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)



V33 TRAITEMENT POUTRES ET CHARPENTES

Product type 8

Permethrin

Case Number in R4BP: BC-CU022896-15

Evaluating Competent Authority: FR

Date: May 2018

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# CONCLUSION

**Conclusion for Physico-chemistry:**

The product V33 POUTRES ET CHARPENTES is a yellow translucent water based formulation. It has a pH of 6.8 at 20°C and the surface tension is 31.48mN/m. The product forms stable emulsions.

The product is stable after storage 7 days at 0°C, 14 days at 54°C and 48 months at 20°C. Compatibility with HDPE and steel can coated inside with an epoxy pigmented varnish has been demonstrated with storage stability studies.

The product is not classified from a physico chemical aspect.

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

**Conclusion for Efficacy:**

French competent authorities (FR CA) assessed that the product V33 POUTRES ET CHARPENTES 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 V33 POUTRES ET CHARPENTES / m² of wood.
* Curative treatment: superficial application at 300 mL of product V33 POUTRES ET CHARPENTES / m² of wood (injection with 150 mL of product V33 POUTRES ET CHARPENTES / m² of wood if need be).

**Conclusion for Human health:**

Concerning professional users:

For application by brushing with and without injection, the risk is considered acceptable without PPE.

For spray application and spray application combined with injection, the risk is acceptable considering the wear of gloves and coated coverall.

Concerning non-professional users, the risk is acceptable for all applications.

Concerning secondary exposure, the risk is acceptable.

**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 V33 POUTRES ET CHARPENTES must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion for Ecotoxicology:**

Considering the intended uses of the product 04LBCEOL689/2, 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)** |
| --- | --- |
| V33 TRAITEMENT POUTRES ET CHARPENTES |  |

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

* V33 TRAITEMENT BOIS POUTRES ET CHARPENTES (France)
* TRATAMENTO MADEIRA INTERIOR NUANCE (Portugal)

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | V33 |
| **Address** | La Muyre  39 210 Domblans  France |
| **Authorisation number** | **FR-2018-0049** | |
| **Date of the authorisation** | **21/08/2018** | |
| **Expiry date of the authorisation** | **20/08/2028** | |

#### 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 |
| **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 | 0,60 |

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

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

The active substance and the biocidal product are not classified from a physico chemical point of view.

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1 – H400  Aquatic Chronic 1 – H410 |
| Hazard statement | H400, Very toxic to aquatic life  H410, Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | **Warning** |
| Hazard statements | 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  P391 : Collect spillage  P501 : Dispose of contents/container to hazardous waste |
|  | |
| Note | EUH 208: Contains Permethrin and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction. |

### Authorised use(s)

#### Use description[[4]](#footnote-4)

Table 1. Use # 1 – Preventive treatment

|  |  |
| --- | --- |
| **Product Type** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood (softwood and hardwood) 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 |
| **Application method(s)** | Superficial application / brush  Superficial application / spray treatment |
| **Application rate(s) and frequency** | The product is ready to use  The application is performed by brushing and spraying  Application rate is in the analytical zone:  UC1: 200 mL/m² of wood |
| **Category(ies) of users** | Professionnals and non professionals |
| **Pack sizes and packaging material** | Bottles of 0.5-0.75-1L made of steel coated with epoxy phenolic layer  Containers of 2.5-5-6-20L made of steel coated with epoxy phenolic layer  Barrels of 25-30L made of steel coated with epoxy phenolic layer |

#### Use-specific instructions for use[[5]](#footnote-5)

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
| Professional use:   * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a coverall category 3 type 6 during spray 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

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| --- |
|  |

#### Use description

Table 2. Use # 2 – Curative application for wood in service

|  |  |
| --- | --- |
| **Product Type(s)** | PT08 – wood preservatives |
| **Where relevant, an exact description of the authorised use** | Curative treatment for wood (hardwood and softwood) in service |
| **Target organism (including development stage)** | Wood boring beetles   * House longhorn beetle (*Hylotrupes bajulus*) - larvae * Common furniture beetle (*Anobium punctatum*) - larvae * Powder post beetles (*Lyctus brunneus*) - larvae   Termites (*Reticulitermes spp.,* *Coptotermes spp*. and *Heterotermes spp.*) - Workers, soldiers and nymphs |
| **Field of use** | Curative treatment for wood in service (indoor) |
| **Application method(s)** | Superficial application / brush  Superficial application / spray  Injection (combined with a superficial application) |
| **Application rate(s) and frequency** | The product is ready to use.  The application is performed by brushing or spraying.  The application rate is :   * 300 mL of product / m² of wood   When the application is performed by injection (combined with superficial application), the application rate is :  150 mL of product / m² of wood (+ 300 mL of product / m² of wood for superficial application) |
| **Category(ies) of user(s)** | Professionnals and non professionals |
| **Pack sizes and packaging material** | Bottles of 0.5-0.75-1L made of steel coated with epoxy phenolic layer  Containers of 2.5-5-6-20L made of steel coated with epoxy phenolic layer  Barrels of 25-30L made of steel coated with epoxy phenolic layer |

#### Use-specific instructions for use[[6]](#footnote-6)

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
| Professional use:  - Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a coverall category 3 type 6 during spray application and spray 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

|  |
| --- |
|  |

### General directions for use

#### Instructions for use[[7]](#footnote-7)

|  |
| --- |
| - 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 registration holder. |

#### Risk mitigation measures

|  |
| --- |
| - 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

|  |
| --- |
| - 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.  - Inhalation (spray mist): 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.  - 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 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 : 48 months |

### Other information

|  |
| --- |
| - Treated wood should not be intended for uses involving contact with food, feed or livestock.  - The presence of perméthrine, MIT, BIT and C(M)IT/MIT, skin sensitizers that may produce an allergic reaction, must be reported on the label. |

### 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 with internal epoxy varnish | 0.5, 0.75, 1, 2.5, 5, 6, 20, 25 or 30 L | Steel Internal epoxy varnish | Polyethylene closure systems | Professional and nonprofessional | Yes |

### 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 V33 TRAITEMENT POUTRES ET CHARPENTES (04LBCEOL689/2). Some studies were performed on another formulation (06LBCEOL20/2PT). Bridging data has been reported in confidential annex.

**Efficacy:**

The product 04LBCEOL 689/2 is identical to the product V33 POUTRES ET CHARPENTES.

The following efficacy studies were submitted:

* Laboratory efficacy study conducted according to the standard EN 46-1[[8]](#footnote-8), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[9]](#footnote-9), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[10]](#footnote-10), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin), after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 118[[11]](#footnote-11), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin), after ageing following EN 73 (evaporating procedure) against *Reticulitermes santonensis*;
* Laboratory efficacy study conducted according to the standard EN 118, with the product 04LBCEOL 689/2 (0.6 % 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 04LBCEOL 689/2 (0.6 % w/w permethrin), after ageing following EN 73 (evaporating procedure) against *Coptotermes gestroi*;
* Laboratory efficacy study conducted according to the standard EN 370[[12]](#footnote-12), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin) after ageing following EN 73 (evaporating procedure)
* Laboratory efficacy study conducted according to the standard EN 1390[[13]](#footnote-13), with the product 04LBCEOL 689/2 (0.6 % w/w permethrin).

**Residue data**

No specific residue data were submitted in the context of this dossier. The product V33 TRAITEMENT POUTRES ET CHARPENTES 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.

#### **Human health**

The applicant has provided one study performed on the formulation V33 TRAITEMENT POUTRES ET CHARPENTES (04LBCEOL689/2) for skin sensitisation. A study for eye irritation was performed on another formulation (06LBCEOL20/2PT). Results of this study have not been considered extrapolable to V33 TRAITEMENT POUTRES ET CHARPENTES (04LBCEOL689/2), based on composition variation. Comparison of the two compositions has been reported in confidential annex.

#### 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 3. Intended use # 1 – Preventive application

|  |  |
| --- | --- |
| Product Type(s) | PT08 – wood preservatives |
| Where relevant, an exact description of the authorised use | The product is a ready-to-use water-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 g/m² (or 200 mL/m² with a product density of 1.0) |
| Category(ies) of user(s) | Professional and non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel coated with epoxy phenolic layer  Containers of 2.5-5-6-20L made of steel coated with epoxy phenolic layer  Barrels of 25-30L made of steel coated with epoxy phenolic layer |

Table 4. 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 is a ready-to-use water-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 | Superficial application: 300 g/m² (or 300 mL/m² with a product density of 1.0)  Injection: 150 g/m² (or 150 mL/m² with a product density of 1.0) |
| Category(ies) of user(s) | Professional and non-professional |
| Pack sizes and packaging material | Bottles of 0.5-0.75-1L made of steel coated with epoxy phenolic layer  Containers of 2.5-5-6-20L made of steel coated with epoxy phenolic layer  Barrels of 25-30L made of steel coated with epoxy phenolic layer |

