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 MULTI USAGES

Product type 8

Cypermethrin, Propiconazole and Tebuconazole as included in the Union list of approved active substances

Case Number in R4BP: BC-TF017337-39

Evaluating Competent Authority: FR

Date: April 2017

# Contents

# 1 CONCLUSION

- *Physico-chemical properties*

V33 TRAITEMENT MULTI USAGES is not considered to be potentially explosive nor contains an oxidising agent. The product is not intended to be used in combination with other products. The product is not flammable. Its technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

- *Efficacy assessment*

The product shows a sufficient efficacy for the preservation of wood. The product is used:

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

The application rates validated are the following:

- Preventive treatments: superficial application at 200 g of product 06LBCEOL20/2PT / m² of wood
- Curative treatment: superficial application at 300 g of product 06LBCEOL20/2PT / m² of wood (injection 150 g of product 06LBCEOL20/2PT / m² of wood if need be).

- *Risk assessment for human health*

Risks related to the use of V33 TRAITEMENT MULTI USAGE by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

Risks related to a secondary exposure to treated wood are considered acceptable except in the case of chewing of a piece of treated wood by an infant, considering a curative treatment (spraying or brushing combined with injection) with an application dose of 450 g/m$^2$. Therefore, the curative treatments with the highest application doses and combining a superficial treatment and injection should be restricted to inaccessible woods (construction wood).

- *Risk 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 TRAITEMENT MULTI USAGES must contain label restrictions against use in contact with livestock, food and feed.

- *Risk assessment for environment*

For use classes 1 and 2, emissions are considered negligible according to PT08 ESD. The risks for the application phase and service life are therefore considered acceptable for treatment in classes 1 and 2.

For the application phase for wood in class 3, risks are only acceptable if emissions to the aquatic and terrestrial compartments are prevented whatever the type of treatment. As a consequence, no application above or near surface water is allowed to protect the aquatic compartment and the ground has to be covered with an appropriate plastic sheet to prevent any emission to the terrestrial compartment.

For the service-life phase of treated wood, considering that no emissions occurs during application with the use of appropriate risk mitigation measures and considering the systematic application of a top-coat after the wood treatment, risks can be considered acceptable for all the compartments whatever the type of treatment.

The risks are also acceptable for the service-life phase using the bridge over pond and noise barrier scenarios, which covers urban direct and indirect releases to the aquatic compartment.

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### *2.1.1 Administrative information*

#### 2.1.1.1 Identifier of the product

| **Identifier** | **Country (if relevant)** |
|---|---|
| 06LBCEOL20/2PT<br>V33 TRAITEMENT MULTI USAGES | France |

#### 2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | V33 |
| | **Address** | La Muyre<br>39210 Domblans<br>FRANCE |
| **Authorisation number** | FR-2017-0027 | |
| **Date of the authorisation** | 10/05/2017 | |
| **Expiry date of the authorisation** | 09/05/2022 | |

#### 2.1.1.3 Manufacturer(s) of the product

| | |
|---|---|
| **Name of manufacturer** | V33 |
| **Address of manufacturer** | La Muyre<br>39210 Domblans<br>FRANCE |
| **Location of manufacturing sites** | La Muyre<br>39210 Domblans<br>FRANCE |

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

| | |
|---|---|
| **Active substance** | Cypermethrin |
| **Name of manufacturer** | Arysta LifeScience Benelux |
| **Address of manufacturer** | 26/1 Rue Renory<br>BE-4102 Ougrée<br>Belgium |
| **Location of manufacturing sites** | Mitchell Cotts Chemicals<br>Steanard Lane, Mirfield<br>West Yorkshire, WF14 8QB<br>United Kingdom |
| | Gharda Ltd<br>D, ½, MIDC, LOTE PARSHURAM TAL. KHED DIST.<br>Ratnagiri 415 722, Maharashtra<br>India |

| | |
|---|---|
| **Active substance** | Propiconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH<br>Material Protection Products |
| **Address of manufacturer** | Kennedyplatz 1<br>D-50569 Köln<br>Germany |
| **Location of manufacturing sites** | Syngenta Crop Protection AG<br>CH-1870 Monthey<br>Switzerland |
| | Jiangsu Yangnong Chemical Group Co., Ltd<br>Wenfeng Road<br>Yangzhou<br>Jiangsu 225009, P.R.<br>China |
| | Jiangsu SevenContinent Green Chemical Co., Ltd<br>North Area of Dongsha Chem-Zone<br>Zhanjiagang<br>Jiangsu, 215600, P.R.<br>China |

| | |
|---|---|
| **Active substance** | Tebuconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH<br>Material Protection Products |
| **Address of manufacturer** | Kennedyplatz 1<br>D-50569 Köln<br>Germany |
| **Location of manufacturing sites** | Bayer Corp., Agriculture Division<br>P.O. Box 4913 Hawthorn Road<br>MO 64120-0013 Kansas City<br>United-States |

