrin amount in mg/L), r = 0.9968 as r² = 0.993544). The correlation coefficient r was > 0.99 showing a good linearity.

**Accuracy**  
The accuracy was determined by analysing six reconstituted samples (blank matrix spiked with permethrin reference standard at the target value). The content of permethrin for each analysis was calculated with the calibration equations obtained before analysis. Then, the recovery rates, mean recovery rate, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated.

The accuracy results of permethrin were in conformity with the Guidelines requirements for formulations containing lower than 1% of an active substance. Indeed, the recovery results should be in the range 95% - 105% and they were experimentally between 102.30% and 103.25%. Mean recovery rate = 102.8% (n= 6) and RSD was equal to 0.38%. The precision obtained during accuracy measurements was acceptable as the R.S.D. were lower than the result of the modified Horwitz equation: < 2.83% (C = 0.0070).

**Precision**  
The precision was determined by precision obtained in accuracy measurements (see above) and by analysing six test item solutions. The content of permethrin for each analysis was calculated with the calibration equations obtained before analysis. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated. The concentration of permethrin in the test item was equal to 0.71% w/w and the RSD was equal to 1.69%. In the case of permethrin, the precision was acceptable as the R.S.D. were lower than the result of the modified Horwitz equation: < 2.83% (C = 0.0070).

|  |  |
| --- | --- |
| **Validation results** | |
| **Specificity** | Retention time for permethrin peaks (permethrin I and permethrin II) matches between reference item and test item, confirming the identity of the analyte. No interference was observed in formulation blank at the retention time of permethrin. Therefore, the analytical method showed a good specificity for analysis of permethrin in formulation 11LBCEOL03. |
| **Linearity** | Calibration range: 16.00 mg/L to 24.00 mg/L of permethrin (n = 5; 80% – 120%): y = 1.75 \* 104 \* x + 5.44 \* 104, r = 0.9968 as r² = 0.993544. (y = sum of the two peaks areas (permethrin I + permethrin II),  x= permethrin amount in mg/L) |
| **Accuracy** | Blank formulation samples fortified with permethrin at nominal content (approx 0.7%w/w, eq to 20mg/L in solution after dilutio of the sample)  Mean recovery rate = 102.8% (n = 6)  RSD = 0.38% (n = 6) < modified Horwitz 2.83% |
| **Precision** | 6 injections of six test item solutions Mean average content = 0.71% w/w (n = 6) RSD = 1.69% (n = 6) < modified Horwitz 2.83% |

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| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The permethrin content in the product 11LBCEOL03 is determined using a liquid chromatography method with UV detector (HPLC-UV at 210 nm). Quantification is performed using external standard calibration.  This analytical method for the determination of permethrin content in the product 11LBCEOL03 was validated by definition of the specificity, the linearity, the accuracy and the precision of the method. For these validation parameters, the criteria of SANCO 3030/99 rev.4, from 11/07/00 were fulfilled. |

Analytical methods for the determination of permethrin residues in food, soil, water and air

Analytical methods for permethrin residues in soil, air, water (drinking water) and sediment  
are available in Assessment Report permethrin Product-type 08 (Wood preservative), April 2014. A Letter of Access from Tagros and Lanxess (including data to Bayer and Sumitomo) has been granted.

**Soil (principle of method and LOQ)**

Soil samples were extracted in a microwave extractor with a mixture of acetonitrile/water and ammoniumformate. The sample was cleaned up by centrifugation. Identification and quantification of the test item was done using HPLC MS/MS detection in the Multiple Reaction Monitoring mode.

The method was validated using a slit loam soil (Höfchen) and a sandy loam soil (Laacher Hof).  
LOQ = 5.0 µg/kg in soil (permethrin)

**Air (principle of method and LOQ)**

Air is sucked through XAD adsorption tubes at about 1.5 L/min for 6 hours (total air sampling volume about 0.5 m3). Subsequently, the adsorption material is extracted with acetone. The extract is diluted with methanol/water (1/2 v/v) and analysed by HPLC/MS/MS, monitoring two parent-daughter ion transitions.

LOQ = 5 µg/m3 air.

Air is sucked through adsorption tubes at about 1.8 L/min for 6 hours at 35°C. Subsequently, the adsorption material is extracted with acetone. The extract was analysed for permethrin using GC/ECD.

GC-MS/MS was used as a confirmatory method (three ions with an m/z > 100).

LOQ = 0.0001 mg/m3 air

**Water (principle of method and LOQ)**

Acidified water samples are diluted with acetonitrile and analysed by HPLC-MS/MS using positive  
ionisation mode without further clean-up. Concentrations were quantified using external matrix-matched standard solutions.

LOQ = 0.05 µg/L for drinking and surface water, Permethrin only.

**Body fluids and tissues (principle of method and LOQ)**

Not data required. Molecule does not classify as toxic or highly toxic

**Active substance residues in food and feeding stuff**

As the product 11LBCEOL03 is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of permethrin residue in food/feed of plant and animal origin is unnecessary.

### Efficacy against target organisms

#### Function and field of use

MG 02: preservatives

Product Type 08: wood preservative

The product TX201 TRAITEMENT MEUBLES ET PARQUETS (development code 11LBCEOL03) is a solvent-based wood preservative product ready to use which is intended to be used by superficial application for preventive treatment for wood used in use class 1, and for curative treatments by superficial application (that could be completed by injection for curative treatments), indoor, for wood in service.

The product is applied by professional and non-professional users.

The application rates recommended by the applicant are the following:

* Preventive treatments: superficial application at 200 mL of product 11LBCEOL03 / m² of wood
* Curative treatment: superficial application at 300 mL of product 11LBCEOL03 / m² of wood (+ injection 150 mL of product / m² of wood).

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

According to the uses claimed by the applicant, the product TX201 TRAITEMENT MEUBLES ET PARQUETS is intended to be used for the preventive preservation of wood used in use class 1 by superficial application against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), and termites (*Reticulitermes spp*., *Heterotermes spp*., and *Coptotermes spp.*).

This product is also intended to be used for the curative treatment of wood in service against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*) and termites (*Reticulitermes spp., Heterotermes spp*., and *Coptotermes spp.)* indoor, by superficial application that could be completed by injection for curative treatments.

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

The product TX201 TRAITEMENT MEUBLES ET PARQUETS kills the insects after ingestion.

#### Mode of action, including time delay

Permethrin is a neurotoxin. It is a synthetic pyrethroid acting after ingestion. The target organisms ingest a small amount of the treated wood which, once ingested, results in death of the target pests. Permethrin when formulated as a wood preservative, is an axonic poison, binding to protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation, leading to death. Permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lambda-cyhalothrin) and is known as the “hot-foot effect” and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect (see Assessment Report permethrin, PT08, April 2014).

For preventive treatment against wood-boring insects and termites, the effect is immediate, even if efficacy is complete only after a few weeks of exposure of the insects. For curative treatment, the product is fast acting against house longhorn beetles and against common furniture beetles.

#### Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product 11LBCEOL03 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 99.3 g/m² and 102 g/m² (mean 100.8 g/m²).  10 recently hatched larvae of *H. bajulus* for each are used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (83%).  On the treated test block, 100 % of the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 100.81 g of product / m² of wood against *Hylotrupes bajulus* larvae**  **No control the solvent has been performed** | Arana M. et al., 2012  Report N° 27766-1a  S6.7\_01  IC 2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product 11LBCEOL03 is applied by brushing on hardwood test blocks (*Quercus petraea ou Quercus robur*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 99.4 g/m² and 100.3 g/m² (mean 99.8 g/m²).  10 recently hatched larvae of *L. brunneus* are used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  The method for recording / scoring effects is the recovery and the counting of the insects (alive/dead) and the number of drilled openings. | The study is validated as:   * At least, for each control, 20 insects are found * Adult emergence has started at the end test in the control and at least 85 % of the insects are found alive   **This study demonstrated the efficacy of the product at 100 g of product / m² of wood against *Lyctus brunneus* larvae**  **No control the solvent has been performed** | Paulmier et al.,2017  Report N° 401/15/283F/a  S6.7\_06  IC 2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | Common furniture beetle: *Anobium punctatum (L.)* | EN 49-1 + EN 73 (evaporation) | The ready to use product 11LBCEOL03 is applied by brushing on hardwood test blocks (*Quercus petraea ou Quercus robur*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test is 199 mL/m².  5 females and at least 5 males of *A.punctatum* are used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the number of layed and hatched eggs, and the number of alive larvae at the end of the tests  - Intervals of examination is one examination, 26 weeks after beginning of exposure of the adults. | The study is validated as:   * At least, for each control set, 50 insects larvae are found * Alive larvae are found in each control   **This study demonstrated the efficacy of the product at 199 mL of product / m² of wood against *Anobium punctatum* larvae**  **No control the solvent has been performed** | Schumacher et al. 2016  Report N°32/15/9938/02  S6.7\_05  IC 2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | Subterranean termite: *Reticulitermes grassei* | EN 118 + EN 73 (evaporation) | The ready to use product 11LBCEOL03² is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 197.35 mL/m² and 199.12 mL/m² (mean 198.8 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 12 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (90 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 11LBCEOL03** **at the application rate of 198.8 ml of product / m² of wood.** | Arana M. et al., 2012  Report N° 27766-2a  S6.7\_02  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | Subterranean termite: *Heterotermes tenuis* | EN 118 + EN 73 (evaporation) | The ready to use product 11LBCEOL03² is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 199.0 mL/m² and 200.1 mL/m² (mean 199.7 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (88 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 11LBCEOL03** **at the application rate of 200 ml of product / m² of wood.** | Paulmier et al., 2016  Report N° 401/15/283F/b  S6.7\_08  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | 11LBCEOL03 | Subterranean termite: *Coptotermes gestroi* | EN 118 + EN 73 (evaporation) | The ready to use product 11LBCEOL03² is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The product is applied at the application rate of 200 mL/m².  250 workers and 10 soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59.7%) and the control test blocks are ranked 4.  **Except one treated block that is ranked 2, all the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 11LBCEOL03** **at the application rate of 200 mL of product / m² of wood.** | Vuillemin et al., 2016,  Report N° 14-15  S6.7\_07  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 11LBCEOL03 | Common furniture beetle: *Anobium punctatum (L.)* | EN 370 + EN 73 | The ready to use product 11LBCEOL03is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 298.7 mL/m² and 299 mL/m² (mean 298.9 mL/m²).  12 larvae of *Anobium punctatum* were used per test blocks  6 replicates for the treated block and 6 replicates for the control are performed.  The investigated effects is the mortality of the larvae and hatched beetles  - Method for recording / scoring effects: count of the holes in the test blocks and of the hatched beetles. After splitting up of the test blocks, count of the dead and alive larvae and beetles.  - Intervals of examination: one time, 12 weeks after beginning of the hatching in the control blocks. | The study is validated as at least 30 (33) larvae have emerged in the control  No emergence of adult is observed in the treated blocks.  **Then this demonstrated the differed curative efficacy of the product 11LBCEOL03** **at the application rate of 298.9 mL product / m² of wood.** | Schumacher P. et al., 2012 Report N° 32/11/9471/03A  S6.7\_04  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 11LBCEOL03 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product 11LBCEOL03 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 233.72 g/m² and 235.22 g/m² (mean 234.3 g/m²), equivalent to 296.7 ml/m².  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 24 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | The study is validated as the survival rate in the control is higher than 80 % (91.7%).  **This one validated the low action efficacy of the product 11LBCEOL03, at the application rate of 296.7 ml of product / m² of wood, 24 weeks after the application.** | Arana M. et al., 2012  Report N° 27766-3b  S6.7\_03  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 11LBCEOL03 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product 11LBCEOL03 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block is 299.8 mL/m².  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 12 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | The study is validated as the survival rate in the control is higher than 80 % (98%).  **This one validated the fast action efficacy of the product 11LBCEOL03, at the application rate of 299.8 mL of product / m² of wood, 12 weeks after the application.** | Schumacher P. and Fennert E.-M., 2017,  Report 32/16/10030/01  S6.7\_03bis,  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | 11LBCEOL03 | Common furniture beetle:  *Anobium punctatum (L)* | EN48 | The ready to use product 11LBCEOL03 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block is 300 mL/m².  12 larvae of *Anobium punctatum* were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 8 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is mortality higher than 85 %. | The study is validated as the survival rate in the control is higher than 70 % (91%).  **The mortality observed in the treated block is higher than 80 % (100 %) validated the efficacy of the product 11LBCEOL03, at the application rate of 300 mL of product / m² of wood.** | Schumacher et al., 2017  Report N° 32/16/10030/02  6.7-04bis  IC1 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities considers that the data submitted in the dossier demonstrated the efficacy of the product TX201 TRAITEMENT MEUBLES ET PARQUETS (11LBCEOL03) according the uses and the application rates claimed:   * Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product 11LBCEOL03 is efficient according to respectively EN 46 (+EN73), EN 49 (+EN73) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* for use class 1 at the application rate of 200 mL of product 11LBCEOL03 / m² of wood. * Regarding the preventive efficacy claim against termites, for superficial application, the product 11LBCEOL03 is efficient according to EN 118 (+EN73), against *Reticulitermes spp*, *Heterotermes spp*., and *Coptotermes spp*. for use class 1, at the application rate of 200 mL of product 11LBCEOL03 per m² of wood. * Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product 11LBCEOL03 is efficient according to respectively EN 1390 and EN 48 against *Hylotrupes bajulus* and against *Anobium punctatum* with a fast activity, at the application rate of 300 mL of product 11LBCEOL03 per m² of wood. According to EN 14128[[15]](#footnote-15), if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes bajulus* and *Anobium punctatum*" should be applied. The curative efficacy against wood boring beetles is then validated. * Regarding the curative efficacy claim against termites (*Reticulitermes spp., Heterotermes spp. and Coptotermes 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), to protect wood against termites and to eliminate termites in the wood. Indeed, 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. * 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 mL of product 11LBCEOL03 / m² of wood is validated. |