### Physical, chemical and technical properties

The product 04LBCEOL689/2 (V33 POUTRES ET CHARPENTES) is a ready-to-use water-based wood preservative (AL) containing 0.60% w/w permethrin. Some studies (storage at low temperature, viscosity, surface tension and emulsion stability) have been performed with formulation 06LBCEOL20/2PT. A bridging has been performed and is reported in the confidential annex.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Product 04LBCEOL689/2 Batch number: 301115689/2 Containing 0.60% w/w of permethrin | Translucent yellow liquid at initial time and translucent yellow stronger liquid after 14 days at 54 ± 2°C. No deposit, no phase partition. | Acceptable. | XX |
| Colour at 20 °C and 101.3 kPa | Visual observation |
| Odour at 20 °C and 101.3 kPa | No guideline required | The product 04LBCEOL689/2 has a slight odour |
| Acidity / alkalinity | CIPAC MT 75 | Product 04LBCEOL689/2 Batch number: 301115689/2 Containing 0.60% w/w of permethrin | The pH of the pure test item 04LBCEOL689/2 was 6.8 at 20.0°C before storage and 6.2 at 20.7°C after 14 days at 54 ± 2°C in metallic packaging (steel coated with varnish). | Acceptable. | XX |
| Relative density / bulk density | Statement | Product 04LBCEOL689/2 | The product 04LBCEOL689/2 contains more than 95% w/w water, its relative density calculated with the relative density of each components is 1.003. | Acceptable. | / |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 method (storage stability)  CIPAC MT 75.3  Analytical method validated | Product 04LBCEOL689/2 Batch number: 301115689/2 Containing 0.60% w/w of permethrin | The test item in its commercial packaging (steel can coated inside with an epoxy pigmented varnish) and in inert packaging (glass flasks) 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 in steel coated with varnish packaging | | Appearance of the test item in inert packaging | Translucent yellow liquid No deposit or phase partition | Translucent yellow stronger liquid No deposit or phase partition | | Permethrin content (% w/w) (in glass flask) | 0.585 | 0.601 (+ 2.7% *vs.* the value at initial time) | | Appearance of the commercial packaging containing the test item | 1L steel can coated inside with an epoxy pigmented varnish. No sign of deformation and leakage | | | Mass change of the commercial packaging | / | + 0.001% | | pH (pure test item) | 6.8 at 20.0°C | 6.2 at 20.7°C | | Acceptable.  The product is stable after storage 14 days 54°C in glass Flask. Compability with commercial packaging (steel coated with varnish packaging) has been demonstrated.  Emulsion stability has not been performed. However, results obtained with the similar formulation 06LBCEOL20/2PT are acceptable. | XX |
| Storage stability test – **accelerated storage** | Analytical methods validated  CIPAC MT 46.3  CIPAC MT 75.3  CIPAC MT 36.3 | Test item: 06LBCEOL20/2PT  Batch n°: 16011520/2PT | Packaging: 1 L steel can with epoxy varnish   |  |  |  | | --- | --- | --- | |  | Initial | After 14 days at 54°C | | Appearance | Translucent pale yellow liquid, with no deposit no phase partition. | No change | | Appearance of packaging containing the test item | No sign of corrosion, or degradation | No change | | Content of tebuconazole (% w/w) | 0.138 | 0.135 | | % variation | / | -2.2% | | Content of Cypermethrin (% w/w) | 0.168 | 0.164 | | % variation | / | -2.4% | | Content of propiconazole (% w/w) | 0.129 | 0.131 | | % variation | / | +1.6% | | Weight | 580.46 | 580.3 | | Variation of weight | / | -0.028% | | Acceptable,  The product 06LBCEOL20/2PT is stable 14 days at 54°C in in steel coated with varnish packaging.  Emulsion stability results can be extrapolated to formulation 04LBCEOL689/2. | XX |
|  |  |  | |  |  |  | | --- | --- | --- | | pH undiluted | 6.86 at 20 °C | 6.29 at 20 °C | | Emulsion stability of the pure test item  initially  after 30 minutes  after 2 hours  after 24 hours  after re-emulsification after 24 h  30 minutes after the  re-emulsification | Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous | Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous | |  |  |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife | Product 04LBCEOL689/2 Batch number: 250313689/2 Containing 0.60% w/w of permethrin | |  |  |  | | --- | --- | --- | | Test | At initial time | After 30 months at 20 ± 2°C in steel coated with varnish packaging | | Appearance of the test item | Liquid, yellow and translucent No deposit or phase partition | | | Permethrin content (% w/w) | 0.590 | 0.596 (+ 1.0% *vs.* the value at initial time) | | Appearance of the commercial packaging containing the test item | 1L steel can coated inside with an epoxy pigmented varnish. No sign of corrosion or degradation | | | Mass change of the commercial packaging | / | 0.00% |   The test item and its commercial packaging (steel can coated inside with an epoxy pigmented varnish) are considered to be stable after the long term storage procedure (30 months at 20 ± 2°C). | Acceptable. The product is stable after 30 months at 20°C in steel coated with varnish packaging. | XX |
| Product 04LBCEOL689/2 Batch number: 020211689/2 Containing 0.60% w/w of permethrin | |  |  |  | | --- | --- | --- | | Test | At initial time | **after 48 months** **at 20 ± 2°C in noncommercial 5 L** **HDPE packaging** | | Permethrin content (% w/w) | 0.620 | 0.615 (- 0.8% *vs.* the value at initial time) |   The test item in a non-commercial packaging (HDPE 5 L can) is considered to be stable after the long term storage procedure (48 months at 20 ± 2°C). | Acceptable. The product is stable after 48 months at ambient temperature in HDPE packaging. | XX |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 method (2000) | Product 06LBCEOL20/2PT Batch number: 16011520/2PT Containing 0.15% w/w of cypermethrin, 0.13% w/w of propiconazole, 0.14% w/w of tebuconazole | The products 04LBCEOL689/2 and 06LBCEOL20/2PT have very close compositions. It was demonstrated that low temperature stability of 04LBCEOL689/2 can be extrapolated from the study performed with 06LBCEOL20/2PT.   |  |  |  | | --- | --- | --- | |  | Initial | After 7days at 0°C | | Appearance | Homogeneous transparent clear yellow liquid, with a chemical odour. | No change | | Emulsion stability in pure test item  initially  after 30 minutes  after 2 hours  after 24 hours  after re-emulsification after 24 h  30 minutes after the  re-emulsification | Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous | Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous  Homogeneous |   The test item 04LBCEOL689/2 is expected to be stable after storage for 7 days at 0 ±2°C: no deposit or phase partition observed. The emulsion characteristics and re-emulsification properties of the pure test item are expected to be stable after a storage procedure for 7 days at 0 ± 2°C. | Acceptable. The product 04LBCEOL689/2 is stable at low temperature. Bridging with 06LBCEOL20/2PT is acceptable. | XX |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required as the commercial packagings of the product 04LBCEOL689/2 are opaque (steel cans coated inside with an epoxy pigmented varnish). | Acceptable. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item 04LBCEOL689/2 is considered to be stable after 14 days at 54 ± 2°C and after 7 days at 0 ± 2°C. The individual commercial packaging (steel cans coated inside with an epoxy pigmented varnish) is 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 procedure and long term storage at ambient temperature** | Acceptable. Compatibility with steel can has been demonstrated. |  |
| Wettability |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable |  |
| Wet sieve analysis and dry sieve test |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 method | Product 06LBCEOL20/2PT Batch number: 16011520/2PT Containing 0.15% w/w of cypermethrin, 0.13% w/w of propiconazole, 0.14% w/w of tebuconazole | The products 04LBCEOL689/2 and 06LBCEOL20/2PT have very close compositions. It was demonstrated that the emulsifiability, re-emulsifiability and emulsion stability after low temperature stability procedure (7 days at 0 ± 2°C) can be extrapolated from study obtained with 06LBCEOL20/2PT.  Undiluted   |  |  | | --- | --- | | initially | Homogeneous | | after 30 minutes | Homogeneous | | after 2 hours | Homogeneous | | after 24 hours | Homogeneous | | after re-emulsification after 24 h | Homogeneous | | 30 minutes after the re-emulsification | Homogeneous |   The product 04LBCEOL689/2 is expected to form and maintain a stable uniform emulsion without free oil, cream or solid matter. | Acceptable. Data can be extrapolated to 04LBCEOL689/2. | XX |
| Disintegration time |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Persistent foaming |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Flowability/Pourability/Dustability |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Burning rate — smoke generators |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Burning completeness — smoke generators |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Composition of smoke — smoke generators |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Spraying pattern — aerosols |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Physical compatibility |  |  | Not applicable. 04LBCEOL689/2 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. 04LBCEOL689/2 is a ready-to-use product and is not intended to beused 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 emulsion. | Not applicable. |  |
| Surface tension | OECD Test Guideline115 | Product 06LBCEOL20/2PT Batch number: 16011520/2PT Containing 0.15% w/w of cypermethrin, 0.13% w/w of propiconazole, 0.14% w/w of tebuconazole | The products 04LBCEOL689/2 and 06LBCEOL20/2PT have very close compositions. It was demonstrated that the surface tension can be extrapolated from study obtained with 06LBCEOL20/2PT. Please refer to bridging data.  The product 04LBCEOL689/2 is expected to have a surface tension of 31.48 mN/m at 20.0°C and is considered as surface active. | Acceptable. See bridging in confidential annex. The product is considered surface active. | XX |
| Viscosity | OECD Test Guideline 114 ISO Standard 2431 (flow cup method) | Product 06LBCEOL20/2PT Batch number: 16011520/2PT Containing 0.15% w/w of cypermethrin, 0.13% w/w of propiconazole, 0.14% w/w of tebuconazole | The products 04LBCEOL689/2 and 06LBCEOL20/2PT have very close compositions. It was demonstrated that the viscosity can be extrapolated from study obtained with 06LBCEOL20/2PT. Please refer to bridging data.  The kinematic viscosity of the test item 04LBCEOL689/2 is expected to be < 6.62 mm²/s at 20.0 ± 0.5°C and < 6.62 mm²/s at 40.0 ± 0.5°C. | Acceptable. See bridging in confidential annex. | XX |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product 04LBCEOL689/2 is a yellow translucent liquid with a slight odour. The pH of pure product is about 6.8 at 20°C.  After accelerated storage procedure (14 days at 54 ± 2°C) the appearance of the product 04LBCEOL689/2 and its commercial packaging (steel can coated inside with an epoxy pigmented varnish) are considered to be stable. The permethrin content was 0.585% w/w at initial time and 0.601% w/w after 14 days at 54 ± 2°C in glass flask. With a variation of + 2.7% *vs.* the value at initial time, the test item is considered to be chemically stable after the accelerated storage procedure. The pH of the test item is considered to be stable after an accelerated storage procedure of 14 days at 54 ± 2°C.  After a long term storage procedure (30 months at 20 ± 2°C) the appearance of the product 04LBCEOL689/2 and its commercial packaging (steel can coated inside with an epoxy pigmented varnish) are considered to be stable. The permethrin content was 0.590% w/w at initial time, 0.603% w/w after 12 months, 0.611% w/w after 24 months and 0.596% w/w after 30 months at 20 ± 2°C. With variation respectively of + 2.2% after 12 months, + 3.6% after 24 months and + 1.0% after 30 months *vs.* the value at initial time of permethrin, the test item is considered to be stable after the long term storage procedure.  A long term storage procedure (48 months at 20 ± 2°C) has also demonstrated the stability of the product 04LBCEOL689/2 in a non-commercial 5 L HDPE packaging. The permethrin content was 0.620% w/w at initial time, 0.595% w/w after 31 months, 0.597% w/w after 36 months and 0.615% w/w after 48 months at 20 ± 5°C. With variation respectively of - 4.0% after 31 months, - 3.7% after 36 months and - 0.8% after 48 months *vs.* the value at initial time of permethrin, the test item is considered to be stable after the long term storage procedure.  Furthermore, concerning the biocidal product 04LBCEOL689/2, it was demonstrated that physicochemical properties can be extrapolated from studies performed with 06LBCEOL20/2PT (see the confidential annex). The relative density of the product 04LBCEOL689/2 is expected to be 1.003. The test item 04LBCEOL689/2 and its emulsion characteristics and re-emulsification properties are expected to be stable after 7 days at 0°C. The surface tension of 04LBCEOL689/2 is expected to be similar to 31.48 mN/m (surface active material), and its kinematic viscosity is expected to be < 6.62 mm²/s at 20.0 ± 0.5°C and < 6.62 mm²/s at 40.0 ± 0.5°C.  Based on the results of the storage stabilities, a shelf life of 48 months can be granted. Compatiblity with the commercial packaging (steel can with internal epoxy varnish) has been demonstrated during the accelerated storage stability at 54°C and confirmerd with the long term storage stability (30months) at ambient temperature.  The effect of light has not been investigated. However, the commercial packaging (steel can) is considered barrier to light. Therefore, no specific mitigation measure is needed.  Shelf life: 48 months |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives |  |  | The product 04LBCEOL689/2 is not explosive. Test is not required as 04LBCEOL689/2 contains more than 95% w/w of inert solvent and as no ingredient is classified as explosive | Acceptable. The product is not explosive. |  |
| Flammable gases |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Flammable aerosols |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Oxidising gases |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Gases under pressure |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Flammable liquids |  |  | The product 04LBCEOL689/2 is not flammable. Test is not required as 04LBCEOL689/2 contains more than 95% w/w of inert solvent and as no ingredient is classified as flammable. | Acceptable. The product is not flammable. |  |
| Flammable solids |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Self-reactive substances and mixtures |  |  | The product 04LBCEOL689/2 is not a self-reactive mixture. Test is not required as 04LBCEOL689/2 contains more than 95% w/w of inert sovlent and as no ingredient is classified as self-reactive substance. | Acceptable. |  |
| Pyrophoric liquids |  |  | The product 04LBCEOL689/2 is not a pyrophoric liquid. Test is not required as 04LBCEOL689/2 contains more than 95% w/w inert solvent and 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 emulsion | Not applicable. |  |
| Self-heating substances and mixtures |  |  | Not required as the product is a ready-to-use emulsion | Due to the composition, the product is not expected to be a self heating mixture. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The product 04LBCEOL689/2 does not emit flammable gases when in contact with water. Test is not required as 04LBCEOL689/2 contains more than 95% w/w inert solvent and forms a stable mixture. | Acceptable. |  |
| Oxidising liquids |  |  | The product 04LBCEOL689/2 is not oxidising. Test is not required as 04LBCEOL689/2 contains more than 95% w/w inert solvent and as no ingredient is classified as oxidising liquid or solid. | Acceptable. The product has no oxidising properties. |  |
| Oxidising solids |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Organic peroxides |  |  | Not required as the product does not contain organic peroxides. | Not applicable. |  |
| Corrosive to metals |  |  | The product 04LBCEOL689/2 is not corrosive to metal. Test is not required as experience shows that the product is not corrosive to metal. Moreover, no sign of corrosion and no loss of weight of the packaging have been noticed during the accelerated and ambient 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) |  |  | The product 04LBCEOL689/2 is not expected to present a significant hazard for autoflammability. Test is not required as 04LBCEOL689/2 contains more than 95% w/w of inert solvent and as no ingredient is considered to be auto-flammable based on available data found in safety data sheets. | Acceptable. The product is not expected to be auto flammable in the conditions of use. |  |
| Relative self-ignition temperature for solids |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |
| Dust explosion hazard |  |  | Not required as the product is a ready-to-use emulsion. | Not applicable. |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product 04LBCEOL689/2 is not expected to present a hazard for explosive properties, flammability, self-reactivity, oxidising properties and auto-flammability. The product is not corrosive since no degradation of the steel packaging has been noticed during the storage stability studies. |

### Methods for detection and identification

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| Study report | Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product 04LBCEOL689/2 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); Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France) , Raphalen E., 2016 |
| *Report* | 402/15/1171F-e |
| *GLP* | *Y* |

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| --- | --- |
| Study report | Chemical analysis no.4 of the test item ready-to-use 04LBCEOL689/2 (Batch no.020211689/2), Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France), Legay S., 2015 |
| *Report* | 402/15/1060F/a-e |
| *GLP* | *Y* |

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| --- | --- |
| Study report | Chemical analysis no.3 of the test item ready-to-use 04LBCEOL689/2 (Batch no.020211689/2), Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France), Legay S, 2014 |
| *Report* | 402/14/1035F/a-e |
| *GLP* | *Y* |

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| Study report | Chemical analysis of the test item ready-to-use 04LBCEOL689/2 (Batch no.250313689/2), Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France), Legay S., 2013 |
| *Report* | 402/13/1036F/a-e |
| *GLP* | *Y* |

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| --- | --- |
| Study report | Chemical analysis on 04LBCEOL689/2 (Batch no.020211689/2), Laboratoire de Chimie-Écotoxicologie, FCBA (Bordeaux, France), Legay S., 2011 |
| *Report* | 402/11/1001F/a-e |
| *GLP* | *Y* |

**Test item**: 04LBCEOL689/2 (Batch no.020211689/2), blank formulation of 04LBCEOL689/2 (ref 15/1171F/2)

**Principle of the method**

A quantity of the test item (45-60 mg) was weighed into a 20 – 25 mL volumetric flask and the volume was made up with acetonitrile in order to obtain a concentration near 10 mg/L of permethrin. Permethrin is analysed by Liquid Chromatography with UV detector (HPLC-UV at 210nm) by external standard calibration, at retention time of about 15.1 min for permethrin I peak and about 17.3 min for permethrin II peak with the column ODS1.