### *2.1.2 Product composition and formulation*

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

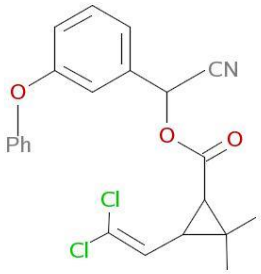
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

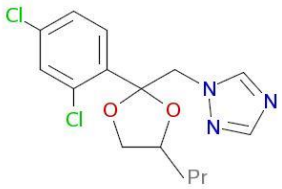
#### 2.1.2.1 Identity of the active substance

- **Cypermethrine**

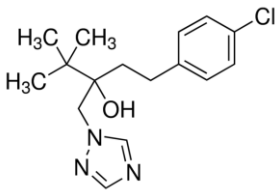
| **Main constituent(s)** | |
|---|---|
| **ISO name** | Cypermethrin cis/trans +/- 40/60 |
| **IUPAC or EC name** | (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 02-2119680758-20-0000 |
| **Minimum purity / content** | 92.0% |

| | |
|---|---|
| **Structural formula** |  |

- **Propiconazole**

| **Main constituent(s)** | |
|---|---|
| **ISO name** | Propiconazole |
| **IUPAC or EC name** | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole |
| **EC number** | 262-104-4 |
| **CAS number** | 60207-90-1 |
| **Index number in Annex VI of CLP** | 613-205-00-0 |
| **Minimum purity / content** | 94.0% |
| **Structural formula** |  |

- **Tebuconazole**

| **Main constituent(s)** | |
|---|---|
| **ISO name** | Tebuconazole |
| **IUPAC or EC name** | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol |
| **EC number** | 403-640-2 |
| **CAS number** | 107534-96-3 |
| **Index number in Annex VI of CLP** | 603-197-00-7 |
| **Minimum purity / content** | 95.0% |
| **Structural formula** |  |

### 2.1.2.2 Candidate(s) for substitution

- **Tebuconazole**

According to the PT07-AR of tebuconazole (2013), tebuconazole does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance is candidate for substitution, as it fulfils the P and T criteria.

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

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|---|---|---|---|
| Cypermethrin cis/trans +/- 40/60 (technical) | RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.18 % (technical)<br><br>(0.17% pure) |
| Preventol A 8 Tebuconazole (technical) | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol.Ratio (1:1) | Active substance | 107534-96-3 | 403-640-2 | 0.15 % (technical)<br><br>(0.14% pure) |
| Preventol A 12 Propiconazole (technical) | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.14 % (technical)<br><br>(0.13% pure) |

### 2.1.2.4 Information on technical equivalence

The origin of propiconazole “Monthey” is the one assessed for the approbation of the active substances as PT8.

The origin for propiconazole “Jiangsu Yangnong Chemical Group Co., Ltd” is not the origin assessed for the approbation of the active substance for PT8. This origin has been found equivalent to the reference source.

The origin for propiconazole “Jiangsu Seven continent Green Chemical Co. Ltd” is not the origin assessed for the approbation of the active substance for PT8. This origin has been found equivalent to the two reference source (decision TAP-D-1182636-27-00 on February 2016).

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

The product contains 2 preservatives, both under review as active substance in PT06:
- 2-methyl-2H-isothiazol-3-one (MIT, CAS N°2682-20-4);
- 1,2-benzisothiazol-3(2H)-one (BIT, CAS N°2634-33-5).

These 2 substances should therefore be considered as substances of concern. However, as both active substances are under review as PT06, they cannot be currently taking into account for the risk assessment of the product.