##### Occurrence of resistance and resistance management

Resistance to permethrin 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 permethrin 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 permethrin, PT08, April 2014).

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

##### Known limitations

none

##### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product TX201 TRAITEMENT MEUBLES ET PARQUETS (11LBCEOL03) has shown a sufficient efficacy for the preservation of wood in service used:

* for the preventive control of wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), and termites (*Reticulitermes spp*., *Heterotermes spp*. and *Coptotermes spp.*), in use class 1 by superficial application
* for the curative control of wood against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and termites (*Reticulitermes spp.,* *Heterotermes spp*. and *Coptotermes spp.*), indoor, by superficial application,

The application rates validated are the following:

* Preventive treatments: superficial application at 200 mL of product 11LBCEOL03/ m² of wood
* Curative treatment: superficial application at 300 mL of product 11LBCEOL03/ m² of wood (injection 150 mL of product 11LBCEOL03 / m² of wood if need be).

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

The product TX201 TRAITEMENT MEUBLES ET PARQUETS is not intended to be used with another biocidal product

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No study on skin corrosion nor on skin irritation is provided for 11LBCEOL03. Classification is based on the available data on each component and according to the CLP Regulation 1272/2008/EC,.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritant to skin |
| Justification for the value/conclusion | 11LBCEOL03 product does not contain substance classified for skin irritation. |
| Classification of the product according to CLP | Not classified for skin corrosion and irritation according to the CLP regulation |

***Eye irritation***

No study on eye irritation is provided for 11LBCEOL03. Classification is based on the available data on each component and according to the CLP Regulation 1272/2008/EC.

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| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritant to the eye |
| Justification for the value/conclusion | 11LBCEOL03 product does not contain substance classified for eye irritation. |
| Classification of the product according to CLP | Not classified for eye irritation according to the CLP regulation |

***Respiratory tract irritation***

No studies of respiratory tract irritation are available. Classification is based on the available data on each component and according to the CLP Regulation 1272/2008/EC.

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| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Classification of the product according to CLP | Not classified for respiratory tract irritation according to the CLP regulation |

***Skin sensitization***

A skin sensitization test conducted on 11LBCEOL03 product is provided.

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results**  *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks**  *(e.g. major deviations)* | **Reference** |
| OECD No.442-B  GLP  1 (reliable  without  restriction) | Mouse  CBA/J  Female  1 animal in preliminary  study  4/test  group (3 groups)  4 in control  group (vehicle only) | 11LBCEOL03 in  acetone/olive oil  (4:1, v:v)  3 doses: 25% (v/v),  50% (v/v) in the  vehicle, and 100% | Stimulation index:  1.01, 1.48, 1.47 for  25% (v/v), 50% (v/v),  100% (v/v) respectively.  EC1.6 not determined  No mortality and no  signs of toxicity | No  deviation | Richeux, F.; 2014  (IUCLID  Section 8.3) |

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitizing |
| Justification for the value/conclusion | Stimulation index < 1.6 |
| Classification of the product according to CLP | Not classified for skin sensitization according to the CLP regulation.  According to the concentrations of permethrin, the additional labelling information “EUH208 Contains permethrin. May produce an allergic reaction” should be mentioned on the label. |

***Respiratory sensitization (ADS)***

No studies of respiratory sensitization are available. Classification is based on the available data on each component.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Classification of the product according to CLP | Not classified for respiratory sensitization according to the CLP regulation |

***Acute toxicity***

*Acute toxicity by oral route*

No study on acute toxicity by oral route is provided for 11LBCEOL03. Classification is based on the available data on each component and according to the Regulation 1272/2008/EC. The Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values of all relevant ingredients according to the following formula for Oral Toxicity:



where:

Ci = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE oral of 11LBCEOL03 is greater than 2000 mg/kg.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | ATE oral > 2000 mg/kg |
| Justification for the selected value | Calculation according to the Regulation 1272/2008/EC of the ATE value from the ATE values of all relevant ingredients. |
| Classification of the product according to CLP | Not classified in accordance to the CLP regulation |

*Acute toxicity by inhalation*

No study on acute toxicity by inhalation is provided for 11LBCEOL03. Classification is based on the available data on each component and according to the Regulation 1272/2008/EC. The Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values of all relevant ingredients according to the following formula for Inhalation Toxicity:



where:

Ci = concentration of ingredient i ( % w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE inhalation of 11LBCEOL03 is greater than 5 mg/L.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | ATE inhalation > 5 mg/L |
| Justification for the selected value | Calculation according to the Regulation 1272/2008/EC of the ATE value from the ATE values for all relevant ingredients. |
| Classification of the product according to CLP | Not classified in accordance to the CLP regulation |

*Acute toxicity by dermal route*

No study on acute toxicity by dermal route is provided for 11LBCEOL03. Classification is based on the available data on each component and according to the Regulation 1272/2008/EC. The Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values of all relevant ingredients according to the following formula for Dermal Toxicity:



where:

Ci = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE inhalation of 11LBCEOL03 is greater than 2000 mg/kg.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | ATE dermal > 2000 mg/kg |
| Justification for the selected value | Calculation according to Regulation 1272/2008/EC of the ATE value from the ATE values for all relevant ingredients. |
| Classification of the product according to CLP | Not classified in accordance to the CLP regulation |

None of the components of the product 11LBCEOL03 is classified for short- and long-term toxicity, genotoxicity, developmental toxicity and reprotoxicity.

However, the product contains a component which may be fatal if swallowed and enters airways and which may cause skin dryness or cracking after repeated exposure. Based on the available data 11LBCEOL03 is classified:

Asp. Tox. 1: H304 May be fatal if swallowed and enters airways.

Following mention should be applied on the label:

- EUH 208: Contains permethrin. May produce an allergic reaction.

- EUH066 Repeated exposure may cause skin dryness or cracking.

***Information on dermal absorption***

A dermal absorption study conducted on 11LBCEOL03 product is provided.

| **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** |
| OCDE 428  GLP  1 (reliable  without  restriction) | Human skin  4 donors, 8 skin discs | 14C-permethrin in  reconstituted  11LBCEOL03  1 dose: 100% | Skin excess: 68.51 ± 6.78%  First two layers of the stratum  corneum: 2.59 ± 0.83%  Strips 3 to 15: 5.98 ± 2.61%  Skin = Epidermis + partial  dermis: 10.2 ± 4.78%  Receptor fluid compartment:  3.50 ± 1.32%  Final absorption value:  19.68 ± 5.79% | No  deviation | Bernal, J.; 2015  (IUCLID  Section 8.6) |

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 28% |
| Justification for the selected value(s) | As less than 75% of the total permethrin absorption was recovered at half of the study duration (*i.e.* 12 hours), radioactivity in strips 3 to 15 were considered as absorbable.  Standard deviations were taken into account because of the significant variation between replicates (larger than 25% of the mean of the absorption).  Therefore the absorbable fraction of the applied permethrin was 19.7 ± 5.8 % of the applied dose, resulting in 25.5%.  The mean total recovery of the radioactivity was 91% validating the results obtained. According to EFSA Guidance on dermal absorption (EFSA Journal 2012;10(4):2665), when the recovery is low (mean <95%), normalisation approach is applied: 25.5/100\*91 = 28%.  Therefore, a dermal absorption value of 28% is retained for the assessment. |

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

Due to the proposed classification including in the submitted MSDS and their impact on the classification of the product, the solvent Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics has been identified as a substance of concern.

This substance leads to a classification Asp Tox 1 – H304; of the product and the label ”EUH066 Repeated exposure may cause skin dryness or cracking”. Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A evaluation scheme is applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

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

Not available

Exposure assessment

**Introductory note**

11LBCEOL03 is a solvent-based ready-to-use product (steel cans) for wood preservative containing 0.75% w/w permethrin. It is 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.

The application rate is 200 mL/m² for preventive use and 300 mL/m² for curative use. The product can be applied by brushing or spraying. It can also be applied by injection (150 mL/m²), in combination with a surface application (brushing or spraying).

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

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

**General considerations:**

Dermal and inhalation exposure to the product 11LBCEOL03 can occur during the mixing and loading, the application and the equipment’s cleaning.

The assessment of exposure during curative treatment (300 mL/m²) is presented below is considered as a worst-case covering the preventive treatment (200 mL/m²).