**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 (04LBCEOL689/2). The specificity was assessed by checking for any interference in HPLC-UV (210 nm) at the retention time of each peak of permethrin. Chromatograms were provided for test item, blank formulation and standards. No interferences were notices at the retention times of the peaks of permethrin. Therefore, the analytical method showed a good specificity for analysis of permethrin in formulation 04LBCEOL689/2.

**Linearity**

To define the linearity of the detector answer of permethrin, five concentrations taken between 50% and 500% (eq to 5.00 mg/L to 50.00 mg/L) of the permethrin reference items were analysed (two determinations for each concentration). Regressions were linear with a correlation coefficient >0.99.

**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.

For the study 402/15/1171F-e, 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 97.48% and 99.69%.

Mean recovery rate = 98.4% (n = 6) and RSD was equal to 0.80%. The precision obtained during accuracy measurements was acceptable as the R.S.D. was lower than the result of the modified Horwitz equation: < 2.89% (C = 0.0060).

**Precision**

The precision was determined 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.

For the study 402/15/1171F-e, the concentration of permethrin in the test item was equal to 0.585% w/w and the RSD was equal to 1.78%.

For the study 402/13/1036F/a-e, the concentration of permethrin in the test item was equal to 0.590% w/w and the RSD was equal to 0.97%.

For the study 402/11/1001F/a-e, the concentration of permethrin in the test item was equal to 0.616% w/w and the RSD was equal to 1.29%.

For the study 402/14/1035F/a-e, the concentration of permethrin in the test item was equal to 0.597% w/w and the RSD was equal to 2.16%.

For the study 402/15/1060F/a-e, the concentration of permethrin in the test item was equal to 0.615% w/w and the RSD was equal to 1.46%.

In the case of permethrin, the precision was acceptable as the R.S.D. were lower than the result of the modified Horwitz equation: < 2.89% (C = 0.0060).

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| **Validation results** | | |
| **Specificity** | Permethrin | To identify the peaks, standard of permethrin was injected. 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 04LBCEOL689/2. |
| **Linearity** | Permethrin | Calibration range: 5.00 – 50.00 mg/L of permethrin (n = 5, 50% – 500%):  Report 402/15/1171F-e:  y = 5.34 \* 104 \* x + 3.29 \* 102, r = 0.9999;  Report 402/15/1060F/a-e  y = 5.62 \* 104 \* x + 2.35 \* 103, r = 0.9999;  Report 402/14/1035F/a-e:  y = 5.47 \* 104 \* x – 8.30 \* 102, r = 0.9999;  Report 402/13/1036F/a-e:  y = 5.45 \* 104 \* x – 2.38 \* 104, r = 0.9999;  Report 402/11/1001F/a-e  y = 5.37 \* 104 \* x – 1.82 \* 104, r = 0.9997    (y = sum of the two peaks areas (permethrin I + permethrin II), x = permethrin amount in mg/L) |
| **Accuracy** | Permethrin | Report 402/15/1171F-e  Blank formulation fortified at nominal level of permethrin in the product 04LBCEOL689/2 (i.e at approx 0.6%w/w in the formulation, equivalent to 10mg/L in solution after dilution of the sample)  Mean recovery rate = 98.4% (n = 6), RSD=0.80% < modified Horwitz 2.89% |
| **Precision** | Permethrin | In precision samples:  Report 402/15/1171F-e:  Mean average content = 0.585% w/w (n = 6)  RSD = 1.78% (n = 6) < modified Horwitz 2.89%  Report 402/15/1060F/a-e  Mean average content = 0.590% w/w (n = 6)  RSD = 0.97% (n = 6) < modified Horwitz 2.89%  Report 402/14/1035F/a-e:  Mean average content = 0.616% w/w (n = 6)  RSD = 1.29% (n = 6) < modified Horwitz 2.89%  Report 402/13/1036F/a-e:  Mean average content = 0.597% w/w (n = 6)  RSD = 2.16% (n = 6) < modified Horwitz 2.89%  Report 402/11/1001F/a-e  Mean average content = 0.615% w/w (n = 6)  RSD = 1.46% (n = 6) < modified Horwitz 2.89% |

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| **Conclusion on the methods for detection and identification of the product** |
| The permethrin content in the product 04LBCEOL689/2 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 04LBCEOL689/2 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. |

The following method has been used to quantify active ingredients in the formulation 06LBCEOL20/2PT (used for bridging data) during the storage stability studies.

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| --- | --- |
| Study report | Content of active substances in the biocidal product 06LBCEOL20/2PT after a method validation according to SANCO/3030/99/rev.4, laboratoire de Chimie Ecotoxicologie, FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux Cédex – France, report N°.402/16/1011F/ab-e, 2016, Legay S. |
| Report | N°.402/16/1011F/ab-e |
| GLP | *Y* |

Test item: 06LBCEOL20/2PT; Batch 16011520/2PT

Blank matrix: 69168920M; batch 080116M

Nominal content: 0.17% w/w cypermethrin; 0.13% w/w propiconazole; 0.14% w/w tebuconazole

**Principle:** Samples are dissolved into acetonitrile and determination is performed by HPLC-UV (210nm for cypermethrin and 230nm for tebuconazole/propiconazole) using a Lichrospher 5 ODS1 C18 column.

**Specificity**

Chromatograms were provided for solvent, calibration standards, test item, blank matrix, fortified matrix and no interferences are the retention time of the active ingredients. Specificity is acceptable.

**Linearity**

Linearity has been performed with 5 calibration standards (external calibration), over a concentration range at the nominal content +/-20%. The linearity range of each active ingredient in solution is:

* 40 to 60mg/L for cypermetrhin
* 8 to 12mg/L for propiconazole
* 8 to 12mg/L for tebuconazole

Regressions were linear with a correlation coefficient >0.99 for each active ingredient. Linearity is acceptable.

**Accuracy**

Accuracy was performed with blank matrix fortified with known amounts of reference item of each active substance to approx. their nominal contents.

* Cypermethrin (fortification at approx. 0.17% w/w): mean=98.3%; RSD=0.30%; n=6
* Propiconazole (fortification at approx. 0.13% w/w): mean=96.9%; RSD=2.40%; n=6
* Tebuconazole (fortification at approx.. 0.13% w/w): mean=97.1%; RSD=2.81; n=6

**Precision**

Precision was performed on 6 replicate samples of test item.

* Cypermethrin: RSD=1.12%
* Propiconazole: RSD=2.23%
* Tebuconazole: RSD=5.00%

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| Analytical method for the determination of the active ingredients in the product 06LBCEOL20/2PT has been provided and validated according to guidance SANCO/3030/99/rev.4. |

**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 04LCBCEOL689/2 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 V33 POUTRES ET CHARPENTES (development code 04LBCEOL 689/2) is a water-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 treatment by superficial application (that could be completed by injection if needed), 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 V33 POUTRES ET CHARPENTES / m² of wood
* Curative treatment: superficial application at 300 mL of product V33 POUTRES ET CHARPENTES / m² of wood (+ injection 150 mL of product V33 POUTRES ET CHARPENTES / m² of wood if need be).

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

According to the uses claimed by the applicant, the product V33 POUTRES ET CHARPENTES is intended to be used for the preventive preservation of wood in service 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 gestroi*).

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

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

The product V33 POUTRES ET CHARPENTES 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 slow acting against house longhorn beetles, and its efficacy is deferred against common furniture beetles.

#### Efficacy data

The results of the studies conducted with the product 04LBCEOL 689/2 are presented in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2 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 100.00 g/m² and 101.84 g/m² (mean 101.17 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.  - Interval 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 were dead and had not tunnelled.  **The efficacy of the product is demonstrated at 101.17 g of product / m² of wood against *Hylotrupes bajulus* larvae** | XX |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2 is applied by brushing on hardwood test blocks (*Quercus spp.*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 99.5 g/m² and 100.6 g/m² (mean 99.98 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.  - Interval of examination: one examination, 20 weeks after beginning of exposure of the adults. | 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   **The efficacy of the product is demonstrated at 100 g of product / m² of wood against *Lyctus brunneus* larvae** | XX |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | Common furniture beetle: *Anobium punctatum (L.)* | EN 49-1 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2 is applied by brushing on hardwood test blocks (*Quercus petraea*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 198.2 ml/m² and 199.8 ml/m² (mean 199.3.0 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  - Interval of examination: one examination, 26weeks 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   **The efficacy of the product is demonstrated at 200 ml of product / m² of wood against *Anobium punctatum* larvae** | XX |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | Subterranean termite: *Reticulitermes santonensis* | EN 118 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2² 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 200 mL/m² and 202 mL/m² (mean 200.8 mL/m²).  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).  - Interval 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 % (69.3 %) and the control test blocks are ranked 4.  All the treated blocks are ranked 1, except one ranked 2 at the end of the study: efficacy criteria of the norm are fulfilled.  **The efficacy of the product 04LBCEOL 689/2** **is demonstrated** **at the application rate of 200 ml of product / m² of wood against *R.santonensis.*** | XX |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | Subterranean termite: *Heterotermes tenuis* | EN 118 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2² 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 200.3 mL/m² and 201.6 mL/m² (mean 201.0 mL/m²).  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 % (74.7 %) and the control test blocks are ranked 4.  All the treated blocks are ranked 0 or 1 at the end of the study: efficacy criteria of the norm are fulfilled.  **The efficacy of the product 04LBCEOL 689/2** **is demonstrated** **at the application rate of 200 ml of product / m² of wood against *H.tenuis*.** | XX |
| MG 02: preservatives | Wood preservative  Preventive treatment | 04LBCEOL 689/2 | Subterranean termite: *Coptotermes gestroi* | EN 118 + EN 73 (evaporation) | The ready to use product 04LBCEOL 689/2² 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 is not presented in the report. The target dose is 200 ml/m².  250 workers and 10 soldier termites were used for each test block.  5 replicates for the treated block and 6 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).  - Interval 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 % (59.74 %) and the control test blocks are ranked 4.  All the treated blocks are ranked 1, except one ranked 2 at the end of the study: efficacy criteria of the norm are fulfilled.  **The efficacy of the product 04LBCEOL 689/2** **is demonstrated** **at the application rate of 200 ml of product / m² of wood against *C.gestroi*.** | XX |
| MG 02: preservatives | Wood preservative  Curative treatment | 04LBCEOL 689/2 | Common furniture beetle: *Anobium punctatum (L.)* | EN 370 + EN 73 | The ready to use product 04LBCEOL 689/2is 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 249.93 mL/m² and 250.26 mL/m² (mean 250.1 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.  - Interval of examination: one time, 12 weeks after beginning of the hatching in the control blocks. | The study is validated at least 30 (33) larvae has emerged in the control  No emergence of adult is observed in the treated blocks.  **The differed curative efficacy of the product 04LBCEOL 689/2is demonstrated** **at the application rate of 250 ml product / m² of wood, 12 weeks after its application.** | XX |
| MG 02: preservatives | Wood preservative  Curative treatment | 04LBCEOL 689/2 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product 04LBCEOL 689/2 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.68 mL/m² and 300.35 mL/m² (mean 299.9 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.  - Interval 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 % (82.17 %).  **The slow action efficacy of the product 04LBCEOL 689/2 is demonstrated at the application rate of 300 ml of product / m² of wood, 24 weeks after its application.** | XX |

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| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities consider that the data submitted in the dossier demonstrated the efficacy of the product V33 POUTRES ET CHARPENTES (04LBCEOL 689/2) according to the uses and the application rates claimed:   * Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product 04LBCEOL 689/2 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 04LBCEOL 689/2 / m² of wood. * Regarding the preventive efficacy claim against termites, for superficial application, the product 04LBCEOL 689/2 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 04LBCEOL 689/2 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 04LBCEOL 689/2 is efficient according to respectively EN 1390 and EN 370 (+EN73) against *Hylotrupes bajulus* with a slow activity and against *Anobium punctatum* with a differed activity, at the application rate of 300 ml of product 04LBCEOL 689/2 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 *Anobiu 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. 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 04LBCEOL 689/2 / 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 V33 POUTRES ET CHARPENTES (04LBCEOL 689/2) 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 gestroi*), 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 gestroi.*), 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 04LBCEOL 689/2 / m² of wood
* Curative treatment: superficial application at 300 mL of product 04LBCEOL 689/2 / m² of wood (injection 150 mL of product 04LBCEOL 689/2 / m² of wood if need be).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

- 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 registration holder.

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

The product V33 POUTRES ET CHARPENTES 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 performed with V33 TRAITEMENT POUTRES ET CHARPENTES has been provided for skin corrosion and irritation, and no human data are available.