### 2.1.2.6 Type of formulation

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| EW (emulsion oil in water, ready to use) |

### *2.1.3 Hazard and precautionary statements[1]*

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

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|---|---|
| **Classification** | |
| Hazard category | Aquatic Acute 1<br>Aquatic Chronic 1 |
| Hazard statement | H400 – Very toxic to aquatic life<br>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.<br>P103: Read label before use<br>P273 – Avoid release to the environment<br>P501 – Dispose of contents/container in accordance with local/regional/national/international regulation (to be specified). |
| | |
| Note | EUH 208 – Contains propiconazole and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction.<br>EUH 210: Safety data sheet available on request. |

### *2.1.4 Authorised use(s)*

#### 2.1.4.1 Use description: Preventive treatment for wood of use classes 1 and 2

**Table 2.1-1. Use # 1 – Preventive treatment for wood of use classes 1 and 2**

| | |
|---|---|
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood on use classes 1 and 2 |
| **Target organism (including development stage)** | Wood rotting fungi (brown rot and white rot)<br><br>Wood boring beetles<br>- House longhorn beetle (*Hylotrupes bajulus*)<br>- Common furniture beetle (*Anobium punctatum*)<br>- Powder post beetles (*Lyctus brunneus*)<br><br>Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| **Field of use** | Preventive treatment for wood on use classe 1<br>Preventive treatment for wood on use classe 2 |
| **Application method(s)** | Superficial application / brush<br>Superficial application / spray |

1 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

| | |
|---|---|
| **Application rate(s) and frequency** | The produit is ready to use.<br><br>The application is performed by brushing or spraying.<br>The application rate is :<br>- CU1 and 2 : 200 g of product / m² of wood |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | The product is packed in<br>- can in steel with polyethylene closure of 0,5L and 1L<br>- can in steel with polyethylene closure of 5L and 6L<br>- tin in steel with polyethylene closure of 25L and 30L.<br><br>All cans are coated inside with an epoxy pigmented varnish. |

#### *2.1.4.1.1 Use-specific instructions for use*

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#### *2.1.4.1.2 Use-specific risk mitigation measures*

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

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

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

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### 2.1.4.2 Use description: Preventive treatment for wood of use classe 3

**Table 2.1-2 Use # 2 – Preventive treatment for wood of use classe 3**

| | |
|---|---|
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood on use class 3 |
| **Target organism (including development stage)** | Wood rotting fungi (brown rot and white rot)<br><br>Wood boring beetles<br>- House longhorn beetle (*Hylotrupes bajulus*)<br>- Common furniture beetle (*Anobium punctatum*)<br>- Powder post beetles (*Lyctus brunneus*)<br><br>Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| **Field of use** | Preventive treatment for wood on use classe 3 |
| **Application method(s)** | Superficial application / brush<br>Superficial application / spray |
| **Application rate(s) and frequency** | The produit is ready to use. |

| | |
|---|---|
| | The application is performed by brushing or spraying.<br>The application rate is :<br>- CU3: 200 g of product / m² of wood (with a top coat) |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | The product is packed in<br>- can in steel with polyethylene closure of 0,5L and 1L<br>- can in steel with polyethylene closure of 5L and 6L<br>- tin in steel with polyethylene closure of 25L and 30L.<br><br>All cans are coated inside with an epoxy pigmented varnish. |

#### *2.1.4.2.1 Use-specific instructions for use*

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

#### *2.1.4.2.2 Use-specific risk mitigation measures*

- The outdoor use of treated wood is allowed only if wood preservation is followed by the application of a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood.
- Do not apply where the product can reach surface water during outdoor application.
- For outdoor treatment, cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment.
- For outdoor treatment, do not apply under rainfall or when rainfall is expected during the next 24 hours.

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

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

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

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### 2.1.4.3 Use description: Curative treatment for wood in service

**Table 2.1-3. Use # 3 – Curative treatment for wood in service**

| | |
|---|---|
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Curative treatment for wood in service |
| **Target organism (including development stage)** | Wood boring beetles<br>- House longhorn beetle (*Hylotrupes bajulus*)<br>- Common furniture beetle (*Anobium punctatum*)<br>- Powder post beetles (*Lyctus brunneus*)<br><br>Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| **Field of use** | Curative treatment for wood in service (except for wood in permanent contact with soil or submerged) |

| | |
|---|---|
| **Application method(s)** | Superficial application / brush<br>Superficial application / spray<br>Injection (combined with a superficial application) |
| **Application rate(s) and frequency** | The produit is ready to use.<br><br>The application is performed by brushing or spraying.<br>The application rate is :<br>- 300 g of product / m² of wood<br><br>When the application is performed by injection (combined with superficial application), the application rate is :<br>- 150 g of product / m² of wood (+ 300 g of product / m² of wood) |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | The product is packed in<br>- can in steel with polyethylene closure of 0,5L and 1L<br>- can in steel with polyethylene closure of 5L and 6L<br>- tin in steel with polyethylene closure of 25L and 30L.<br><br>All cans are coated inside with an epoxy pigmented varnish. |

#### *2.1.4.3.1 Use-specific instructions for use*

- Curative treatments performed by injection must always be combined with curative treatments applied by surperficial application.