For the primary exposure to the product, professional and non-professional users are in contact with the product during application (brushing, spraying or injection) and cleaning of the equipment. Dermal and inhalation routes were considered as the main exposure routes during the primary exposure. Combined scenarios are made for application phase (with or without injection) and cleaning phase, and taking into account secondary exposure inhalation of volatilizing residues indoors.

For the secondary exposure, consumers and also professionals might be in contact with the product. Exposure may occur soon after application with a short exposure period (acute phase) or with a long-term and repeated exposure (chronic phase).

* For acute phase the following scenarios are: sanding or processing of treated wood composites (adult) and chewing treated wood offcuts (infant),
* For chronic phase the following scenarios are: sanding or processing of treated wood composites (adult), inhalation of volatilizing residues indoors (adult, toddler and infant), child playing on playground structure outdoors and infant playing on weathered (playground) structure and mouthing.

Combined scenarios are made for chronic exposure for adults (inhalation of volatilizing residues indoors and sanding/processing of treated wood composites) and for infants (inhalation of volatilizing residues indoors and playing on weathered (playground) structure and mouthing).

***List of scenarios***

| **Summary table: scenarios** | | | | |
| --- | --- | --- | --- | --- |
| **no.** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | | **Exposed group** |
| **Primary exposure** | | | | |
| 1 | Brush application | | **Inhalation and dermal exposures during brush application**  11LBCEOL03 is a solvent-based ready-to-use product. Therefore no mixing/loading phase is necessary, the product being directly applied with a brush from can. During the application, users are exposed to the vapours of the product and by dermal contact. | Professional and non-professional users |
| 2 | Cleaning of equipment after brush application | | **Dermal exposure during cleaning of brush equipment**  During the cleaning of the brush, users are dermally exposed to the biocidal product. Inhalation exposure during this phase has been considered negligible. | Professional and non-professional users |
| 3 | Brush application + injection | | **Inhalation and dermal exposures during application (brushing + injection)**  No specific model for injection is available. In a conservative approach, exposure values have been multiplied by two, in order to simulate an application by brush and injection. | Professional and non-professional users |
| 4 | Cleaning of equipment after brush application + injection | | **Dermal exposure during cleaning of brush and injection equipments**  Exposure during the cleaning of spray equipment has been added to the cleaning of brush equipment, in order to simulate the cleaning of both apparatus. Therefore this scenario is composed of scenario 2 and scenario 7. | Professional and non-professional users |
| 5 | Spray application | | **Inhalation and dermal exposures during spray application**  During the mixing/loading and spraying of the biocidal product, professional users are exposed by dermal and inhalation routes. | Professional users |
| 6 | Spray application | | **Inhalation and dermal exposures during spray application**  During spraying of the biocidal product, non-professional users are exposed by dermal and inhalation routes. | Non-professional users |
| 7 | Cleaning of equipment after spray application | | **Dermal exposure during cleaning of spray equipment**  During the cleaning of the spray, users are dermally exposed to the biocidal product. Inhalation exposure during this phase has been considered negligible. | Professional and non-professional users |
| 8 | Spray application + injection | | **Inhalation and dermal exposures during application (spraying + injection)**  No specific model for injection is available. In a conservative approach, exposure values have been multiplied by two in order to simulate an application by spray followed by an application by injection. | Professional and non-professional users |
| 9 | Cleaning after spray application + injection | | **Dermal exposure during cleaning of spray equipment**  In order to simulate an application by spray followed by an application by injection, the exposures values of the exposure model for the cleaning of a spray has been multiplied by two. | Professional and non-professional users |
| **Secondary exposure** | | | | |
| 10 | Sanding or processing of treated wood composites | **Acute and chronic dermal and inhalation exposures**  After treatment of the wood, adults can be exposed by inhalation and dermal contact to the product when sanding or processing of treated wood composites. | | General public (adult) |
| 11 | Infant chewing wood composites chips | **Acute oral exposure**  Oral exposure to the product can occur for infant putting into his mouth treated wood chips. | | General public (infant) |
| 12 | Inhalation of volatilised residues indoors | **Chronic inhalation exposure**  In the post-application phase, inhalation exposure of volatile residues is assessed for adults, toddlers and infants. | | General public (adult, toddler and infant) |
| 13 | child or toddler playing on playground structure | **Chronic oral and dermal exposures**  In the playground (outdoors), toddler and child can play on wood structures that can be treated with biocidal product.  Chronic exposure of toddler via dermal route and ingestion has been performed. | | General public (child and toddler) |

***Industrial exposure***

No industrial exposure is foreseen.

***Professional exposure***

*Scenario [1]* *Brush application*

| **Description of Scenario [1] Brush application** | | | |
| --- | --- | --- | --- |
| Professional exposure by inhalation and dermal contact during the application phase of the product by brushing has been assessed using the scenario “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure.  The product being a ready-to-use, the mixing/loading phase is not considered, as the product can be directly applied with a brush from can. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% w/w | Applicant data |
| Density of product | 0.79 | Applicant data |
| Exposure duration of body and hands | 240 min | Recommendation No. 6 |
| Body weight | 60 kg | Default |
| Dermal exposure of hands (solvent-based paint) | 9.14 µl/min | Recommendation No. 10 (75th) |
| Dermal exposure of the body (solvent-based paint) | 1.12 µl/min | Recommendation No. 10 (75th) |
| Dermal penetration | 28% | Dermal absorption study |
| Vapour pressure of the active substance (at 20°C) | 2.155 x 10-6 Pa | Physico-chemical data on active substance |
| Inhalation exposure for low-volatile active substance | 1.63 mg/m3 | Recommendation No. 10 (50th) |
| Inhalation rate | 1.25 m3/hour  (= 2.08 x 10-2 m3/min) | Recommendation No. 14 |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves **(Tier 2)** | 10% penetration | HEEG opinion 9 |

**Calculations for Scenario [1] Brush application**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [1] | Tier 1 | 1.02E-03 | 6.81E-02 | - | 6.91E-02 |
| Tier 2 | 1.02E-03 | 1.35E-02 | - | 1.45E-02 |

*Scenario [2] Cleaning of the equipment for brush application*

| **Description of Scenario [2] Cleaning of the equipment for brush application** | | | |
| --- | --- | --- | --- |
| Professional users are dermally exposed during the cleaning of the brush. Inhalation exposure is considered negligible during this phase.  Scenario ”*Exposure model –washing out of a brush*” from the Opinion no. 11 of HEEG[[16]](#footnote-16) has been used. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Density of product | 0.79 g/mL | Applicant data |
| Brush size : 10 x 10 x 2 cm | 200 mL | HEEG Opinion 11 |
| Volume of residual solution in brush (1/8 of brush volume) | 25 mL | HEEG Opinion 11 |
| Volume of each washing solution | At least 400 mL | HEEG Opinion 11 |
| Percentage of residues remaining in brush after each washing step | 10% | HEEG Opinion 11 |
| Percentage of residues remaining in brush after squeezing | 50% | HEEG Opinion 11 |
| Percentage of residues absorbed by cloth | 90% | HEEG Opinion 11 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| No PPE | 100% penetration | Default |

**Calculations for Scenario [2] Cleaning of the equipment for brush application**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [2] | Tier 1 | Negligible | 3.69E-03 | - | 3.69E-03 |

*Scenario [3] Brush application + injection*

| **Description of Scenario [3] Brush application + injection** | | | |
| --- | --- | --- | --- |
| No specific model for injection is available to assess exposure.  Considering that the injection will not lead to higher exposure than spray application, in a conservative approach, the exposure values set in the scenario “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, has been used and multiplied by two in order to simulate an application by brush and injection (worst-case). | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% w/w | Applicant data |
| Density of product | 0.79 | Applicant data |
| Exposure duration of body and hands | 240 min | Recommendation No. 6 |
| Body weight | 60 kg | Default |
| Dermal exposure of hands (solvent-based paint) | 9.14 **x 2** = 18.28 µl/min | Recommendation No. 10 (75th) |
| Dermal exposure of the body (solvent-based paint) | 1.12 **x 2** = 2.24 µl/min | Recommendation No. 10 (75th) |
| Dermal penetration | 28% | Dermal absorption study |
| Vapour pressure of the active substance (at 20°C) | 2.155 x 10-6 Pa | Physico-chemical data on active substance |
| Inhalation exposure for low-volatile active substance | 1.63 **x 2** = 3.26 mg/m3 | Recommendation No. 10 (50th) |
| Inhalation rate | 1.25 m3/hour  (= 2.08 x 10-2 m3/min) | Recommendation No. 14 |
| Inhalation absorption | 100% | Default |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves **(Tier 2)** | 10% penetration | HEEG opinion 9 |

**Calculations for Scenario [3] Brush application + injection**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [3] | Tier 1 | 2.04E-03 | 1.36E-01 | - | 1.38E-01 |
| Tier 2 | 2.04E-03 | 2.70E-02 | - | 2.90E-02 |

*Scenario [4] Cleaning of the equipment for brush application + injection*

| **Description of Scenario [4] Cleaning of the equipment for brush application + injection** | | | |
| --- | --- | --- | --- |
| **In the table below only the parameters for the cleaning of injection system is presented. For the cleaning of brush equipment please refer to scenario 2.**  No specific model for injection is available to assess exposure. For the cleaning of the equipment, exposure during the cleaning of an equipment spray (as presented for the spray application) has been added to the cleaning of a brush scenario, in order to simulate the cleaning of both apparatus.  Therefore this scenario is composed of scenario 2 (Cleaning of the brush) and scenario 7 (Cleaning of spray equipment).  Inhalation exposure is negligible. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Density of product | 0.79 g/mL | Applicant data |
| Penetration through cleaning rag during squeezing the brush by hand | 90% | HEEG Opinion 11 |
| Exposure duration | 10 min | Expert judgment |
| Potential dermal exposure (body) | 19.28 µL/min | Recommendation No. 4 |
| Potential dermal exposure (hands) | 35.87 µL/min | Recommendation No. 4 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| No PPE | 100% penetration | Default |
| Tier 2 | Only for cleaning of the injection system Gloves + coated coverall  **No PPE for the cleaning of brush equipment** | Gloves 10% penetration  20% penetration | HEEG opinion no. 9 |

**Calculations for Scenario [4] Cleaning of the equipment for brush application + injection**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [4] | Tier 1 | Negligible | 1.89E-02 | - | 1.89E-02 |
| Tier 2 | Negligible | 5.75E-03 | - | 5.75E-03 |