The potential of skin corrosion and irritation of the biocidal product is therefore assessed by calculation, according to the CLP calculation rules, and considering the content of substances classified as skin irritant or corrosive in the formulation.

Considering the content of substances classified as skin irritant (H315 category 2) and as skin corrosive (H314 cat 1 A and 1B), no classification is required for the product V33 TRAITEMENT POUTRES ET CHARPENTES.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not classified as a skin irritant/corrosive product. |
| Justification for the value/conclusion | The content of classified substances is lower than the cut of values stated in the CLP guidance, which triggers classification. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Eye irritation***

An eye irritation study has been performed with another biocidal product containing cypermethrin, propiconazole and tebuconazole (V33 Multiusages) and no human data are available.

These 3 active substances being different from the one present in V33 TRAITEMENT POUTRES ET CHARPENTES, the study is not considered extrapolable to assess the eye irritation potential of the product.

Therefore, the classification is performed by calculation method according to the CLP calculation rules and considering the content of substances classified as eye irritant.

Considering the content of substances classified as eye irritant in the biocidal product V33 TRAITEMENT POUTRES ET CHARPENTES, no classification is required.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not classified as an eye irritant product |
| Justification for the value/conclusion | Based on the calculation method taking into account the content of substances classified as eye irritant. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Respiratory tract irritation***

No *in vivo*/*in vitro* respiratory tract irritation test has been performed with V33 TRAITEMENT POUTRES ET CHARPENTES product and no human data are available.

The respiratory tract irritation potential of the biocidal product is therefore assessed by calculation, according to the CLP calcultaion rules and considering the content of substances classified as irritant for the respiratory tract.

The biocidal product contains substances classified for respiratory tract irritation (H335 category 3). However, according to the CLP Regulation (EC) criteria, no classification is required.

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The content of substances classified as respiratory tract irritant is below the cut-off value set in the Regulation (EC) No 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified as an irritant product for respiratory tract according to Regulation (EC) No 1272/2008 (CLP). |

***Skin sensitization***

A skin sensitization study has been performed on the biocidal product V33 TRAITEMENT POUTRES ET CHARPENTES.

According to this study, no classification is required for the product.

| **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 Guideline 442-B (LLNA: BrdU) | Mouse CBA/J Female  1 animal in preliminary  study  4 animals/group (3 groups)  4 animals in control  group (vehicle only) | V33 TRAITEMENT POUTRES ET CHARPENTES 9/2 in  acetone/olive oil  (4:1, v:v)  Preliminary test: 100%  Main study :  3 doses: 25% (v/v),  50% (v/v) in the  vehicle, and 100%. | Stimulation index:  1.10, 1.38, 1.05 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 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not classified as a skin sensitizer product. |
| Justification for the value/conclusion | The stimulation index is < 1.6 for all tested doses. |
| Classification of the product according to CLP | Not classified for skin sensitization according to Regulation (EC) No 1272/2008 (CLP).  According to the concentrations of permethrin, the additional labelling information “EUH208 Contains permethrin and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction” should be mentioned on the label. |

***Respiratory sensitization (ADS)***

No *in vivo*/*in vitro* respiratory sensitization test has been performed with V33 TRAITEMENT POUTRES ET CHARPENTES and no human data are available.

The respiratory sensitization potential of the biocidal product is therefore assessed by calculation, according to the CLP calculation rules and considering the content of substances classified as respiratory sensitizers.

The biocidal product doesn’t contain any substance classified for respiratory sensitization (H334). Therefore, no classification is required.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | There are no components of the product classified for respiratory sensitization. |
| Classification of the product according to CLP | The product does not require classification for respiratory sensitization according to Regulation (EC) No 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

No acute toxicity studies were conducted. Classification is based on the available data on each component (oral, inhalation and dermal route).

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | - |
| Justification for the selected value | According to the composition, the content of the components classified for acute oral toxicity does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | - |
| Justification for the selected value | According to the composition, the content of the components classified for acute toxicity by inhalation does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | - |
| Justification for the selected value | According to the composition, the content of the components classified for acute dermal toxicity does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

Based on the available data, the product V33 TRAITEMENT POUTRES ET CHARPENTES is not classified for human health according to CLP Regulation.

However, the following mention should be applied on the label:

* EUH 208: Contains Permethrin and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction.

***Information on dermal absorption***

| **Summary table of in vitro studies on dermal absorption** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **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 (2 cells for each donor), 8 skin  discs | 14C-permethrin in  reconstituted  V33 TRAITEMENT POUTRES ET CHARPENTES  1 dose: 100% (test item : 0.60% w/w)  8 hours of exposure | Skin excess: 94.43 ± 1.53%  First two layers of the stratum  corneum: 1.03 ± 0.49%  Strips 3 to 15: 1.23 ± 0.59%  Skin = Epidermis + partial  dermis: 1.17 ± 0.78%  Receptor fluid compartment:  0.19 ± 0.11%  Final absorption value: 2.59 ±  1.27 % | No deviation  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. | Bernal J.  (2015)  IUCLID  Section 8.6 |

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | 14C-permethrin in reconstituted V33 TRAITEMENT POUTRES ET CHARPENTES |
| Value(s)\* | Strips 3 to 15 + Skin + Receptor fluid:  2.59 ± 1.27% = 3.86% rounded to 4% according to the EFSA Guidance on Dermal Absorption[[16]](#footnote-16) (2012) |
| Justification for the selected value | The mean total recovery of the radioactivity was 98.05% validating the results obtained.  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. The absorbable fraction of the applied permethrin was 2.59 ± 1.27 % of the applied dose. The standard deviation being larger than 25% of the mean of absorption, it has been added to the mean value.  According to the EFSA guidance on dermal absorption (2012), the  rounded value used for the human risk assessment is 4.0%. |

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

V33 TRAITEMENT POUTRES ET CHARPENTES contains no substance of concern.

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

No toxicological data for the mixture are available.

#### Exposure assessment

V33 TRAITEMENT POUTRES ET CHARPENTES is a water-based ready-to-use product for wood preservative containing 0.645% 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 or spray application at an application dose of 200 mL/m2 for preventive treatment and 300 mL/m2 for curative treatment. An application dose of 150 mL/m2 is considered for injection, in combination with superficial treatment (brush or spray) in curative treatment.

A dermal and inhalation exposure to the product can occur during the mixing and loading, the application and the equipment’s cleaning.

The assessment of exposure during curative treatment presented below is considered a worst-case covering the preventive treatment.

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

For the primary exposure to the product, only 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.

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 exposure may be long-term and repeated (chronic phase).

| **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 |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| **Primary exposures** | | | |
| 1. Brush application | Inhalation and dermal exposures during the application of the product by brush. | **Primary inhalation and dermal exposures during application**  V33 TRAITEMENT POUTRES ET CHARPENTES is a water based ready to use product sold in steel box. Therefore no mixing/loading phase is necessary, the product being directly applied with a brush from can.  During the application, professional and non-professional users are exposed to the vapours of the product and by dermal contact.  Dermal and inhalation exposures during the application phase has been considered using ”*Non-professional application of paints by brushing and rolling*”scenario, from the Recommendation n°10 of the BPC Ad hoc Working Group on Human Exposure[[17]](#footnote-17) (water based product). The mixing and loading phase is not considered since the product is a RTU that can be applied directly with a brush. | Professional and non-professional users |
| 2. Cleaning of the equipment for brush application | Dermal exposure during cleaning of the brush | **Primary dermal exposure during cleaning**  During the cleaning of the brush, users are dermally exposed to the biocidal product. Inhalation exposure during this phase has been considered negligible.  For the assessment of this exposure, the scenario ”*Exposure model –washing out of a brush*” from the Opinion n°11 of HEEG[[18]](#footnote-18) has been used. | Professional and non-professional users |
| 3. Brush application + injection | Inhalation and dermal exposures during application of the product | **Primary inhalation and dermal exposures**  No specific model for injection is available.  In a conservative approach, the exposure values set in the “*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. | Professional and non-professional users |
| 4. Cleaning of the equipment for brush application+injection | Dermal exposure during cleaning of the equipment | **Primary dermal exposure**  In the framework of a brush application + injection, 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 two scenarii: 2 and 7. | Professional and non-professional users |
| 5. Spray application | Inhalation and dermal exposures during spray application of the product | **Primary inhalation and dermal exposures**  During the 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 spraying model 2” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. | Professional users |
| 6. Spray application | Inhalation and dermal exposures during spray application of the product | **Primary inhalation and dermal exposures**  During 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 phases has been considered using the “Consumer spraying and dusting Model 3” taken from the TNsG second version of 2007.  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). | Non-professional users |
| 7. Cleaning of the equipment after spray application | Dermal exposure during cleaning of spray equipment | **Primary dermal exposure**  Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[20]](#footnote-20) for professional and non-professional users. | Professional and non-professional users |
| 8. Spray application + injection | Inhalation and dermal exposures during spray application of the product and cleaning of the equipment | **Primary inhalation and dermal exposures**  Professional and non-professional users: For this scenario, no model is available for exposure during injection without PPE. So, for Tier 1 the exposure value 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.  Professional users only: For Tier 2, Subsoil treatment model 2 has been used since data on exposure during injection with PPE are available. | Professional and non-professional users |
| 9. Cleaning after spray application + injection | Dermal exposure during cleaning of spray equipment | **Primary dermal exposure**  Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[21]](#footnote-21) for professional and non-professional users.  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 exposures** | | | |
| 10. Adult amateur sanding/processing of treated wood composites | Inhalation and dermal acute exposures during sanding of treated wood | **Acute secondary dermal and inhalation exposures**  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. | Adult amateur (general public) |
| 11. Toddler chewing wood composite chips treated with application dose of 450 g/m² | Oral exposure during chewing of treated wood offcuts | **Acute secondary oral exposure**  Oral exposure to the product can occur for infant putting into his mouth treated wood chips.  In this scenario, it has been calculated the oral exposure 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 infant’s mouth.  As a worst-case, it has been considered that the wood was treated with a total application dose of 450g/m2, corresponding to a curative treatment by brushing or spraying followed by injection. | Infant (general public) |
| 12. Toddler chewing wood composite chips treated with application dose of 300 g/m² | Oral exposure during chewing of treated wood offcuts | **Acute secondary oral exposure**  Oral exposure to the product can occur for infant putting into his mouth treated wood chips.  In this scenario, it has been calculated the oral exposure 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 infant’s mouth.  A second worst-case corresponds to a curative treatment without injection, with an application dose of 300 g/m2. | Toddler (general public) |
| 13. Adult amateur sanding/processing of treated wood composites (chronic) | Inhalation and dermal chronic exposures during sanding of treated wood | **Chronic secondary dermal and inhalation exposures**  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. | Adult (general public) |
| 14. Inhalation of volatilisedresidues indoors (adult) | Passive inhalation exposure indoors (adult) | **Chronic secondary exposure by inhalation**  Inhalation exposure to the biocidal product volatilised residues can occur.  For the assessment of this exposure, the scenario ”*assessment of Inhalation Exposure of Volatilised Biocide*  *Active Substance*” from the Opinion n°13 of HEEG[[22]](#footnote-22) has been used. | Adult (general public) |
| 15. Inhalation of volatilised residues indoors (infant) | Passive inhalation exposure indoors  (infant) | **Chronic secondary exposure by inhalation**  Inhalation exposure to the biocidal product volatilised residues can occur.  For the assessment of this exposure, the scenario ”*assessment of Inhalation Exposure of Volatilised Biocide*  *Active Substance*” from the Opinion n°13 of HEEG has been used. | Infant (general public) |
| 16. Inhalation of volatilised residues indoors (toddler) | Passive inhalation exposure indoors  (toddler) | **Chronic secondary exposure by inhalation**  Inhalation exposure to the biocidal product volatilised residues can occur.  For the assessment of this exposure, the scenario ”*assessment of Inhalation Exposure of Volatilised Biocide*  *Active Substance*” from the Opinion n°13 of HEEG has been used. | Toddler (general public) |
| 17. Child playing on playground structure outdoors | Dermal exposure to treated wood during child recreation | **Chronic secondary exposure by dermal contact**  In the playground (outdoors), children can play on wood structures that can be treated with biocidal product. Dermal exposure occurs therefore.  For the assessment of this exposure, it has been considered according to the Recommendation n°14 of HEEG that 20% of the hand is in contact with the treated surface and a wood-hand transfer factor of 3%. | Child (general public) |
| 18. Toddler playing on weathered (playground) structure and mouthing (450 g/m²) | Oral and dermal exposure during playing and mouthing playground structure | **Chronic secondary oral and dermal exposures**  In the playground (outdoors), children can play on wood structures that can be treated with biocidal product and put its in contact with mouth. Therefore, oral and dermal exposures occur.  For the assessment of this scenario, it has been considered an application rate product of 450 g/m² and a contact surface of 0.02 m² according to the Recommendation n°14 of HEEG. | Toddler (general public) |

***Industrial exposure***

Not applicable.