*Scenario [5] Spray application*

| **Description of Scenario [5] Spray application** | | | |
| --- | --- | --- | --- |
| During mixing/loading and spraying of the biocidal product, professional users are exposed by dermal and inhalation routes.  Professional exposure during the mixing and loading and the application phases has been considered using the scenario “S*praying model 2*” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[17]](#footnote-17). | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Exposure duration | 90 min | Biocides Human Health Exposure Method |
| Potential dermal exposure (body) | 222 mg/min | Recommendation No. 6 |
| Potential dermal exposure (hands) | 273 mg/min | Recommendation No. 6 |
| Actual exposure hand inside gloves | 7.80 mg/min | Recommendation No. 6 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| Indicative inhalation exposure (non-volatile compounds) | 76 mg/m3 | Recommendation No. 6 |
| Vapour pressure of the active substance (at 20°C) | 2.155 x 10-6 Pa | Physico-chemical data on active substance |
| Inhalation rate | 1.25 m3/hour  (equals to 2.08 x 10-2 m3/min) | Recommendation No. 14 |
| Inhalation absorption | 100% | Default |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves + impermeable coverall **(Tier 2)** | Impermeable coverall 5% penetration | Gloves from model  Coverall penetration from HEEG opinion no. 9 |

**Calculations for Scenario [5] Spray application**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [5] | Tier 1 | 1.78E-02 | 1.56 | - | 1.58 |
| Tier 2 | 1.78E-02 | 5.95E-02 | - | 7.73E-01 |

*Scenario [7] Cleaning of the equipment after spray application*

| **Description of Scenario [7] Cleaning of the equipment after spray application** | | | |
| --- | --- | --- | --- |
| Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[18]](#footnote-18).  Inhalation exposure is negligible. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Exposure duration | 10 min | Expert judgment |
| Potential dermal exposure (body) | 19.28 mg/min | Recommendation No. 4 |
| Potential dermal exposure (hands) | 35.87 mg/min | Recommendation No. 4 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves + Coated coverall | Gloves 10% penetration  Coated coverall 20% penetration | HEEG opinion no. 9 |

**Calculations for Scenario [7] Cleaning of the equipment after spray application**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [7] | Tier 1 | Negligible | 1.93E-02 | - | 1.93E-02 |
| Tier 2 | Negligible | 2.61E-03 | - | 2.61E-03 |

*Scenario [8]* *Spray application + injection*

| **Description of Scenario [8] Spray application + injection** | | | |
| --- | --- | --- | --- |
| Considering that the injection will not lead to higher exposure than spray application, for this scenario, the exposure values of the exposure models taken for the spray application have been multiplied by two in order to simulate an application by spray followed by an application by injection. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Exposure duration | 90 min | - |
| Potential dermal exposure (body) | 222 **x 2** = 444 mg/min | Recommendation No. 6 |
| Potential dermal exposure (hands) | 273 **x 2** = 546 mg/min | Recommendation No. 6 |
| Actual exposure hand inside gloves | 7.80 **x 2** = 15.6 mg/min | Recommendation No. 6 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| Indicative inhalation exposure (non-volatile compounds) | 76 **x 2** = 152 mg/m3 | Recommendation No. 6 |
| Vapour pressure of the active substance (at 20°C) | 2.155 x 10-6 Pa | Physico-chemical data on active substance |
| Inhalation rate | 1.25 m3/hour  (= 2.08 x 10-2 m3/min) | Recommendation No. 14 |
| Inhalation absorption | 100% | Default |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves + Impermeable coverall **(Tier 2)** | Impermeable coverall 5% penetration | Gloves from model  Coated Coverall penetration from HEEG opinion no. 9 |

**Calculations for Scenario [8] Spray application + injection**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [8] | Tier 1 | 3.56E-02 | 3.12 | - | 3.15 |
| Tier 2 | 3.56E-02 | 1.19E-01 | - | 1.55E-01 |

*Scenario [9] Cleaning of the equipment after spray application + injection*

| **Description of Scenario [9] Cleaning of the equipment after spray application + injection** | | | |
| --- | --- | --- | --- |
| Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[19]](#footnote-19).  In order to simulate an application by spray followed by an application by injection, the exposures values of the exposure model for the cleaning of a spray has been multiplied by two. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Exposure duration | 10 min | Expert judgment |
| Potential dermal exposure (body) | 19.28 **x 2** = 38.56 mg/min | Recommendation No. 4 |
| Potential dermal exposure (hands) | 35.87 **x 2** = 71.74 mg/min | Recommendation No. 4 |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| No PPE | 100% penetration | Default |
| Tier 2 | Gloves + Coated coverall **(Tier 2)** | Gloves 10% penetration  Coted coverall 20% penetration | HEEG opinion no. 9 |

**Calculations for Scenario [9] Cleaning of the equipment after spray application + injection**

| **Summary table: systemic exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [9] | Tier 1 | Negligible | 3.86E-02 | - | 3.86E-02 |
| Tier 2 | Negligible | 5.21E-03 | - | 5.21E-03 |

*Combined scenarios (application)*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenarios [1+2]  **Tier 1** | 1.02E-03 | 7.18E-02 | - | 7.28E-02 |
| Scenarios [1+2]  **Tier 2** | 1.02E-03 | 1.72E-02 | - | 1.82E-02 |
| Scenarios [3+4]  **Tier 1** | 2.04E-03 | 1.55E-01 | - | 1.57E-01 |
| Scenarios [3+4]  **Tier 2** | 2.04E-03 | 3.27E-02 | - | 3.48E-02 |
| Scenarios [5+7]  **Tier 1** | 1.78E-02 | 1.58 | - | 1.60 |
| Scenarios [5+7]  **Tier 2** | 1.78E-02 | 6.15E-02 | - | 7.93E-02 |
| Scenarios [8+9]  **Tier 1** | 3.56E-02 | 3.16 | - | 3.19 |
| Scenarios [8+9]  **Tier 2** | 3.56E-02 | 1.24E-01 | - | 1.60E-01 |

***Non-professional exposure***

*Scenario [1]* *Brush application*

| **See Scenario [1] Brush application see Professional exposure (Tier 1)** |
| --- |

| **Summary table: estimated exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [1] | Tier 1 | 1.02E-03 | 6.81E-02 | - | 6.91E-02 |

*Scenario [2] Cleaning of the equipment for brush application*

| **See Scenario [2] Cleaning of the equipment for brush application see Professional exposure (Tier 1)** |
| --- |

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [2] | Tier 1 | Negligible | 3.69E-03 | - | 3.69E-03 |

*Scenario [3] Brush application + injection*

| **See Scenario [3] Brush application + injection see Professional exposure (Tier 1)** |
| --- |

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [3] | Tier 1 | 2.04E-03 | 1.36E-01 | - | 1.38E-01 |

*Scenario [4] Cleaning of the equipment for brush application + injection*

| **See Scenario [4] Cleaning of the equipment for brush application + injection, see Professional exposure (Tier 1)** |
| --- |

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [4] | Tier 1 | Negligible | 1.89E-02 | - | 1.89E-02 |

*Scenario [6] Spray application*

| **Description of Scenario [6] Spray application** | | | |
| --- | --- | --- | --- |
| During mixing/loading and spraying of the biocidal product, non-professional users are exposed by dermal and inhalation routes.  Non-professional exposure during the mixing and loading and the application phase has been considered using the “*Consumer spraying and dusting Model 3*” taken from the TNsG (part 2 p197). | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction substance | 0.75% (w/w) | Applicant data |
| Exposure duration | 40 min | Exposure method BPR + TNsG |
| Potential dermal exposure (body) | 84 mg/min | Exposure method BPR + TNsG |
| Potential dermal exposure (hands) | 144 mg/min | Exposure method BPR + TNsG |
| Body weight | 60 kg | Default |
| Dermal penetration | 28% | Dermal absorption study |
| Indicative inhalation exposure (non-volatile compounds) | 6.5 mg/m3 | Exposure method BPR + TNsG |
| Vapour pressure of the active substance (at 20°C) | 2.155 x 10-6 Pa | Physico-chemical data on active substance |
| Inhalation rate | 1.25 m3/hour  (= 2.08 x 10-2 m3/min) | Recommendation No. 14 |
| Inhalation absorption | 100% | Default |
| No PPE | 100% penetration | Default |

**Calculations for Scenario [6] Spray application**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [6] | Tier 1 | 6.77E-04 | 3.19E-01 | - | 3.20E-01 |

*Scenario [7] Cleaning of the equipment after spray application*

| **See Scenario [7] Cleaning of the equipment after spray application see Professional exposure (Tier 1)** |
| --- |

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [7] | Tier 1 | Negligible | 1.93E-02 | - | 1.93E-02 |

*Scenario [8]* *Spray application + injection*

| **Description of Scenario [8] Spray application + injection** |
| --- |
| Considering that the injection will not lead to higher exposure than general public brush application, for this scenario, the exposure during spraying (scenario 6) was added to the exposure during brushing (scenario 1). |

**Calculations for Scenario [8] Spray application + injection**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [8] | Tier 1 | 1.70E-03 | 3.87E-01 | - | 3.89E-01 |

*Scenario [9] Cleaning of the equipment after spray application + injection*

| **See Scenario [9] Cleaning of the equipment after spray application + injection see Professional exposure (Tier 1)** |
| --- |

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [9] | Tier 1 | Negligible | 3.86E-02 | - | 3.86E-02 |

*Combined scenarios (application)*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | mg/kg bw/d | | | |
| Scenarios [1+2] | 1.02E-03 | 7.18E-02 | - | 7.28E-02 |
| Scenarios [3+4] | 2.04E-03 | 1.55E-01 | - | 1.57E-01 |
| Scenarios [6+7] | 6.77E-04 | 3.39E-01 | - | 3.39E-01 |
| Scenarios [8+9] | 1.70E-03 | 4.26-01 | - | 4.28E-01 |

***Exposure of the general public***

*Scenario [10] Adult sanding/processing of treated wood composites*

| **Description of Scenario [10] Adult sanding/processing of treated wood composites (acute and chronic exposure)** | | | |
| --- | --- | --- | --- |
| After treatment of the wood, adult can be exposed by inhalation and dermal contact to the product when sanding or processing of treated wood composites. This scenario is composed of acute exposure (1 hour) and chronic exposure (6 hours).  The area of wood to be sanded was calculated with a length of 250 cm, 4 cm large and a height of 4 cm (surface area of 4032 cm²). The active substances are in the outer 1 cm layer. The volume of outer layer is about 3008 cm3.  The density of the wood is assumed 0.4 g/cm³. It is not possible to predict how much wood dust an operator would inhale while sanding wood treated. As a surrogate parameter, it is assumed that the wood dust concentration does not exceed the applicable occupational exposure limits for dust at the workplace (5 mg/m³). | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Active substance | 0.75% w/w | Applicant data |
| Application rate | 45 µL/cm2 | Applicant data |
| Product density | 0.79 g/mL | Applicant data |
| Wood density | 0.4 g/cm3 | HEEG - MOTA (version 6, 2013) |
| Dust concentration in air | 5 mg/m3 | Directive 2004/37/EC and TNsG 2002 (part 3 p. 50) |
| Exposure duration | 1 hour (acute)  6 hour (chronic) | TNsG 2002 (part 3 p. 50) |
| Inhalation rate | 1.25 m3/h | Recommendation no. 14 |
| No PPE | 100% penetration | Default |
| Retention active substance | 100% | Default |
| Percentage dislodgeable  (painted wood, dried fluid) | 3% | Biocides Human Health Exposure Methodology 2015 (p. 171) |
| Surface area of palms of hands | 410 cm² | Recommendation no. 14 |
| Dermal absorption | 28% | Dermal absorption study |

**Calculations for Scenario [10] Adult amateur sanding/processing of treated wood composites (acute and chronic exposure)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [10.1] (acute exposure) | Tier 1 | 9.31E-05 | 1.53E-02 | - | 1.54E-02 |
| Scenario [10.2] (chronic exposure) | Tier 1 | 5.58E-04 | 1.53E-02 |  | 1.59E-02 |

*Scenario [11] Infant chewing wood composite chips (acute exposure)*

| **Description of Scenario [11] Infant chewing wood composite chips (acute exposure)** | | | |
| --- | --- | --- | --- |
| In this scenario, oral exposure has been calculated considering the size of the wood composite chips, the amount of active substance contained in treated wood and that 10% of this content is released during chewing into the toddler’s mouth according to TNsG 2002.  As a worst-case, total application dose of 450 g/m2 has been considered (curative treatment by brushing or spraying followed by injection). | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Active substance | 0.75% w/w | Applicant data |
| Application rate | 450 g/m2 | Applicant data |
| Product density | 0.79 g/mL | Applicant data |
| Release of bound active substance by chewing | 10% | TNsG Human Exposure 2002 (part 3 p. 51) |
| Size of wood composites chip | 48 cm² | (4x4)x2 + (4x1)x4 = 48 |
| Oral absorption | 100% | Permethrin (Final CAR 2016) |
| Dermal absorption | 28% | Dermal absorption study |
| Body weight | 8 kg | Recommendation No. 14 |

**Calculations for Scenario [11] Infant chewing wood composite chips (acute exposure)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [11] | Tier 1 | - | Negligible | 1.60E-01 | 1.60E-01 |

*Scenario [12] Inhalation of volatilised residues indoors (adult, toddler and infant)*

| **Description of Scenario [12] Inhalation of volatilised residues indoors** | | | |
| --- | --- | --- | --- |
| Chronic inhalation exposure to volatilised residues indoors has been assessed for adult, toddler and infant, considering the scenario ”*Assessment of Inhalation Exposure of Volatilised Biocide Active Substance*” from the Opinion no. 13 of HEEG[[20]](#footnote-20) with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula :  The inhalation exposure of an adult, toddler and infant over a total of 24 hours can then be calculated as follows: | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Vapour pressure of active substance (*vp*) | 2.155 x 10-6 Pa | Physico-chemical data on active substance (Permethrin Final CAR, 2016) |
| Molecular weight (*mw*) | 391.29 g.mol-1 | Physico-chemical data on active substance (Permethrin Final CAR, 2016) |
| Gas constant (*R*) | 8.31451 J.mol-1.K-1 | Physical constant |
| Temperature (*T*) | 293 K | Assumed room of 20°C |
| Body weight (*bw*) | 60 kg (adult)  10 kg (toddler)  8 kg (infant) | Recommendation No. 14 |
| Inhalation rate (*ir*) | 16 m3/24h (adult)  8 m3/24h (toddler)  5.4 m3/24h (infant) | Recommendation No. 14 |

**Calculations for Scenario [12] Inhalation of volatilised residues indoors**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier / PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [12.1] Adult | Tier 1 | 9.23E-05 | - | - | 9.23E-05 |
| Scenario [12.2] Toddler | Tier 1 | 2.77E-04 | - | - | 2.77E-04 |
| Scenario [12.3] Infant | Tier 1 | 2.34E-04 | - | - | 2.34E-04 |

*Scenario [13] Child and toddler playing on playground structure outdoors*

| **Description of Scenario [13]** *Child and toddler playing on playground structure outdoors* | | | |
| --- | --- | --- | --- |
| For the assessment of this exposure, amount of active substance on hand has been calculated. For this calculation, it has been considered according to the TNsG 2002 and Biocides Human Health Exposure Methodology 2015 that 20% of hand is in contact with the treated surface and a wood-hand transfer factor of 3%.  Additionally, chronic exposure of infant via ingestion of a piece of wood cut-off has been performed, taking into consideration 100% ingestion of surface deposit on 5 x 10 cm² of wood.  For the assessment of this scenario, application rate product of 450 g/m² has been considered as a worst-case. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Application rate | 45 µL/cm2 | Applicant data |
| Product density | 0.79 g/mL | Applicant data |
| Hand surface area contact | 330.9 cm² (child)  230.4 cm² (toddler) | Recommendation No. 14 |
| Contaminated area | 20% | TNsG 2002 (part 3 p. 50) |
| Percentage dislodgeable  (painted wood, dried fluid) | 3% | Biocides Human Health Exposure Methodology 2015 (p. 171) |
| Amount of ingested wood (infant) | 0.005 m² | TNsG 2002 (part 3 p. 51) |
| Dermal absorption | 28% | Dermal absorption study |
| Body weight | 15 kg (child)  10 kg (toddler) | Recommendation No. 14 |

**Calculations for Scenario [13] Child and toddler playing on playground structure outdoors**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenario [13.1] Child | Tier 1 | - | - | 9.88E-03 | 9.88E-03 |
| Scenario [13.2] Toddler | Tier 1 | - | 1.03E-02 | 4.00E-06 | 1.03E-02 |

*Combined scenarios (general public)*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | mg/kg bw/d | | | |
| Scenarios [10.2+12.1]  Adult | 6.51E-04 | 1.53E-02 | - | 1.60E-02 |
| Scenarios [12.2+13.2]  Toddler | 2.77E-04 | 1.03E-02 | 4.00E-06 | 1.06E-02 |

*Combined scenarios (application and inhalation of volatilised residues indoors) for professional uses*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenarios [1+2+12.1]  **Tier 1** | 1.11E-03 | 7.18E-02 | - | 7.29E-02 |
| Scenarios [1+2+12.1]  **Tier 2** | 1.11E-03 | 1.72E-02 | - | 1.83E-02 |
| Scenarios [3+4+12.1]  **Tier 1** | 2.13E-03 | 1.55E-01 | - | 1.57E-01 |
| Scenarios [3+4+12.1]  **Tier 2** | 2.13E-03 | 3.27E-02 | - | 3.49E-02 |
| Scenarios [5+7+12.1]  **Tier 1** | 1.79E-02 | 1.58 | - | 1.60 |
| Scenarios [5+7+12.1]  **Tier 2** | 1.79E-02 | 6.15E-02 | - | 7.94E-02 |
| Scenarios [8+9+12.1]  **Tier 1** | 3.57E-02 | 3.16 | - | 3.19 |
| Scenarios [8+9+12.1]  **Tier 2** | 3.57E-02 | 1.24E-01 | - | 1.60E-01 |

*Combined scenarios (application and inhalation of volatilised residues indoors) for non-professional uses*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  (mg/kg bw/d) | **Estimated dermal uptake**  (mg/kg bw/d) | **Estimated oral uptake**  (mg/kg bw/d) | **Estimated total uptake**  (mg/kg bw/d) |
| Scenarios [1+2+12.1] | 1.11E-03 | 7.18E-02 | - | 7.29E-02 |
| Scenarios [3+4+12.1] | 2.13E-03 | 1.55E-01 | - | 1.57E-01 |
| Scenarios [6+7+12.1] | 7.69E-04 | 3.39E-01 | - | 3.39E-01 |
| Scenarios [8+9+12.1] | 1.79E-03 | 4.26E-01 | - | 4.28E-01 |

***Dietary exposure***

The product is to be used for preventive and curative treatment of interior woods that does not come in direct contact with food and feedstuff. According to the label and proposed risk mitigation measures, no contact with food and feedstuff is expected. these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)**  mg/kg bw/d | **AF1** | **Correction for oral absorption** | **Value**  mg/kg bw/d |
| AELshort-term | 2-year rat toxicity study | 50 | 100 | No | 0.5 |
| AELmedium-term and long-term | 1-year dog chronic toxicity study | 5 | 100 | No | 0.05 |
| ARfD | 2-year rat toxicity study | 50 | 100 | No | 0.5 |
| ADI | 1-year dog study | 5 | 100 | No | 0.05 |

1 AF 10x10 for inter- and intraspecies.

**Maximum residue limits or equivalent**

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

PPP: plant protection product

VMP: veterinary medicinal product

As the product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food and feedstuff, the existing MRLs are not expected to be exceeded.

***Risk for industrial users***

No exposure is foreseen.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [1]  Brush application | Tier 1 | 5 | 0.05 | 6.91E-02 | **138.2** | **No** |
| Scenario [1]  Brush application | Tier 2 | 5 | 0.05 | 1.45E-02 | 29.0 | Yes |
| Scenario [2]  Cleaning brush | Tier 1 | 5 | 0.05 | 3.69E-03 | 7.4 | Yes |
| Scenario [3]  Brush + Injection | Tier 1 | 5 | 0.05 | 1.38E-01 | **276.4** | **No** |
| Scenario [3]  Brush + Injection | Tier 2 | 5 | 0.05 | 2.90E-02 | 58.1 | Yes |
| Scenario [4]  Cleaning brush + Injection | Tier 1 | 5 | 0.05 | 1.89E-02 | 37.9 | Yes |
| Scenario [5]  Spray application | Tier 1 | 5 | 0.05 | 1.58 | **3154** | **No** |
| Scenario [5]  Spray application | Tier 2 | 5 | 0.05 | 7.73E-02 | **155** | **No** |
| Scenario [7]  Cleaning spray | Tier 1 | 5 | 0.05 | 1.93E-02 | 38.6 | Yes |
| Scenario [8]  Spray + Injection | Tier 1 | 5 | 0.05 | 3.15 | **6308** | **No** |
| Scenario [8]  Spray + Injection | Tier 2 | 5 | 0.05 | 1.55 E-01 | **309** | **No** |
| Scenario [9]  Cleaning spray + Injection | Tier 1 | 5 | 0.05 | 3.86E-02 | 77.2 | Yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenarios [1+2]  Brush application + Cleaning | Tier 1 | 5 | 0.05 | 7.28E-02 | **146** | **No** |
| Scenarios [1+2]  Brush application + Cleaning | Tier 2 | 5 | 0.05 | 1.82E-02 | 36.4 | Yes |
| Scenarios [3+4]  Brush + Injection + Cleaning | Tier 1 | 5 | 0.05 | 1.57E-01 | **314** | **No** |
| Scenarios [3+4]  Brush + Injection + Cleaning | Tier 2 | 5 | 0.05 | 3.48E-02 | 69.6 | Yes |
| Scenarios [5+7]  Spray application + Cleaning | Tier 1 | 5 | 0.05 | 1.60 | **3193** | **No** |
| Scenarios [5+7]  Spray application + Cleaning | Tier 2 | 5 | 0.05 | 7.93E-02 | **159** | **No** |
| Scenarios [8+9]  Spray + Injection + Cleaning | Tier 1 | 5 | 0.05 | 3.19 | **6386** | **No** |
| Scenarios [8+9]  Spray + Injection + Cleaning | Tier 2 | 5 | 0.05 | 1.60E-01 | **320** | **No** |

**Local effects**

According to the BPR Guidance Volume III Human health – Part B and C Risk Assessment, the BAND A evaluation scheme is applied for the labelling EUH 066.