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 model “*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, the product can be directly applied with a brush from the can. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for application | *Non-professional application of paints by brushing and rolling* |  | Recommendation N°. 10 of the BPC Ad hoc Working Group on Human Exposure |
| Weight fraction substance | 0.645 | % (w/w) |  |
| Exposure duration of body and hands | 240 | min |  |
| Body weight | 60 | kg |  |
| Density of the product | 1 | g/mL |  |
| Dermal exposure of hands (water-based paint) | 4.07 | mg/min | Recommandation N°10 of the BPC Ad hoc Working Group on Human Exposure (HEAd hoc) |
| Dermal exposure of the body (water-based paint) | 1.70 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE : gloves and clothing penetration | 100 | % |  |
| Inhalation exposure | | | |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation exposure for low-volatile | 1.63 | mg/m3 | Recommandation N°10 HEAd hoc |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Opinion 17 on default human factor values |
| Inhalation absorption | 100 | % |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [1] Brush application | 1 / No PPE | 8.76 x 10-4 | 5.95 x 10-3 | - | 6.83 x 10-3 |

*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.  The assessment has been performed with the exposure model from the Opinion N° 11 of HEEG. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for cleaning of the equipment | *Exposure model –washing out of a brush* | - | Opinion N° 11 of HEEG |
| Penetration through cleaning rag during squeezing the brush by hand | 90 | % | HEEG - MOTA (TMIII2010) |
| Density of the paint | 1 | g/mL |  |
| Body weight | 60 | kg |  |
| Content of active substance in the paint | 0.645 | % (w/w) |  |
| Active substance dermal absorption | 4 | % |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [2] Cleaning of the equipment for brush application | 1 / No PPE | Negligible | 5.64 x 10-4 | - | 5.64 x 10-4 |

*Scenario [3] Brush application + injection*

| **Description of Scenario [3] Brush application + injection** | | | | |
| --- | --- | --- | --- | --- |
| No specific model for injection is available to assess exposure without PPE.  Considering that the injection will not result in exposure higher than brush application, in a conservative approach, the exposure values set in the “*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). | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for application | *Non-professional application of paints by brushing and rolling* |  | Recommendation N°. 10 of the BPC Ad hoc Working Group on Human Exposure |
| Dermal exposure | | | |
| Density of the paint | 1 | g/mL |  |
| Content of active substance in the paint | 0.645 | % (w/w) |  |
| Active substance dermal absorption | 4 | % |  |
| Exposure duration of body and hands | 240 | min |  |
| Body weight | 60 | kg |  |
| Dermal exposure of hands (water-based paint) | 4.07 **x 2** = 8.14 | mg/min | Recommendation N°10 HEAd hoc |
| Dermal exposure of the body (water-based paint) | 1.70 **x 2** = 3.40 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE : gloves and clothing penetration | 100 | % |  |
|  | Inhalation exposure | | | |
| Tier 1 | Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Opinion 17 on default human factor values |
| Inhalation absorption | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [3]  Brush application + injection | Tier 1 / No PPE | 1.75 x 10-3 | 1.19 x 10-2 | - | 1.37 x 10-2 |

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

| **Description of Scenario [4] Cleaning of the equipment for brush application + injection** | | | | | |
| --- | --- | --- | --- | --- | --- |
| 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 two others: scenario 2 + scenario 7 | | | | | |
|  | Parameters1 | Value | | Unit | Reference |
|  | Dermal exposure | | | | |
| Tier 1 | Exposure model for cleaning of the equipment (brush) | *Exposure model –washing out of a brush*  - | | | Opinion N° 11 of HEEG |
| Penetration through cleaning rag during squeezing the brush by hand | 90 | | % | HEEG - MOTA (TMIII2010) |
| Density of the paint | 1 | | g/mL |  |
| Body weight | 60 | | kg |  |
| Content of active substance in the paint | 0.645 | | % (w/w) |  |
| Active substance dermal absorption | 4 | | % |  |
| Exposure model for cleaning of the equipment (spray) | BEAT model, scenario *“Cleaning of the spray equipment”* | | |  |
| Exposure duration | 10 | min | |  |
| Potential dermal exposure (body) | 19.28 | mg/min | |  |
| Potential dermal exposure (hands) | 35.87 | mg/min | |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [4]  Cleaning of the equipment for brush application+injection | Tier 1 / No PPE | Negligible | 5.66 x 10-4 + 2.37 x 10-3 =  2.94 x 10-3 | - | 2.94 x 10-3 |

*Scenario [5] Spray application (professionals)*

| **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 spraying model 2” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | Spraying model 2 | | Recommendation N° 6 of HEAd hoc WG |
| Exposure duration | 90 | min |
| Potential dermal exposure (body) | 222 | mg/min |
| Potential dermal exposure (hands) | 273 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
| Tier 2 | PPE, gloves and clothing penetration | Coverall: 20  Gloves: 10 | % |  |
|  | Exposure by inhalation | | | |
| Tier 1 | Exposure model | Spraying model 2 | | Recommendation N° 6 of HEAd hoc WG |
| Indicative inhalation exposure (non-volatile compounds) | 76 | mg/m3 |  |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Opinion 17 on default human factor values |
| Inhalation absorption | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [5] Spray application | Tier 1 / No PPE | 1.53 x 10-2 | 1.92 x 10-1 | - | 2.07 x 10-1 |
| Tier 2 / Gloves and coverall (20%) | 2.02 x 10-2 | 3.55 x 10-2 |

*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[[23]](#footnote-23).  For this scenario, the exposure value of the model taken for the cleaning of the spray has been multiplied by two in order to simulate an application by spray followed by an application by injection. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | BEAT model, scenario *“Cleaning of the spray equipment”* | |  |
| Exposure duration | 10 | min |  |
| Potential dermal exposure (body) | 19.28 | mg/min | Recommendation N°4 of HEAd hoc WG |
| Potential dermal exposure (hands) | 35.87 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
| Tier 2 | PPE, gloves and clothing penetration | Coverall: 20  Gloves: 10 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [7] Cleaning of the equipment after spray application | Tier 1 / No PPE | Negligible | 2.37 x 10-3 | - | 2.37 x 10-3 |

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

| **Description of Scenario [8] Spray application + injection** | | | | |
| --- | --- | --- | --- | --- |
| No model is available for exposure during injection without PPE. So for Tier 1, considering that the injection will not result in exposure higher 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.  In tier 2, Subsoil treatment model 2 is a mix of spray and injection events. In an injection process body exposure is not expected, so only hand exposure is considered in recommendation for injection. The model provides only hand exposure inside gloves so it will be considered as a tier 2. | | | | |
|  | Parameters1 | Value | Unit | Reference |
| Tier 1 | Dermal exposure | | | |
| Exposure model | Spraying model 2 | Recommendation N° 6 of HEAd hoc WG | Recommendation N°4 of HEAd hoc WG |
| Exposure duration | 90 | min |
| Potential dermal exposure (body) | 222 **x 2** =444 | mg/min |  |
| Potential dermal exposure (hands) | 273 **x 2** = 546 | mg/min |  |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
| Exposure by inhalation | | | |
| Exposure model | Spraying model 2 | Recommendation N° 6 of HEAd hoc WG |  |
| Indicative inhalation exposure (non-volatile compounds) | 76 **x 2** = 152 | mg/m3 |  |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Opinion 17 on default human factor values |
| Inhalation absorption | 100 | % |  |
| Tier 2 | PPE, gloves and clothing penetration | Coverall: 10  Gloves: 10 | % |  |
| Spray application, potential dermal exposure (hands inside gloves ) | 7.8 | mg/min |  |
| Injection application, potential dermal exposure (hands inside gloves) | 8 | mg/min |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [8] Spray application + injection | Tier 1 / No PPE | 3.06 x 10-2 | 3.83 x 10-1 | - | 4.14 x 10-1 |
| Tier 2 / Gloves and coated coverall (10%) | 1.54 x 10-2 | 1.47 x 10-2 | 3.01 x 10-2 |

*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[[24]](#footnote-24).  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. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | BEAT model, scenario *“Cleaning of the spray equipment”* | |  |
| Exposure duration | 10 | min |  |
| Potential dermal exposure (body) | 19.28 **x 2** = 38.56 | mg/min | Recommendation N°4 of HEAd hoc WG |
| Potential dermal exposure (hands) | 35.87 **x 2** = 71.74 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
| Tier 2 | PPE, gloves and clothing penetration | Coverall: 20  Gloves: 10 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [9] Cleaning of the equipment after spray application + injection | Tier 1 / No PPE | Negligible | 4.74 x 10-3 | - | 4.74 x 10-3 |
| Tier 2 / Gloves and coverall (20%) | 6.40 x 10-4 | 6.40 x 10-4 |

**Further information and considerations on scenario [1, 2, 3, 4, 5, 7, 8 and 9]**

*Combined scenarios*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Combined primary exposures adult | | | | |
| Scenarios [1+2]  Tier 1 | 8.76 x 10-4 | 6.52 x 10-3 | - | 7.40 x 10-3 |
| Scenarios [3+4]  Tier 1 | 1.75-3 | 1.48 x 10-2 | - | 1.66 x 10-2 |
| Scenarios [5+7]  5 : Tier 1  7 : Tier 1 | 1.53 x 10-2 | 1.94 x 10-1 | - | 2.09x 10-1 |
| Scenarios [5+7]  5: Tier 2  7 : Tier 1 | 2.26 x 10-2 | - | 3.79 x 10-2 |
| Scenarios [8+9]  8 & 9 :Tier 1 | 3.06 x 10-2 | 3.88 x 10-1 | - | 4.19 x 10-1 |
| Scenarios [8+9]  8:Tier 2  9: Tier 1 | 1.54 x 10-2 | 1.94 x 10-2 | - | 3.49 x 10-2 |

***Non-professional exposure***

*Scenario [1] Brush application*

| **Description of Scenario [1] Brush application** | | | | |
| --- | --- | --- | --- | --- |
| Non-professional exposure by inhalation and dermal contact during the application phase of the product by brushing has been assessed using “*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, the product can be directly applied with a brush. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for application | *Non-professional application of paints by brushing and rolling* |  | Recommendation N°. 10 of the BPC Ad hoc Working Group on Human Exposure |
| Weight fraction substance | 0.645 | % (w/w) |  |
| Exposure duration of body and hands | 240 | min |  |
| Body weight | 60 | kg |  |
| Density of the product | 1 | g/mL |  |
| Dermal exposure of hands (water-based paint) | 4.07 | mg/min | Recommendation N°10 HEEG |
| Dermal exposure of the body (water-based paint) | 1.70 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE : gloves and clothing penetration | 100 | % |  |
| Inhalation exposure | | | |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation exposure for low-volatile | 1.63 | mg/m3 | Recommendation N°10 HEEG |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Opinion 17 on default human factor values |
| Inhalation absorption | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [1] Brush application | Tier 1 / No PPE | 8.76 x 10-4 | 5.95 x 10-3 | - | 6.83 x 10-3 |

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

| **Description of Scenario [2] Cleaning of the equipment for brush application** | | | | |
| --- | --- | --- | --- | --- |
| Non-professional users are dermally exposed during the cleaning of the brush. Inhalation exposure is considered negligible during this phase.  The assessment has been performed with the exposure model from the Opinion N° 11 of HEEG. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for cleaning of the equipment | *Exposure model –washing out of a brush* | - | Opinion N° 11 of HEEG |
| Penetration through cleaning rag during squeezing the brush by hand | 90 | % | HEEG - MOTA (TMIII2010) |
| Density of the paint | 1 | g/mL |  |
| Body weight | 60 | kg |  |
| Content of active substance in the paint | 0.645 | % (w/w) |  |
| Active substance dermal absorption | 4 | % |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [2] Cleaning of the equipment for brush application | Tier 1 / No PPE | Negligible | 5.64 x 10-4 | - | 5.64 x 10-4 |

*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 result in exposure higher than brush application, in a conservative approach, the exposure values set in the “*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). | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model for application | *Non-professional application of paints by brushing and rolling* |  | Recommendation N°. 10 of the BPC Ad hoc Working Group on Human Exposure |
| Dermal exposure | | | |
| Density of the paint | 1 | g/mL |  |
| Content of active substance in the paint | 0.645 | % (w/w) |  |
| Active substance dermal absorption | 4 | % |  |
| Exposure duration of body and hands | 240 | min |  |
| Body weight | 60 | kg |  |
| Dermal exposure of hands (water-based paint) | 4.07 **x 2** = 8.14 | mg/min | Recommendation N°10 HEEG |
|  | Dermal exposure of the body (water-based paint) | 1.70 **x 2** = 3.40 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE : gloves and clothing penetration | 100 | % |  |
| Inhalation exposure | | | |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Recommendation n° 14 |
| Inhalation absorption | 100 | % |  |
|

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [3] Brush application + injection | Tier 1 / No PPE | 1.75 x 10-3 | 1.19 x 10-2 | - | 1.37 x 10-2 |