In order to take into account the risk of skin dryness or cracking during the handling of product (repeated exposure), the following RMMs are added:

* Avoid contact with skin;
* Wash hands thoroughly after handling.

**Conclusion**

For application by brushing (combined and not combined injection), the risk is considered acceptable only with gloves during application and without gloves curing cleaning of equipment.

For spray application (combined and not combined with injection), the risk is considered unacceptable.

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

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [1]  Brush application | Tier 1 | 50 | 0.5 | 6.91E-02 | 13.8 | Yes |
| Scenario [2]  Cleaning brush | Tier 1 | 50 | 0.5 | 3.69E-03 | 0.7 | Yes |
| Scenario [3]  Brush + Injection | Tier 1 | 50 | 0.5 | 1.38E-01 | 27.6 | Yes |
| Scenario [4]  Cleaning Brush + Injection | Tier 1 | 50 | 0.5 | 1.89E-02 | 3.8 | Yes |
| Scenario [6]  Spray application | Tier 1 | 50 | 0.5 | 3.20E-01 | 64.0 | Yes |
| Scenario [7]  Cleaning spray | Tier 1 | 50 | 0.5 | 1.93E-02 | 3.9 | Yes |
| Scenario [8]  Spray + Injection | Tier 1 | 50 | 0.5 | 3.89E-01 | 77.8 | Yes |
| Scenario [9]  Cleaning Spray + Injection | Tier 1 | 50 | 0.5 | 3.86E-02 | 7.7 | Yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenarios [1+2] | Tier 1 | 50 | 0.5 | 7.28E-02 | 14.6 | Yes |
| Scenarios [3+4] | Tier 1 | 50 | 0.5 | 1.57E-01 | 31.4 | Yes |
| Scenarios [6+7] | Tier 1 | 50 | 0.5 | 3.39E-01 | 67.8 | Yes |
| Scenarios [8+9] | Tier 1 | 50 | 0.5 | 4.28E-01 | 85.5 | Yes |

**Local effects**

No exposure is foreseen.

**Conclusion**

For application by brushing combined and not combined injection, the risk is considered acceptable.

For spray application combined and not combined with injection, the risk is considered acceptable.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [10.1]  (acute exposure) Adult | Tier 1 | 50 | 0.5 | 1.54E-02 | 3.0 | Yes |
| Scenario [10.2]  (chronic exposure) Adult | Tier 1 | 5 | 0.05 | 1.59E-02 | 31.7 | Yes |
| Scenario [11]  (acute exposure) Infant | Tier 1 | 50 | 0.5 | 1.60E-01 | 32.0 | Yes |
| Scenario [12.1] Adult | Tier 1 | 5 | 0.05 | 9.23E-05 | 0.2 | Yes |
| Scenario [12.2] Toddler | Tier 1 | 5 | 0.05 | 2.77E-04 | 0.6 | Yes |
| Scenario [12.3] Infant | Tier 1 | 5 | 0.05 | 2.34E-04 | 0.5 | Yes |
| Scenario [13.1] Child | Tier 1 | 5 | 0.05 | 9.88E-03 | 19.8 | Yes |
| Scenario [13.2] Toddler | Tier 1 | 5 | 0.05 | 1.03E-02 | 20.7 | Yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenarios [10.2+12.1]  Adult | Tier 1 | 5 | 0.05 | 1.60E-02 | 31.9 | Yes |
| Scenarios [12.2+13.2]  Toddler | Tier 1 | 5 | 0.05 | 1.06E-02 | 21.1 | Yes |

**Local effects**

not necessary.

**Conclusion**

No unacceptable risk has been identified for secondary exposure.

***Risk for combined exposure***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Professional users (application + secondary exposure)** | | | | | | |
| Scenarios [1+2+12.1]  Brush application + Cleaning | Tier 1 | 5 | 0.05 | 7.29E-02 | **146** | **No** |
| Scenarios [1+2+12.1]  Brush application + Cleaning | Tier 2 | 5 | 0.05 | 1.83E-02 | 36.6 | Yes |
| Scenarios [3+4+12.1]  Brush + Injection + Cleaning | Tier 1 | 5 | 0.05 | 1.57E-01 | **315** | **No** |
| Scenarios [3+4+12.1]  Brush + Injection + Cleaning | Tier 2 | 5 | 0.05 | 3.49E-02 | 69.7 | Yes |
| Scenarios [5+7+12.1]  Spray application + Cleaning | Tier 1 | 5 | 0.05 | 1.60 | **3193** | **No** |
| Scenarios [5+7+12.1]  Spray application + Cleaning | Tier 2 | 5 | 0.05 | 7.94E-02 | **159** | **No** |
| Scenarios [8+9+12.1]  Spray + Injection + Cleaning | Tier 1 | 5 | 0.05 | 3.19 | **6386** | **No** |
| Scenarios [8+9+12.1]  Spray + Injection + Cleaning | Tier 2 | 5 | 0.05 | 1.60E-01 | **320** | **No** |
| **Non-professional users (application + secondary exposure)** | | | | | | |
| Scenarios [1+2+12.1] | Tier 1 | 50 | 0.5 | 7.29E-02 | 14.6 | Yes |
| Scenarios [3+4+12.1] | Tier 1 | 50 | 0.5 | 1.57E-01 | 31.4 | Yes |
| Scenarios [6+7+12.1] | Tier 1 | 50 | 0.5 | 3.39E-01 | 67.8 | Yes |
| Scenarios [8+9+12.1] | Tier 1 | 50 | 0.5 | 4.28E-01 | **85.5** | YES |

**Local effects**

Not necessary.

**Conclusion**

For professionals, for application by brushing (combined and not combined with injection), the risk is considered acceptable only with gloves.

For spray application (combined and not combined with injection), the risk is considered unacceptable.

For non-professionals, for application by brushing (combined and not combined with injection), the risk is considered acceptable. For spray application (combined and not combined with injection), the risk is considered acceptable..

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

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with TX201 TRAITEMENT MEUBLES ET PARQUETS must contain label restrictions against use in contact with livestock, food and feed.

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

The product TX201 TRAITEMENT MEUBLES ET PARQUETS contains one substance of concern (Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics, CAS 64742-48-9)

According to Guidance for Human Health Risk Assessment, Volume III, Part B, the SoC is identified in Band A. This band includes SoCs which trigger products to be classified for moderate acute toxicity, including narcosis, and/or mild irritation. It should be noted that for these hazards, a fully quantitative risk assessment is not usually performed because only qualitative or semi-quantitative dose-response information is normally available.

It is proposed that for these SoCs, appropriate risk mitigation measures, in the form of the precautionary (P)-statements normally associated with the concerned hazard (H)-statements under the CLP Regulation, should be applied.

### Risk assessment for animal health

Not relevant.

### Risk assessment for the environment

|  |
| --- |
| Please notice that the environmental risk assessment is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes at the end of each part of the environmental section.** |

#### Effects assessment on the environment

The product 11LBCEOL03 is a ready-to-use solvent-based wood preservative containing 0.70% w/w permethrin.

A summary of the available ecotoxicity data on the active substance permethrin is presented below. All the data are coming from the Assessment Report of the active substance (see Assessment Report of permethrin, PT08, April 2014).

**Table 2.2.8.1-1: Available aquatic ecotoxicity data on permethrin**

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Time scale** | **Endpoint** | **Toxicity (mg/L)** |
| **Aquatic organisms** | | | |
| *Oncorhynchus mykiss* | 96h | LC50 (mortality) | 5.1\*10-3 mg/L |
| *Danio rerio* | 35 days | NOEC (reduced survival) | 4.1\*10-4 mg/L |
| *Daphnia magna* | 48h | LC50 (immobility and mortality) | 1.27\*10-3 mg/L |
| *Daphnia magna* | 21 days | NOEC (reproduction) | 4.7\*10-6 mg/L |
| *Pseudokirchneriella subcapitata* | 72h | ErC50 (cell density) | > 1.13 mg/L |
| *Pseudokirchneriella subcapitata* | 72h | NOEC (cell density) | < 0.0131 mg/L |
| *Pseudokirchneriella subcapitata* | 72h | ErC10 (cell density) | 2.3\*10-3 mg/L |
| *Chironomus riparius* | 10 days | LC50 (adult emergence) | 2.11 mg/kg (spiked sediment) |
| *Chironomus riparius* | 96h | LC50 (survival) | 2.89\*10-3 mg/L (spiked water) |
| *Chironomus riparius* | 5 days after last emergence | NOEC (adult emergence) | 0.1 mg/kg (spiked sediment) |
| Activated sewage sludge | 3h | EC50 | > 0.42 mg/L |
| Activated sewage sludge | 3h | NOEC | 4.95\*10-3 mg/L |

**Table 2.2.8.1-2: Available terrestrial ecotoxicity data on permethrin**

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Time scale** | **Endpoint** | **Toxicity (mg/L)** |
| **Terrestrial organisms** | | | |
| Earthworms | acute | EC50 | 371 mg/kgwwt 126 mg/kgdwt |
| Soil micro-organisms | 18 days | NOEC (nitrogen mineralisation) | > 31.7 mg/kgdwt |
| Soil micro-organisms | 42 days | NOEC (nitrogen mineralisation) | 9.17 mg/kgdwt |
| Soil micro-organisms | 40 days | NOEC (carbon mineralisation) | > 31.7 mg/kgdwt |
| Soil micro-organisms | 28 days | NOEC (carbon mineralisation) | 9.17 mg/kgdwt |
| Plants | Permethrin has been used in the crop protection field since 1977. During that time it has been cleared for use on several monocotyledonous and dicotyledonous crops, including cotton plants, corn, soybean, coffee, tobacco, oilseed rape, wheat, barley, alfalfa, vegetables, and fruits | | |
| Helianthus annuus (seedling emergence) | Not mentionned | NOER (emergence) | < 0.0128 mg/kg dwt |
| Plants (seedling emergence) | Not mentionned | NOER (biomass) | 1.6 mg/kg dwt |
| *Avena sativa* and *Allium cepa* (vegetative vigour) | 21 days | Effects on biomass | < 20% at 6875 g/ha (9.17 mg/kg dwt) |
| Birds | Acute | LD50 (acute toxicity) | > 4 640 mg/kg b.w. |
| Birds | Short-term | LC50 (dietary toxicity) | > 10 000 ppm |
| Bobwhite quail | Long term | NOEC (reproduction) | 500 ppm |
| Honeybees | Acute | LD50 (oral toxicity) | 0.163 µg/bee |
| Honeybees | Acute | LD50 (contact toxicity) | 0.0235 µg/bee |
| Rat | Acute | LD50 (oral) | 480 mg/kg b.w. |

##### 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

There is no ecotoxicological data available for the product 11LBCEOL03. The classification of the product is therefore based on data on the active substance and co-formulants.

Several aquatic ecotoxicological data on the active substance are available and are presented in the Table 2.2.8.1-1 above. Based on these data, the active substance permethrin is classified according to the Regulation (EC) No. 1272/2008 (CLP) as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410, very toxic to aquatic life with long-lasting effects. Permethrin is assigned an acute M-factor of 100 and a chronic M-factor of 10000.

Based on the classification and the M-factor values of permethrin, the product 11LBCEOL03 is classified according to Regulation (EC) No. 1272/2008 (CLP) with the worst-case classification:

Signal Word: Warning

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

The other co-formulant of the product is not classified for the environment and is not considered as substance of concern for the environment. Therefore, this co-formulant is not expected to have a significant impact on the ecotoxicological classification of the product 11LBCEOL03 as it is already classified with the worst classification H400/H410 due to the presence of permethrin.

Taking into account all these considerations (*i.e.* worst case classification of the product based on active substance data and composition of the product not influencing the ecotoxicological properties of the active substance), the classification of the product 11LBCEOL03 is based on the active substance data, according to the rules laid down in the Regulation (EC) 1272/2008 (CLP). Consequently, no further aquatic ecotoxicity data on the product 11LBCEOL03 are deemed necessary.

The classification of the product is presented in IUCLID, Section 12 Classification & labelling.

|  |
| --- |
| **Infobox 1 – FR:**  We agree with the classification proposed by the applicant. |

##### Further Ecotoxicological studies

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies. |
| Justification | The product 11LBCEOL03 is 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.  As the product is for indoor use only, it is not expected that the environment will be contaminated directly or indirectly. Therefore, the risk of exposure of non-target organisms is negligible when using the product according to the label recommendations. Moreover, several aquatic and terrestrial ecotoxicity data are available on the active substance permethrin and are presented in the Tables 2.2.8.1-1 and 2.2.8.1-2 above.  In addition, it is not suspected that the composition of the product 11LBCEOL03 would influence the ecotoxicological properties of the active substance in a way that may considerably alter the conclusions of the risk characterisation.  Thus, no additional aquatic and terrestrial ecotoxicological study with the product 11LBCEOL03 was conducted to address this point. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. |
| Justification | Based on the intended uses of the product 11LBCEOL03 there is no concern regarding other specific non-target organisms like for instance, sediment dwelling organisms, aquatic macrophytes or brackish, estuarine or marine organisms.  Indeed, as explained under Point 2.2.8.1.2, the product is for indoor use only, it is therefore not expected that the environment will be contaminated directly or indirectly. Therefore, the risk of exposure of non-target organisms is negligible when using the product according to the label recommendations.  Moreover, several aquatic and terrestrial ecotoxicity data are available on the active substance and are presented in the Tables 2.2.8.1-1 and 2.2.8.1-2 above.  In addition, it is not suspected that the composition of the product 11LBCEOL03 would influence the ecotoxicological properties of the active substance in a way that may considerably alter the conclusions of the risk characterisation.  Thus no additional aquatic or terrestrial ecotoxicological study with the product was conducted. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product 11LBCEOL03 is a liquid. Therefore, no additional study is deemed necessary to address this point. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product 11LBCEOL03 is a liquid. Therefore, no additional study is deemed necessary to address this point. |

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

No data is available.

The product 11LBCEOL03 is used for the preventive and curative treatment of interior woods only against wood-boring insects and termites.

As the product is for indoor use only, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the product 11LBCEOL03 and it can be concluded that no secondary ecological effect is expected when using the product 11LBCEOL03 according to the label recommendations.

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

The foreseeable routes of entry in the environment are based on the use envisaged and the behaviour of the product is extrapolated from the information on the active substance itself.

The product 11LBCEOL03 is 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.

Based on the intended uses of the product, no direct or indirect contamination of the STP, the surface water (including sediment) and the soil (including groundwater) is foreseen and the expected concentrations of permethrin in these compartments from the uses of the product are expected to be negligible.

Exposure of atmosphere can be expected considering the mode of application by spraying of the product 11LBCEOL03 resulting in a direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

Moreover, volatilisation of permethrin is considered to be negligible based on the vapour pressure (2.155\*10-6 Pa at 20°C) and Henry constant (4.6\*10-3 to 4.5\*10-2 Pa.m3/mol). In addition, as permethrin is rapidly degraded in the air (DT50 = 0.47 days), it 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 permethrin fate and distribution in the environment.

|  |
| --- |
| **Infobox 2 – FR:**  We agree with the evaluation presented by the applicant. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies on fate and behaviour in the environment. |
| Justification | As explained above, the outdoor environment is not expected to be contaminated as the product is only used indoor.  Moreover, several environmental data are available on permethrin and its metabolites (see Assessment Reports, permethrin, PT08, April 2014) and are presented in the section 2.2.8.2.2 "Fate and distribution in exposed environmental compartments".  Therefore, it can be concluded that there is no need to conduct additional environmental studies with the product 11LBCEOL03. |

##### Leaching behaviour (ADS)

The product 11LBCEOL03 is a liquid intended to be applied indoor for the preventive and curative treatment of interior woods. It is not intended to be used for the treatment of surfaces exposed to weathering. Therefore, leaching is not relevant for the product 11LBCEOL03.

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in soil. |
| Justification | A fugacity model is used to estimate distribution of the active substance permethrin in soil, water and air. The model is Level III fugacity model (in EPI Suite v4.10).  The data on permethrin used for the simulation come from the Assessment Report of permethrin (Product-Type 08 – April 2014), Appendix I, List of endpoints and are reported in the section "2.2.8.2.2 Fate and distribution in exposed environmental compartments" of this PAR.  The results are presented below:  Soil: 53.9%  Water: 5.09%  Sediment: 40.9%  Air: 0.0995%  However, as explained in the sections above, the soil (including groundwater) is not expected to be contaminated by the product 11LBCEOL03 because the product is for indoor use only.  Moreover, several environmental data are available on permethrin and its metabolites (see Assessment Reports, permethrin, PT08, April 2014) and are presented in the section 2.2.8.2.2 "Fate and distribution in exposed environmental compartments".  Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in soil with the product 11LBCEOL03. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in water and sediment. |
| Justification | As explained above, the fugacity model has shown a distribution of 5.09% of permethrin in water and 40.9% in sediment.  However, as explained in the sections above, the surface water (including sediment) is not expected to be contaminated by the product 11LBCEOL03 because the product is for an indoor use only. Moreover, several environmental data are available on permethrin and its metabolites (see Assessment Reports, permethrin, PT08, April 2014) and are presented in the section 2.2.8.2.2 "Fate and distribution in exposed environmental compartments".  Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in water and sediment with the product 11LBCEOL03. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in air. |
| Justification | Exposure of atmosphere can be expected considering the mode of application by spraying of the product 11LBCEOL03 resulting in a direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale. Moreover, volatilisation of permethrin is considered to be negligible based on the vapour pressure (2.155\*10-6 Pa at 20°C) and Henry constant (4.6\*10-3 to 4.5\*10-2 Pa.m3/mol). As explained above, the fugacity model has shown a distribution of 0.0995% of permethrin in air. In addition, as permethrin is rapidly degraded in the air (DT50 = 0.47 days), it would not be transported over large distances in the atmosphere. This is confirmed by the calculated distribution of permethrin in air (with Epi Suite) which is 0.0995% (see point 2.2.8.1.10).  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.  Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in air with the product 11LBCEOL03. |

##### 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 is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The product 11LBCEOL03 is intended to be used for the preventive and curative treatment of interior woods against wood-boring insects and termites.  It is therefore not intended to be sprayed in or near surface water. Therefore no overspray is foreseen.  Based on this assessment, an overspray study is not required for the product 11LBCEOL03. |

##### 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 is available.

The product 11LBCEOL03 is intended to be used for the preventive and curative treatment of interior woods against wood-boring insects and termites.

The product is not intended to be sprayed into the outdoor environment and it has no potential for large scale formation of dust. Therefore there is no risk of exposure of honeybees and non-target arthropods.

Based on this assessment, no additional study with the product 11LBCEOL03 was conducted to address this point

|  |
| --- |
| **Infobox 3 – FR:**  We agree with all the waiving. |

#### 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 11LBCEOL03 is 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.

According to the revised ESD for PT08, the emissions to the environment following indoor treatments by spraying, brushing and injection are considered negligible.

Therefore, as the product 11LBCEOL03 is for indoor use only, an exposure of environmental compartments is unlikely. Exposure of atmosphere can be expected considering the mode of application by spraying of the product 11LBCEOL03 resulting in a direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale. Moreover, volatilisation of permethrin is considered to be negligible based on the vapour pressure (2.155\*10-6 Pa at 20°C) and Henry constant (4.6\*10-3 to 4.5\*10-2 Pa.m3/mol). In addition, as permethrin is rapidly degraded in the air (DT50 = 0.47 days), it 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.

Concerning cleaning, maintenance and waste disposal, all the waste wood, protection foil, cleaning solvents, used cans and unused products should be disposed of according to national waste disposal regulations. These scenarios are not considered in the risk assessment.

**Table 2.2.8.2-1: General information on exposure assessment**

|  |  |
| --- | --- |
| Assessed PT | PT 08 |
| Assessed scenarios | Scenario 1: indoor applications by brushing, spraying or injection |
| ESD(s) used | Revised Emission Scenario Document for wood preservatives, 2013 |
| Approach | Not relevant |
| Distribution in the  environment | Not relevant |
| Groundwater simulation | Not relevant |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1:  Production: No  Formulation No  Use: No  Service life: No |

##### Emission estimation

As explained above, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected when using the product 11LBCEOL03 according to the label recommendations.

Regarding the air compartment, based on the indoor application of the product and on the physical chemical properties of the active substance, it is likely that emissions to the atmosphere will be negligible.

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

**Table 2.2.8.2.2-1: Identification of relevant receiving compartments based on the exposure pathway**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh water | Freshwater sediment | Sea water | Seawater sediment | STP | Air | Soil | Groundwater |
| Indoor use | No | No | No | No | No | No | No | No |

Available data on the fate and the behaviour of permethrin and its relevant metabolites are summarized in the following table. These data are coming from the Assessment Report of permethrin, PT08, April 2014.

**Table 2.2.8.2.2-2: Available fate and distribution data for the active substance permethrin and its metabolites**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input** | **Permethrin** | **3-phenoxybenzyl alcohol** | **PBA** | **DCVA** |
| Molecular weight [g/mol] | 391.29 | No data | No data | No data |
| Melting point [°C] | 33 - 35 | No data | No data | No data |
| Boiling point [°C] | 305 | No data | No data | No data |
| Vapour pressure [Pa] | 2.115\*10-6 at 20°C | No data | No data | No data |
| Henry’s law constant [Pa.m3.mol-1] | 4.6\*10-3 to 4.5\*10-2 | No data | No data | No data |
| Solubility in water [mg/L] | 0.18 - <0.00495 | No data | No data | No data |
| Partition coefficient (log POW) | 4.67 at 25°C | No data | No data | No data |
| Adsorption / desorption Koc [L/kg] | 26930 | No data | 141.2 | 93.2 |
| Biodegradability | Not readily biodegradable | No data | No data | No data |
| DT50 for hydrolysis in surface water | Hydrolytically stable under environmentally relevant pH and temperature conditions | No data | No data | No data |
| DT50 for photolysis in surface water | Photolytically stable under environmentally relevant pH and temperature conditions | No data | No data | No data |
| DT50 for biodegradation in surface water | 27.1 to 46.7 days (whole system) | 5.1 days (whole system) | 60.3 – 63.3 days (whole system) | 80 to145 days for trans DCVA  62 to 188 days for cis-DCVA |
| DT50 for degradation in soil | 106 days (geometric mean) | Not relevant in soil | 1.7 – 2.5 days | 33.1 -174.8 days |
| DT50 for degradation in air | 0.701 d when reacting with hydroxyl radicals 49.27 d when reacting with ozone | No data | No data | No data |

##### Calculated PEC values

As explained above, as the product is for indoors use only, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected when using the product 11LBCEOL03 according to the label recommendations.