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

| **Description of Scenario [4] Cleaning of the equipment for brush application + injection** | | | | | |
| --- | --- | --- | --- | --- | --- |
| 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 two others: scenario 2 + scenario 7 | | | | | |
|  | Parameters1 | Value | | Unit | Reference |
|  | Dermal exposure | | | | |
| Tier 1 | Exposure model for cleaning of the equipment (brush) | *Exposure model –washing out of a brush*  - | | | Opinion N° 11 of HEEG |
| Penetration through cleaning rag during squeezing the brush by hand | 90 | | % | HEEG - MOTA (TMIII2010) |
| Density of the paint | 1 | | g/mL |  |
| Body weight | 60 | | kg |  |
| Content of active substance in the paint | 0.645 | | % (w/w) |  |
| Active substance dermal absorption | 4 | | % |  |
| Exposure model for cleaning of the equipment (spray) | BEAT model, scenario *“Cleaning of the spray equipment”* | | |  |
| Exposure duration | 10 | min | |  |
| Potential dermal exposure (body) | 19.28 | mg/min | |  |
| Potential dermal exposure (hands) | 35.87 | mg/min | |  |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [4] Cleaning of the equipment for brush application + injection | Tier 1 / No PPE | Negligible | 5.64 x 10-4  + 2.37 x 10-3 =  2.94 x 10-3 | - | 2.94 x 10-3 |

*Scenario [6] Spray application (Non-professionals)*

| **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 second version of 2007. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | *Consumer spraying and dusting Model 3* | | Exposure method BPR + TNsG (part 2 p197) second version of 2007 |
| Exposure duration | 40 | min |
| Potential dermal exposure (body) | 84 | mg/min |
| Potential dermal exposure (hands) | 144 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
|  | Exposure by inhalation | | | |
| Tier 1 | Exposure model | *Consumer spraying and dusting Model 3* | | Exposure method BPR + TNsG (part 2 p197) second version of 2007 |
| Indicative inhalation exposure (non-volatile compounds) | 6.5 | mg/m3 |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Recommendation n° 14 |
| Inhalation absorption | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [6] Spray application | Tier 1 / No PPE | 5.82 x 10-4 | 3.92 x 10-2 | - | 3.98 x 10-2 |

*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[[25]](#footnote-25). | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | BEAT model, scenario *“Cleaning of the spray equipment”* | |  |
| Exposure duration | 10 | min |  |
| Potential dermal exposure (body) | 19.28 | mg/min | Recommendation N°4 of HEAd hoc WG |
| Potential dermal exposure (hands) | 35.87 | mg/min |
| Active substance dermal absorption | 4 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [7] Cleaning of the equipment after spray application | Tier 1 / No PPE | Negligible | 2.37 x 10-3 | - | 2.37 x 10-3 |

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

| **Description of Scenario [8] Spray application + injection** | | | | |
| --- | --- | --- | --- | --- |
| Considering that the injection will not result in exposure higher than brush application, for this scenario, the exposure values of the exposure model taken for the spray application have been multiplied by two in order to simulate an application by spray followed by an application by injection. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | *Consumer spraying and dusting Model 3* | | Exposure method BPR + TNsG (part 2 p197) second version of 2007 |
| Exposure duration | 40 | min |
| Potential dermal exposure (body) | 84 **x 2** = 168 | mg/min |
| Potential dermal exposure (hands) | 144 **x 2** = 288 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |
|  | Exposure by inhalation | | | |
| Tier 1 | Exposure model | *Consumer spraying and dusting Model 3* | | Exposure method BPR + TNsG (part 2 p197) second version of 2007 |
| Indicative inhalation exposure (non-volatile compounds) | 6.5 **x 2** = 13 | mg/m3 |
| Vapour pressure of the active substance | 2.16E-06 | Pa |  |
| Inhalation rate | 1.25 equivalent to 2.08E-02 | m3/hour  m3/min | HEEG Recommendation n° 14 |
| Inhalation absorption | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [8] Spray application + injection | Tier 1 / No PPE | 1.16 x 10-3 | 7.84 x 10-2 | - | 7.96 x 10-2 |

*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[[26]](#footnote-26).  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. | | | | |
|  | Parameters1 | Value | Unit | Reference |
|  | Dermal exposure | | | |
| Tier 1 | Exposure model | BEAT model, scenario *“Cleaning of the spray equipment”* | |  |
| Exposure duration | 10 | min |  |
| Potential dermal exposure (body) | 19.28 **x 2** = 38.56 | mg/min | Recommendation N°4 of HEAd hoc WG |
| Potential dermal exposure (hands) | 35.87 **x 2** = 71.74 | mg/min |
| Active substance dermal absorption | 4 | % |  |
| No PPE, clothing penetration | 100 | % |  |

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

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [9] Cleaning of the equipment after spray application + injection | Tier 1 / No PPE | Negligible | 4.74 x 10-3 | - | 4.74 x 10-3 |

1 Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

**Further information and considerations on scenario [1,2,3,4,6,7,8,9]**

*Combined scenarios*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [n1+2]1 | 8.76 x 10-4 | 6.52x 10-3 | - | 7.40 x 10-3 |
| Scenarios [3+4] | 1.75 x 10-3 | 1.48 x 10-2 | - | 1.66 x 10-2 |
| Scenarios [6+7] | 5.82 x 10-4 | 4.16 x 10-2 | - | 4.22 x 10-2 |
| Scenarios [8+9] | 1.16 x 10-3 | 8.32 x 10-2 |  | 8.43 x 10-2 |

1 Please include the Tier where relevant

***Exposure of the general public***

For secondary exposure, as described in TNsG for Human Exposure (2002 and 2007), it was considered occurring soon after application with a short exposure period (acute phase) or with a long-term and repeated exposure (chronic phase). It concerns:

* for acute phase, scenarios of sanding treated wood (adult) and chewing treated wood offcuts (infant),
* for chronic phase the scenarios of professional sanding, cleaning work clothes at home (adult), inhalation of volatilised residues indoors (adult and infant), of child playing on playground structure outdoors and infant playing on weathered (playground) structure and mouthing.

*Scenario [10] Acute secondary dermal and inhalation exposures*

| **Description of Scenario [10]** **Acute secondary dermal and inhalation exposures** | | | | |
| --- | --- | --- | --- | --- |
| For the assessment of dermal and inhalation exposures during sanding/processing of treated wood composites by an adult, it has been considered an application rate product of 450 g/m² (worst-case).  The area of wood to be sanded was calculated considering a piece of wood with a length of 250 cm and a height of 4 cm. It has been considered that the exposure comes from the outer layer of the piece of wood (thickness of 1 cm). | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Application rate | 45 | mg/cm² |  |
| Wood density | 0.4 | g/cm3 | Default |
| Dust concentration in air | 5 | mg/m3 | Default |
|  | Exposure duration | 1 | hour | Acute scenario |
|  | Inhalation rate | 1.25 | m3/h | HEEG Recommendation n° 14 |
|  | Protection factor (No PPE) | 1 | - |  |
|  | Retention active substance | 100 | % |  |
|  | Percentage dislodgeable | 3 | % | TNsG |
|  | Hand surface | 420 | cm² | HEEG Recommendation n° 14 |
|  | Dermal absorption | 4 | % |  |

**Calculations for Scenario [10]** **Acute secondary dermal and inhalation exposures**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [10] Acute secondary dermal and inhalation exposures | Tier 1 / No PPE | 1.0 x 10-4 | 2.4 x 10-4 | - | 3.5 x 10-4 |

*Scenario [11] Toddler chewing wood composite chips treated with application dose of 450 g/m²*

| **Description of Scenario [11] Toddler chewing wood composite chips treated with application dose of 450 g/m** | | | | |
| --- | --- | --- | --- | --- |
| 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, it has been considered that the wood was treated with a total application dose of 450g/m2, corresponding to a curative treatment by brushing or spraying followed by injection. | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Application rate product | 450000 | mg/m² |  |
| Content of active substance | 0.645 | % |  |
| Release of bound active substance by chewing | 10 | % | TNsG Human Exposure 2002 |
| Size of wood composite chips | (4x4)x2 + (4x1)x4 = 48 | cm² |  |
|  | Toddler body weight | 10 | kg | HEAD Hoc Recommendation N°14 |
|  | Oral absorption | 100 | % |  |

1 Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [11] Toddler chewing wood composite chips treated with application dose of 450 g/m**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [11] Toddler chewing wood composite chips treated with application dose of 450 g/m | Tier 1 / No PPE | - | Negligible | 1.39 x 10-1 | 1.39 x 10-1 |

*Scenario [12] Toddler chewing wood composite chips treated with application dose of 300 g/m²*

| **Description of Scenario [12]** **Toddler chewing wood composite chips treated with application dose of 300 g/m²** | | | | |
| --- | --- | --- | --- | --- |
| As above, 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.  A second worst-case corresponds to a curative treatment without injection, with an application dose of 300 g/m2. | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Application rate product | 300000 | mg/m² |  |
| Content of active substance | 0.645 | % |  |
| Release of bound active substance by chewing | 10 | % | TNsG Human Exposure 2002 |
| Size of wood composite chips | (4x4)x2 + (4x1)x4 = 48 | cm² |  |
| Toddler body weight | 10 | kg | HEAD Hoc Recommendation N°14 |
| Oral absorption | 100 | % |  |

**Calculations for Scenario [12]** **Toddler chewing wood composite chips treated with application dose of 300 g/m²**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [12] Toddler chewing wood composite chips treated with application dose of 300 g/m² | Tier 1 / No PPE | - | Negligible | 9.29 x 10-2 | 9.29 x 10-2 |

*Scenario [13] Sanding treated wood (chronic exposure)*

| **Description of Scenario [13]** **Sanding treated wood (chronic exposure)** | | | | |
| --- | --- | --- | --- | --- |
| After treatment of the wood, adult can be chronically exposed by inhalation and dermal contact to the product when sanding or processing of treated wood composites.  In this scenario it has been taken into account a worst-case application rate product of 45 mg/cm² (corresponding to 450 g/m2).  According to TNsG 2002, it is considered a wood composite of 250 cm length, 4 cm large and 4 cm high with an area of wood to be sanded of 4032 cm². Considering an outer layer thickness of 1 cm, the volume of outer layer is about 3008 cm3. | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Exposure duration | 6 | hours |  |
| Application rate product | 450000 | mg/m² |  |
| Surface area of wood to be sanded | 4.03 x 103 | cm² |  |
| Outer layer thickness | 1 | cm |  |
| Volume of outer layer | 3008 | cm3 |  |
| Wood density | 0.4 | g/cm3 | TNsG 2002 |
| Dust concentration in air | 5 | mg/m3 |  |
| Inhalation rate | 1.25 | m3/h | HEAD Hoc Recommendation n° 14 |
| Protection factor (No PPE) | 1 |  |  |
| Inhalation absorption | 100 | % |  |
| Percentage dislodgeable | 3 | % | TNsG 2002 |
| Hand surface | 420 | cm² | HEAD Hoc Recommendation n° 14 |
| Dermal absorption | 4 | % |  |

**Calculations for Scenario [13]** **Sanding treated wood (chronic exposure)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [13] Sanding treated wood (chronic exposure) | Tier 1 / No PPE | 1.0 x 10-4 | 2.4 x 10-4 | - | 3.5 x 10-4 |

*Scenario [14] Inhalation of volatilised residues indoors (adult)*

| **Description of Scenario [14]** **Inhalation of volatilised residues indoors (adult)** | | | | |
| --- | --- | --- | --- | --- |
| Chronic inhalation exposure to volatilised residues indoors has been assessed for adult considering the scenario ”assessment of Inhalation Exposure of Volatilised Biocide Active Substance” from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula :  SVC = Mw x vp : R x T (mg/m3)  The exposure is calculated with the following formula :  Exposure = SVC x inhalation rate / body weight (mg/kg bw/d) | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Vapour pressure (vp) | 2.16 x 10-6 | Pa |  |
| Molecular weight (Mw) | 391.29 | g/mol |  |
| Gas constant (R) | 8.31451 | J.mol-1.K-1 |  |
| Temperature (T) | 293 | K |  |
| Adult body weight | 60 | kg | HEAD Hoc Recommendation n° 14 |
| Adult inhalation rate | 16 | m3/24h | HEAD Hoc Recommendation n° 14 |

**Calculations for Scenario [14]** **Inhalation of volatilised residues indoors (adult)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [14] Inhalation of volatilised residues indoors (adult) | Tier 1 / No PPE | 9.26 x 10-5 | - | - | 9.26 x 10-5 |

*Scenario [15] Inhalation of volatilised residues indoors (infant)*

| **Description of Scenario [15]** **Inhalation of volatilised residues indoors (infant)** | | | | |
| --- | --- | --- | --- | --- |
| Chronic inhalation exposure to volatilised residues indoors has been assessed for adult considering the scenario ”assessment of Inhalation Exposure of Volatilised Biocide Active Substance” from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula :  SVC = Mw x vp : R x T (mg/m3)  The exposure is calculated with the following formula :  Exposure = SVC x inhalation rate / body weight (mg/kg bw/d) | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Vapour pressure (vp) | 2.16 x 10-6 | Pa |  |
| Molecular weight (Mw) | 391.29 | g/mol |  |
| Gas constant (R) | 8.31451 | J.mol-1.K-1 |  |
| Temperature (T) | 293 | K |  |
| Infant body weight | 8 | kg | HEAD Hoc Recommendation n° 14 |
| Infant inhalation rate | 5.4 | m3/24h | HEAD Hoc Recommendation n° 14 |