Regarding the air compartment, considering the indoor application of the product and the physical chemical properties of the active substance, it is likely that emissions to the atmosphere will be negligible.

Therefore, expected concentrations of permethrin are considered negligible in all compartments, when using the product 11LBCEOL03 according to the label recommendations.

##### Primary and secondary poisoning

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product 11LBCEOL03. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product 11LBCEOL03.

Secondary poisoning

As the product is for indoor use only, no risk of secondary poisoning *via* ingestion of potentially contaminated food (*e.g*. earthworm or fish) by birds or mammals is expected.

#### Risk characterisation

##### Atmosphere

Exposure of atmosphere can be expected considering the mode of application by spraying of the product 11LBCEOL03 resulting in a direct emission to air. However, based on the indoor application of the product it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

Moreover, volatilisation of permethrin is considered to be negligible based on the vapour pressure (2.155\*10-6 Pa at 20°C) and Henry constant (4.6\*10-3 to 4.5\*10-2 Pa.m3/mol). In addition, as permethrin is rapidly degraded in the air (DT50 = 0.47 days), it would not be transported over large distances in the atmosphere.

Therefore, the risk of contamination of air can be considered as negligible when using the product 11LBCEOL03 according to the label recommendations.

##### Sewage treatment plant (STP)

As the product is for indoors use only, no contamination of the STP is expected.

Therefore, the risk for the STP is considered as negligible when using the product 11LBCEOL03 according to the label recommendations.

##### Aquatic compartment

As the product is for indoors use only, no contamination of the aquatic compartment, either directly or indirectly, is expected.

Therefore, the risk for the aquatic compartment is considered as negligible when using the product 11LBCEOL03 according to the label recommendations

##### Terrestrial compartment

As the product is for indoors use only, no contamination of the terrestrial compartment, either directly or indirectly, is expected.

Therefore, the risk for the terrestrial compartment is considered as negligible when using the product 11LBCEOL03 according to the label recommendations

##### Groundwater

As the product is for indoors use only, no contamination of the groundwater is expected.

Therefore, the foreseeable concentration in groundwater of the active substance and its relevant metabolites are considered as negligible and are not expected to exceed the maximum permissible concentration laid down by Directive 98/83/EC.

##### Primary and secondary poisoning

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the product 11LBCEOL03. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product 11LBCEOL03

Secondary poisoning

As the product is for indoors use only, no risk of secondary poisoning *via* ingestion of potentially contaminated food (*e.g*. earthworm or fish) by birds or mammals is expected.

##### Mixture toxicity

The mixture toxicity assessment is performed according to the Transitional guidance on mixture toxicity assessment for the environment of May 2014.

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

The product 11LBCEOL03 is 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.

As the product is for indoors use only, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected. Exposure of atmosphere can be expected considering the mode of application by spraying of the product 11LBCEOL03, resulting in direct emission to air. However, based on the indoor application of the product, it is likely that emissions to the atmosphere will be limited negligible.

Therefore, a significant exposure of environment is unlikely and a mixture toxicity assessment is not necessary for the product 11LBCEOL03.

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

An assessment of aggregated exposure is judged not relevant for the product 11LBCEOL03 based on the decision scheme developed by UBA (see Figure 1). Indeed, as the emissions into the environment are negligible because the product is for indoor use only, there is no need for an estimation of aggregated exposure.



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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The product 11LBCEOL03 is a ready-to-use solvent-based wood preservative containing 0.70% w/w permethrin. It is 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.  As the product is for indoor use only, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected. Regarding the air compartment, considering the indoor application of the product and the physical chemical properties of the active substance, it is likely that emissions to the atmosphere will be negligible.  Therefore, the risk for all compartments (STP, air, water, sediment, soil and groundwater) and the risk of primary and secondary poisoning are considered acceptable when using the product 11LBCEOL03 according to the label recommendations.  There is no need for conducting a mixture toxicity assessment and an estimation of aggregated exposure. |

|  |
| --- |
| **Infobox 4 – FR:**  We agree with the conclusions considering the strict practical uses claimed by the applicant. |

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

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

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Not relevant.

# Annexes[[21]](#footnote-21)

## List of studies for the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | | **Essential for the evaluation** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Yes** | **No** | **Yes** | **No** | **Y/N** |
|  |  | Legay S. | 2016 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product 11LBCEOL03 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)  FCBA (Bordeaux, France)  Report 402/15/1172F/abg-e | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2011 | Validation of analytical method and chemical analysis of active ingredient declared in wood preservative11LBCEOL03  FCBA (Bordeaux France)  402/11/1033F/ab-fe | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product 11LBCEOL03  FCBA (Bordeaux, France)  402/15/1172F/cdef-e | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2014 | Certificate of analysis n° : COA-402/11/1033F/c/T3A-e  FCBA (Bordeaux, France) | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2015 | Certificate of analysis n° : COA-402/15/1172F/abg-e  FCBA (Bordeaux, France) | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2013 | Certificate of analysis n° : COA-402/11/1033F/c/T2A-e  FCBA (Bordeaux, France) | V33 |  |  | X |  | Y |
|  |  | Legay S. | 2015 | Certificate of analysis n° : COA-402/11/1033F/c/T4A-e  FCBA (Bordeaux, France) |  |  |  |  |  |  |
|  |  | Shell Chemicals Europe B.V. | 2012 | Safety data sheet – ShellSol D60 | Shell Chemicals Europe B.V. |  |  |  | X | Y |

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| **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)** | **Date of first submission** |
| Arana M., Arancon  J. and Munné O. | 2012 | Determination of preventive action against *Hylotrupes bajulus* (Linnaeus) - Part 1: larvicidal effect according to EN 46-1 (2009) | Yes | V33 | 13/04/2016 |
| Arana M., Arancon  J. and Munné O. | 2012 | Determination of preventive action against *Reticulitermes* species according to EN 118:2005. | Yes | V33 | 13/04/2016 |
| Arana M., Arancon  J. and Munné O. | 2012 | Determination of the eradicant action against *Hylotrupes bajulus* (Linnaeus) larvae according to EN 1390:2006. | Yes | V33 | 13/04/2016 |
| Schumacher P. and Fennert E.-M. | 2017 | Determination of the eradicant action against larvae of *Hylotrupes bajulus* (L.) according to EN 1390 (2006). | Yes | CECIL Division professionnelle groupe V33 | 13/04/2017 |
| Schumacher P. and Fennert E.-M. | 2012 | 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 (1988). | Yes | CECIL Division professionnelle groupe V33 | 13/04/2016 |
| Schumacher P. and Fennert E.-M. | 2017 | Determination of the eradicant action against larvae of *Anobium punctatum De Geer* according to EN 48 (2005). | Yes | CECIL Division professionnelle groupe V33 | 13/03/2017 |
| Schumacher P. and Fennert E.-M. | 2012 | 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 (1988). | Yes | CECIL Division professionnelle groupe V33 | 13/04/2016 |
| Schumacher P. and Fennert E.-M. | 2017 | Determination of the eradicant action against larvae of *Anobium punctatum De Geer* according to EN 48 (2005). | Yes | CECIL Division professionnelle groupe V33 | 13/03/2017 |
| Schumacher P. and Fennert E.-M. | 2016 | 11LBCEOL03. 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). | Yes | CECIL Division professionnelle groupe V33 | 13/03/2017 |
| Brunet C. and Paulmier I. | 2017 | 11LBCEOL03. Efficacité protectrice vis-a-vis de *Lyctus brunneus* selon NF EN 20-1 avec NF EN 73. | Yes | Groupe V33 | 13/03/2017 |
| Vuillemin J. and Paviel F. | 2016 | Evaluation de l'efficacité préventive de deux produits de traitement du bois 04LBCEOL689/2 et 11LBCEOL03 face aux attaques du termite souterrain *Coptotermes gestroi* à la Réunion.  Selon la méthode NF EN 118 (Janvier 2014) avec NF EN 73 | Yes | Groupe V33 | 13/03/2017 |
| Ansard D. and Paulmier I. | 2016 | 11LBCEOL03. Efficacité préventive contre les termites souterrains selon NF EN 118 avec NF EN 73. | Yes | Groupe V33 | 13/03/2017 |

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| --- | --- | --- | --- | --- | --- |
| **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)** | **Date of first submission** |
| Richeux, F. | 2014 | ASSESSMENT OF THE SKIN SENSITISATION POTENTIAL IN THE MOUSE USING THE LOCAL LYMPH NODE ASSAY (LLNA:BrdU) | Y | V33 |  |
| Bernal, J. | 2015 | IN-VITRO HUMAN SKIN PENETRATION OF 14C-PERMETHRIN IN 11LBCEOL03 TEST ITEM, IN ACCORDANCE TO THE GUIDANCE OECD No.428 | Y | V33 |  |

## Output tables from exposure assessment tools

For Human Health:



## New information on the active substance

No new information on the active substance regarding the physico chemical properties were provided.

## Residue behaviour

Not relevant.

## Summaries of the efficacy studies (B.5.10.1-xx)[[22]](#footnote-22)

Not relevant (IUCLID file available).

## Confidential annex

Please refer to the Confidential annex file.

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance. [↑](#footnote-ref-3)
4. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
5. 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-5)
6. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (Laboratory method). [↑](#footnote-ref-6)
7. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-7)
8. Wood preservatives – Determination of the protective effectiveness against *Anobium punctatum (De Geer)* by egg-Iaying and larval survival – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-8)
9. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-9)
10. Wood preservatives – Determination of eradicant efficacy in preventing emergence of *Anobium punctatum (De Geer)* [↑](#footnote-ref-10)
11. Wood preservatives – Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* [↑](#footnote-ref-11)
12. Wood preservatives – Determination of the eradicant action agaisnt larvae of *Anobium punctatum (De Geer)* [↑](#footnote-ref-12)
13. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-13)
14. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-14)
15. Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-15)
16. HEEG opinion on Exposure model: Primary exposure scenario – washing out of a brush which has been used to apply a paint (endorsed at TM III 2010) [↑](#footnote-ref-16)
17. Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure: Methods and models to assess exposure to biocidal products in different product types (6 February 2017, v3). [↑](#footnote-ref-17)
18. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-18)
19. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-19)
20. HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance (endorsed at TM IV 2011 and amended after TM III 2013 to take into account changed default human factor values) [↑](#footnote-ref-20)
21. 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-21)
22. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-22)