**Calculations for Scenario [15]** **Inhalation of volatilised residues indoors (infant)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [15] Inhalation of volatilised residues indoors (infant) | Tier 1 / No PPE | 2.34 x 10-4 | - | - | 2.34 x 10-4 |

*Scenario [16] Inhalation of volatilised residues indoors (toddler)*

| **Description of Scenario [16] Inhalation of volatilised residues indoors (toddler)** | | | | |
| --- | --- | --- | --- | --- |
| Chronic inhalation exposure to volatilised residues indoors has been assessed for adult considering the scenario ”assessment of Inhalation Exposure of Volatilised Biocide Active Substance” from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula :  SVC = Mw x vp : R x T (mg/m3)  The exposure is calculated with the following formula :  Exposure = SVC x inhalation rate / body weight (mg/kg bw/d) | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Vapour pressure (vp) | 2.16 x 10-6 | Pa |  |
| Molecular weight (Mw) | 391.29 | g/mol |  |
| Gas constant (R) | 8.31451 | J.mol-1.K-1 |  |
| Temperature (T) | 293 | K |  |
| Toddler body weight | 10 | kg | HEAD Hoc Recommendation n° 14 |
| Toddler inhalation rate | 8 | m3/24h | HEAD Hoc Recommendation n° 14 |

**Calculations for Scenario [16] Inhalation of volatilised residues indoors (toddler)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [16] Inhalation of volatilised residues indoors (toddler) | Tier 1 / No PPE | 2.78 x 10-4 | - | - | 2.78 x 10-4 |

*Scenario [17] Child playing on playground structure outdoors*

| **Description of Scenario [17]** **Child 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 HEAD Hoc Recommendation n°14 that 20% of hand is in contact with the treated surface and a wood-hand transfer factor of 3%.  For the assessment of this scenario, it has been considered an application rate product of 450 g/m² (worst-case) | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Application rate product | 450000 | mg/m² |  |
| Hand surface area contact | 200 | cm² | TNsG 2002 |
| Contaminated area | 20 | % | TNsG 2002 |
| Dislodgeable fraction | 3 | % |  |
| Dermal absorption | 4 | % |  |
| Child body weight | 15 | kg | HEAD Hoc Recommendation N°14 |

**Calculations for Scenario [17]** **Child playing on playground structure outdoors**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [17] Child playing on playground structure outdoors | Tier 1 / No PPE | - | 9.29 x 10-4 | - | 9.29 x 10-4 |

*Scenario [18] Toddler playing on weathered (playground) structure and mouthing (450 g/m²)*

| **Description of Scenario [18]** **Toddler playing on weathered (playground) structure and mouthing (450 g/m²)** | | | | |
| --- | --- | --- | --- | --- |
| Chronic exposure of infant via dermal route and ingestion has been performed in this scenario.  For the assessment, it has been considered an application rate product of 450 g/m² and a contact surface of 0.02 m² and a dislodgeable fraction of 3% according to the HEAD Hoc Recommendation n°14.  As a worst-case, it has been considered that the wood was treated with a total application dose of 450g/m2, corresponding to a curative treatment by brushing or spraying and injection. | | | | |
|  | Parameters1 | Value | Units | Reference |
| Tier 1 | Application rate product | 450000 | mg/m² |  |
| Hand surface area contact | 200 | cm² | TNsG 2002 |
| Contaminated area | 20 | % | TNsG 2002 |
| Dislodgeable fraction | 3 | % |  |
| Dermal absorption | 4 | % |  |
| Amount of ingested wood | 0.005 | m² |  |
| Toddler body weight | 10 | kg | HEAD Hoc recommendation 14 |

**Calculations for Scenario [18]** **Toddler playing on weathered (playground) structure and mouthing (450 g/m²)**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenario [18] Toddler playing on weathered (playground) structure and mouthing (450 g/m²) | Tier 1 / No PPE | - | 1.39 x 10-3 | 4.35 x 10-2 | 4.49 x 10-2 |

**Further information and considerations on scenario [16 and 18]**

*Combined scenarios*

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  (mg/kw/d) | **Estimated dermal uptake**  (mg/kw/d) | **Estimated oral uptake**  (mg/kw/d) | **Estimated total uptake**  (mg/kw/d) |
| Scenarios [18 + 16]  (Toddler playing on weathered structure and mouthing + inhalation of volatilised residues) | 2.78 x 10-4 | 1.39 x 10-3 | 4.35 x 10-2 | 4.52 x 10-2 |

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  (mg/kw/d) |
| **Primary exposures** | | | |
| 1. Brush application | Professional and non-professional users | Tier 1 / No PPE | 6.83 x 10-3 |
| 2. Cleaning of the equipment for brush application | Professional and non-professional users | Tier 1 / No PPE | 5.64 x 10-4 |
| 3. Brush application + injection | Professional and non-professional users | Tier 1 / No PPE | 1.37 x 10-2 |
| 4. Cleaning of the equipment for brush application+injection | Professional and non-professional users | Tier 1 / No PPE | 2.94 x 10-3 |
| 5. Spray application | Professional users | Tier 1 / No PPE | 2.07 x 10-1 |
| Tier 2 / Gloves and coverall (20%) | 3.55 x 10-2 |
| 6. Spray application | Non-professional users | Tier 1 / No PPE | 3.98 x 10-2 |
| 7. Cleaning of the equipment after spray application | Professional and non-professional users | Tier 1 / No PPE | 2.37 x 10-3 |
| 8. Spray application + injection | Professional users | Tier 1 / No PPE | 4.14 x 10-1 |
| Tier 2 / Gloves and coated coverall (10%) | 3.01 x 10-2 |
| 8. Spray application + injection | Non-professional users | Tier 1 / No PPE | 7.96 x 10-2 |
| 9. Cleaning after spray application + injection | Professional and non-professional users | Tier 1 / No PPE | 4.74 x 10-3 |
| Professional users | Tier 2 / Gloves and coverall (20%) | 6.40 x 10-4 |
| **Secondary exposures** | | | |
| 10. Adult amateur sanding/processing of treated wood composites (acute) | Adult amateur (general public) | Tier 1 / No PPE | 3.5 x 10-4 |
| 11. Toddler chewing wood composite chips treated with application dose of 450 g/m² | Toddler (general public) | Tier 1 / No PPE | 1.39 x 10-1 |
| 12. Toddler chewing wood composite chips treated with application dose of 300 g/m² | Toddler (general public) | Tier 1 / No PPE | 9.29 x 10-2 |
| 13. Adult amateur sanding/processing of treated wood composites (chronic) | Adult amateur (general public) | Tier 1 / No PPE | 3.5 x 10-4 |
| 14. Inhalation of volatilised residues indoors (adult) | Adult amateur (general public) | Tier 1 / No PPE | 9.26 x 10-5 |
| 15. Inhalation of volatilised residues indoors (infant) | Infant (general public) | Tier 1 / No PPE | 2.34 x 10-4 |
| 16. Inhalation of volatilised residues indoors (toddler) | Toddler (general public) | Tier 1 / No PPE | 2.78 x 10-4 |
| 17. Child playing on playground structure outdoors | Child (general public) | Tier 1 / No PPE | 9.29 x 10-4 |
| 18. Toddler playing on weathered (playground) structure and mouthing (450 g/m²) | Toddler (general public) | Tier 1 / No PPE | 4.49 x 10-2 |

#### Risk characterisation for human health

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

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

1 Please explain background and reason for assessment factor.

**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 professional users***

**Systemic effects**

| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Brush application | Tier 1 | 5 | 0.05 | 6.83 x 10-3 | 13.66 | yes |
| 2. Cleaning of the equipment for brush application | Tier 1 | 5 | 0.05 | 5.64 x 10-4 | 1.13 | yes |
| 3. Brush application + injection | Tier 1 | 5 | 0.05 | 1.37 x 10-2 | 27.32 | yes |
| 4. Cleaning of the equipment for brush application + injection | Tier 1 | 5 | 0.05 | 2.94 x 10-3 | 5.87 | yes |
| 5. Spray application | Tier 1 | 5 | 0.05 | 2.07 x 10-1 | **413.77** | **no** |
| Tier 2 | 3.55 x 10-2 | 71.04 | yes |
| 7. Cleaning of the equipment after spray application | Tier 1 | 5 | 0.05 | 2.37 x 10-3 | 4.74 | yes |
| 8. Spray application + injection | Tier 1 | 5 | 0.05 | 4.14 x 10-1 | **827.54** | **no** |
| Tier 2 | 3.01 x 10-2 | 60.28- | yes |
| 9. Cleaning after spray application + injection | Tier 1 | 5 | 0.05 | 4.74 x 10-3 | 9.49 | 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 | 5 | 0.05 | 7.40 x 10-3 | 14.79 | yes |
| Scenarios [3+4] | Tier 1 | 5 | 0.05 | 1.66 x 10-2 | 33.19 | yes |
| Scenarios [5+7] | 5 : Tier 1  7: Tier 1 | 5 | 0.05 | 2.09 x 10-1 | **418.51** | **no** |
| 5: Tier 2  7 : Tier 1 | 3.79 x 10-2 | 75.78 | yes |
| Scenarios [8+9] | 8 : Tier 1  9: Tier 1 | 5 | 0.05 | 4.19 x 10-1 | **837.02** | **no** |
| 8 :Tier 2  9: Tier 1 | 3.49 x 10-2 | 69.77 | yes |

**Conclusion**

For application by brushing with and without injection, the risk is considered acceptable without PPE.

For spray application and spray application combined with injection, the risk is acceptable considering the wear of gloves and coated coverall.

***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)** |
| --- | --- | --- | --- | --- | --- | --- |
| 1. Brush application | Tier 1 | 50 | 0.5 | 6.83 x 10-3 | 1.37 | yes |
| 2. Cleaning of the equipment for brush application | Tier 1 | 50 | 0.5 | 5.64 x 10-4 | 0.11 | yes |
| 3. Brush application + injection | Tier 1 | 50 | 0.5 | 1.37 x 10-2 | 2.73 | yes |
| 4. Cleaning of the equipment for brush application + injection | Tier 1 | 50 | 0.5 | 2.94 x 10-3 | 0.59 | yes |
| 6. Spray application | Tier 1 | 50 | 0.5 | 3.98 x 10-2 | 7.96 | yes |
| 7. Cleaning of the equipment after spray application | Tier 1 | 50 | 0.5 | 2.37 x 10-3 | 0.47 | yes |
| 8. Spray application + injection | Tier 1 | 50 | 0.5 | 7.96 x 10-2 | 15.92 | yes |
| 9. Cleaning after spray application + injection | Tier 1 | 50 | 0.5 | 4.74 x 10-3 | 0.95 | yes |

**Combined Non-professional 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 | 7.40 x 10-3 | 1.48 | yes |
| Scenarios [3+4] | Tier 1 | 50 | 0.5 | 1.66 x 10-2 | 3.32 | yes |
| Scenarios [6+7] | Tier 1 | 50 | 0.5 | 4.22 x 10-2 | 8.43 | yes |
| Scenarios [8+9] | Tier 1 | 50 | 0.5 | 8.43 x 10-2 | 16.87 | yes |

**Conclusion**

In conclusion for non-professional users, the risk is acceptable for all scenarios without PPE

***Risk for the general public***

The acute exposure values are compared to short-term AEL of permethrin.

Chronic exposure values are compared to long-term AEL of permethrin.

The following scenarios represent secondary exposures.

**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)** |
| --- | --- | --- | --- | --- | --- | --- |
| 10. Adult amateur sanding/processing of treated wood composites (acute) | Tier 1 | 50 | 0.5 | 3.5 x 10-4 | 0.07 | yes |
| 11. Toddler chewing wood composite chips treated with application dose of 450 g/m² | Tier 1 | 50 | 0.5 | 1.39 x 10-1 | 27.86 | yes |
| 12. Toddler chewing wood composite chips treated with application dose of 300 g/m² | Tier 1 | 50 | 0.5 | 9.29 x 10-2 | 18.58 | yes |
| 13. Adult amateur sanding/processing of treated wood composites (chronic) | Tier 1 | 5 | 0.05 | 3.5 x 10-4 | 0.69 | yes |
| 14. Inhalation of volatilised residues indoors (adult) | Tier 1 | 5 | 0.05 | 9.26 x 10-5 | 0.19 | yes |
| 15. Inhalation of volatilised residues indoors (infant) | Tier 1 | 5 | 0.05 | 2.34 x 10-4 | 0.47 | yes |
| 16. Inhalation of volatilised residues indoors (toddler) | Tier 1 | 5 | 0.05 | 2.78 x 10-4 | 0.56 | yes |
| 17. Child playing on playground structure outdoors (chronic) | Tier 1 | 5 | 0.05 | 9.29 x 10-4 | 1.9 | yes |
| 18. Toddler playing on weathered (playground) structure and mouthing (450 g/m²) | Tier 1 | 5 | 0.05 | 4.49 x 10-2 | 89.86 | yes |

**Conclusion**

No unacceptable risk has been identified for secondary exposure.

**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)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Combined exposure professional users(chronic)** | | | | | | |
| Scenarios [1+2+14]  (Primary exposure brushing application and cleaning + secondary exposure inhalation of volatilised residues) | Tier 1 | 5 | 0.05 | 7.49 x 10-3 | 14.98 | yes |
| Scenarios [3+4+14]  (Primary exposure brushing+injecting application and cleaning + secondary exposure inhalation of volatilised residues) | Tier 1 | 5 | 0.05 | 1.67 x 10-2 | 33.38 | yes |
| Scenarios [5+7+14]  (Primary exposure spraying application and cleaning + secondary exposure inhalation of volatilised residues) | Tier 2 (gloves + coverall 20%) | 5 | 0.05 | 3.80 x 10-2 | 75.97 | yes |
| Scenarios [8+9+14]  (Primary exposure spraying+injecting application and cleaning + secondary exposure inhalation of volatilised residues) | Tier 2 (gloves + coverall 10%) | 5 | 0.05 | 3.48 x 10-2 | 69.70 | yes |
| **Combined exposure non-professional users (medium term)** | | | | | | |
| Scenarios [1+2+14] | Tier 1 | 50 | 0.5 | 7.75 x 10-3 | 1.55 | yes |
| Scenarios [3+4+14] | Tier 1 | 50 | 0.5 | 1.69 x 10-2 | 3.39 | yes |
| Scenarios [6+7+14] | Tier 1 | 50 | 0.5 | 4.25 x 10-2 | 8.50 | yes |
| Scenarios [8+9+14] | Tier 1 | 50 | 0.5 | 8.47 x 10-2 | 16.94 | yes |
| **Combined exposure infant (chronic)** | | | | | | |
| Scenarios [16 + 18]  (Primary exposure toddler playing on a wood structure + mouthing + secondary exposure inhalation of volatilised residues) | Tier 1 | 5 | 0.05 | 4.52 x 10-2 | 90.42 | yes |

**Conclusion**

Concerning professional users:

For application by brushing with and without injection combined with secondary exposure, the risk is considered acceptable without PPE.

For spray application combined with secondary exposure and for spray application combined with injection and secondary exposure by inhalation of volatilised residues, the risk is acceptable considering the wear of gloves and coated coverall.

Concerning non-professional users, the risk is acceptable for all applications (primary exposure during application and cleaning + inhalation of volatilised residues).

Concerning toddler playing on a wood structure with mouthing + chewing a wood composite chips + inhalation of volatilised residues, the risk of combined exposure is 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 V33 TRAITEMENT POUTRES ET CHARPENTES 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***

Not relevant.

### 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 04LBCEOL689/2 is a ready-to-use water-based wood preservative containing 0.60% w/w permethrin as active substance.

A summary of the available ecotoxicity data on the active substance permethrin is presented below. All the data are coming from the Assessment Report on 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 |
| (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 04LBCEOL689/2. 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 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.

Signal Word: Warning

H400: Very toxic to aquatic life.

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

According to the SDS (see Section 13 in the IUCLID file), two components of the product 04LBCEOL689/2 other than the active substance are classified for the environment according to Regulation (EC) 1272/2008 (CLP) and have the following classification:  
-"Component 4": Aquatic Chronic 3, H412 with a content < 1% w/w in the product

-"Component 6": Aquatic Chronic 3, H412 with a content < 1% w/w in the product

These co-formulants are not expected to have a significant impact on the ecotoxicological classification of the product 04LBCEOL689/2 as it is already classified with the worst classification H400/H410 due to the presence of permethrin.

Therefore, it is not suspected that the composition of the product 04LBCEOL689/2 would influence the ecotoxicological properties of the active substance in a way that may considerably alter the conclusions, of the classification.

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 04LBCEOL689/2 is based on the active substance data, according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and no further aquatic ecotoxicity data on the product 04LBCEOL689/2 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 04LBCEOL689/2 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 04LBCEOL689/2 would influence the ecotoxicological properties of the active substance in a way that may considerably alter the conclusions of the risk characterization.  Thus, no additional aquatic and terrestrial ecotoxicological study with the product 04LBCEOL689/2 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 04LBCEOL689/2 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 04LBCEOL689/2 would influence the ecotoxicological properties of the active substance in a way that may considerably alter the conclusions of the risk characterization.  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 04LBCEOL689/2 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 04LBCEOL689/2 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 04LBCEOL689/2 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 04LBCEOL689/2 and it can be concluded that no secondary ecological effect is expected when using the product 04LBCEOL689/2 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 04LBCEOL689/2 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.

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 the atmosphere can be expected considering the mode of application by spraying of the product 04LBCEOL689/2 resulting in a direct emission to air. However, based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to a local scale. Moreover, the 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 Report, 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 04LBCEOL689/2. |

##### Leaching behaviour (ADS)

The product 04LBCEOL689/2 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 04LBCEOL689/2.

##### 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 04LBCEOL689/2 because the product is for indoor use only.  Moreover, several environmental data are available on permethrin and its metabolites (see Assessment Report, 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 04LBCEOL689/2. |

##### 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 in the sections above, the surface water (including sediment) is not expected to be contaminated by the product 04LBCEOL689/2 because the product is for an indoor use only. Moreover, several environmental data are available on permethrin and its metabolites (see Assessment Report, permethrin, PT18, 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 04LBCEOL689/2. |

##### 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 the atmosphere can be expected considering the mode of application by spraying of the product 04LBCEOL689/2, resulting in a direct emission to air.  However, based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to local scale. Moreover, the 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. 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 04LBCEOL689/2. |

##### 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 04LBCEOL689/2 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 04LBCEOL689/2. |

##### 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.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The product 04LBCEOL689/2 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 04LBCEOL689/2 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 04LBCEOL689/2 is a ready-to-use water-based wood preservative containing 0.60% 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.

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 04LBCEOL689/2 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 04LBCEOL689/2, resulting in a direct emission to air. However, based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to a local scale. Moreover, the 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, 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.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT8 |
| Assessed scenarios | Scenario 1: Indoor applications |
| 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 04LBCEOL689/2 according to 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 the 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] | 26 930 | 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) (geometric mean = 61.8 days) | 80 to 145 days for trans-DCVA 62 to 188 days for cis-DCVA |
| DT50 for degradation in soil at 12°C | 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 indoor 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 04LBCEOL689/2 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 the emissions to the atmosphere will be negligible.

Therefore, the expected concentrations of permethrin are considered negligible in all compartments, when using the product 04LBCEOL689/2 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 04LBCEOL689/2. 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 04LBCEOL689/2.

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 the atmosphere can be expected considering the mode of application by spraying of the product 04LBCEOL689/2, resulting in a direct emission to air. However, based on the indoor application of the product, it is likely that the emissions to the atmosphere will be limited in time and restricted to a local scale. Moreover, the 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, 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 04LBCEOL689/2 according to the label recommendations.

##### Sewage treatment plant (STP)

As the product is for indoor use only, no contamination of the STP is expected. Therefore, the risk for the STP is considered as negligible when using the product 04LBCEOL689/2 according to the label recommendations.

##### Aquatic compartment

As the product is for indoor 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 04LBCEOL689/2 according to the label recommendations.

##### Terrestrial compartment

As the product is for indoor 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 04LBCEOL689/2 according to the label recommendations.

##### Groundwater

As the product is for indoor 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 04LBCEOL689/2. 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 04LBCEOL689/2.

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.

##### 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 04LBCEOL689/2 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.  
Exposure of the atmosphere can be expected considering the mode of application by spraying of the product 04LBCEOL689/2, resulting in a direct emission to air. However, based on the indoor application of the product, it is likely that the emissions to the atmosphere will be negligible.

Therefore, a significant exposure of environment is unlikely and a mixture toxicity assessment is not necessary for the product 04LBCEOL689/2.

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

An assessment of aggregated exposure is judged not relevant for the product 04LBCEOL689/2 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 04LBCEOL689/2 is a ready-to-use water-based wood preservative containing 0.60% 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 the emissions to the atmosphere will be negligible.  Therefore, the risk for all compartments (air, water, sediment, soil and groundwater) and the risk of primary and secondary poisoning are considered acceptable when using the product 04LBCEOL689/2 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 conclusions considering the strict practical uses claimed by the applicant. |

***Dietary exposure***

The intended use descriptions of the permethrine containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. 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. No further data are required concerning the residue behaviour.

### 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[[27]](#footnote-27)

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| XX | 2012 | Determination of preventive action against *Hylotrupes bajulus* (Linnaeus) - Part 1: larvicidal effect according to EN 46-1 (2009) |  | V33 |  |
| XX | 2006 | Determination of preventive efficacy against *Reticulitermes santonensis* according to NF EN 118 with NF EN 73. |  | CECIL |  |
| XX | 2006 | Corrective action against *Hylotrupes bajulus L.* larvae (house longhorn beetle) according to XP ENV 1390. |  | CECIL |  |
| XX | 2007 | Determination of corrective efficacy against the emergence of *Anobium punctatum* |  | CECIL |  |
| XX | 2016 | Determination of the protective effectiveness against *Anobium punctatum* by egg-laying and larval survival according to EN 49 part 1 (2016) after evaporative ageing procedure according to EN 73 (2014) |  | CECIL |  |
| XX | 2017 | Efficacité protectrice vis-à-vis de *Lyctus brunneus* selon NF EN 20-1 avec NF EN 73 |  | CECIL |  |
| XX | 2016 | Efficacité préventive contre les termites souterrains selon NF EN 118 avec NF EN 73 |  | CECIL |  |
| XX | 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 188 (Janvier 2014) |  | CECIL |  |
| XX | 2015 | *In-vitro human skin penetration of 14C-permethrin in* 04LBCEOL689/2 test item, in accordance to the guidance OECD No.428 |  | V33 |  |
| XX | 2014 | Assessment of the skin sensitisation potential in the mouse using the local lymph node assay (LLNA:BrdU) |  | V33 |  |

| **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** |
| **2.2.2** |  | XX | 2014 | Chemical analysis no.3 of the test item ready-to-use 04LBCEOL689/2 (Batch no.020211689/2)  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2016 | Physico-chemical properties, validation of the analytical method and chemical analyses of the biocidal product 04LBCEOL689/2 before and after an accelerated storage procedure for 14 days at 54 ± 2°C, in compliance with CIPAC MT 46.3 method.  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2013 | Chemical analysis of the test item ready-to-use 04LBCEOL689/2 (Batch no.250313689/2)  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Physical, chemical and technical characteristics of the biocidal product 06LBCEOL20/2PT  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Chemical analysis no.4 of the test item ready-to-use 04LBCEOL689/2 (Batch no.020211689/2)  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2011 | Chemical analysis on 04LBCEOL689/2 (Batch no.020211689/2)  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Chemical analysis no.4 of the test item ready-to-use 04LBCEOL689/2 (Batch no.020211689/2)  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2013 | Certificate of analysis n° : COA-402/13/1036F/a-e  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2013 | Certificate of analysis n° : COA-402/13/1159F/a-e  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Certificate of analysis n° : COA-402/13/1036F/b/T24M-e  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2014 | Certificate of analysis n° : COA-402/13/1036F/b/T12M-e  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Certificate of analysis n° : COA-402/13/1036F/b/T30M-e  XX | V33 |  |  | X |  | Y |
| **2.2.2** |  | XX | 2015 | Certificate of analysis n° : COA-402/15/1060F/a-e  XX | V33 |  |  | X |  | Y |
| **2.2.4** |  | XX | 2016 | Content of active substances in the biocidal product 06LBCEOL20/2PT after a method validation according to SANCO/3030/99/rev.4,  XX | V33 |  | X | X |  | Y |

## Output tables from exposure assessment tools

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## New information on the active substance

No new data were submitted.

## Residue behaviour

Not relevant.

## Summaries of the efficacy studies (B.5.10.1-xx)[[28]](#footnote-28)

Please see IUCLID files.

## 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. 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-3)
4. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#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. 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-6)
7. 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-7)
8. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (laboratory method). [↑](#footnote-ref-8)
9. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-9)
10. 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-10)
11. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-11)
12. Wood preservatives – Determination of eradicant efficacy in preventing emergence of *Anobium punctatum (De Geer)* [↑](#footnote-ref-12)
13. Wood preservatives – Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* [↑](#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. [EFSA journal 2012; 10(4):2665](http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2665/full) [↑](#footnote-ref-16)
17. “The most appropriate model to use for the scenario of non-professional application of paints by brushing and rolling”, agreed at the HH WG III on 26 May 2016. [↑](#footnote-ref-17)
18. 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-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. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-20)
21. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-21)
22. 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-22)
23. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-23)
24. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-24)
25. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-25)
26. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-26)
27. 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-27)
28. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-28)