#### *2.1.4.3.2 Use-specific risk mitigation measures*

- Curative treatments by brushing or spraying, combined with treatment by injection, should only be applied to timber inaccessible to children.
- The outdoor use of treated wood is allowed only if wood preservation is followed by the application of a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood.
- Do not apply where the product can reach surface water during outdoor application.
- For outdoor treatment, cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment.
- For outdoor treatment, do not apply under rainfall or when rainfall is expected during the next 24 hours.

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

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

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

-

### *2.1.5 General directions for use*

#### 2.1.5.1 Instructions for use

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

#### 2.1.5.2 Risk mitigation measures

- Wear protective chemical resistant gloves (glove material to be specified by the authorization holder within the product information) protective and a coverall type VI during handling of the product for spray application.
- Keep out of reach of children.
- Do not apply on wood likely to be in contact with food, feed, drinks and livestock.

#### 2.1.5.3 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 water. Seek medical advice or call a poison control centre 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. Continue to rinse with warm water for at least 15 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Seek medical advice immediately or call a poison control centre.
- Inhalation of spray mist: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately or call a poison control centre if symptoms occur.
- Do not drink or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- Keep the container or label available.

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

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

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

Shelf life: 3 years

### *2.1.6 Other information*

- The presence of propiconazole, MIT and BIT, skin sensitizer that may produce a allergic reaction, must be reported on the label.
- Treated wood should not be intended for uses involving contact with food, feed or livestock.

### *2.1.7 Packaging of the biocidal product*

The packaging of the biocidal product for non-professional users and professional users are:

- can in steel with polyethylene closure of 0,5L and 1L,
- can in steel with polyethylene closure of 5L and 6L,
- can in steel with polyethylene closure of 25L and 30L.

All cans are coated inside with an epoxy pigmented varnish.

## *2.1.8 Documentation*

### 2.1.8.1 Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product V33 TRAITEMENT MULTI USAGES were provided by V33.

**Efficacy data**

The product 06LBCEOL20/2PT is identical to the product V33 TRAITEMENT MULTI USAGES. The following efficacy studies were submitted:

- Laboratory efficacy study conducted according to the standard EN113, with the product 06LBCEOL20/2PT concentrate after ageing following EN 73 (evaporating procedure);
- Laboratory efficacy study conducted according to the standard EN113, with the product 06LBCEOL20/2PT concentrate after ageing following EN 84 (leaching procedure);
- Laboratory efficacy study conducted according to the standard EN 46-1, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure);
- Laboratory efficacy study conducted according to the standard EN 49-1, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure);
- Laboratory efficacy study conducted according to the standard EN 49-1, with the product 06LBCEOL20/2PT, after ageing following EN 84 (leaching procedure);
- Laboratory efficacy study conducted according to the standard EN 46-1, with the product 06LBCEOL20/2PT, after ageing following EN 84 (leaching procedure);
- Laboratory efficacy study conducted according to the standard EN 20-1, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure);
- Laboratory efficacy study conducted according to the standard EN 118, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure) against *Reticulitermes grassei*;
- Laboratory efficacy study conducted according to the standard EN 118, with the product 06LBCEOL20/2PT, after ageing following EN 84 (leaching procedure) against *Reticulitermes grassei*;
- Laboratory efficacy study conducted according to the standard EN 118, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure) against *Heterotermes tenuis*;
- Laboratory efficacy study conducted according to the standard EN 118, with the product 06LBCEOL20/2PT, after ageing following EN 84 (leaching procedure) against *Heterotermes tenuis*;
- Laboratory efficacy study conducted according to the standard EN 370, with the product 06LBCEOL20/2PT, after ageing following EN 73 (evaporating procedure)
- Laboratory efficacy study conducted according to the standard EN 1390, with the product 06LBCEOL20/2PT.

**Toxicology data**

An eye irritation study in rabbit and a skin sensitizer in mice performed with V33 TRAITEMENT MULTI USAGES habe been submitted in the context of this dossier.

An *in vitro* dermal absorption study performed with V33 TRAITEMENT MULTI USAGES has also been submitted.

**Residue data**

No specific residue data were submitted in the context of this dossier. The product TRAITEMENT MULTI USAGES is intended to be used as preventive and curative treatment of interior woods especially in wet situation (beams, frames, wood in cellars, basements and bathrooms) and exterior woods (shutters, doors,

siding, fences, gates, awnings, roof overhangs). 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.

**Ecotoxicology data**

The product 06LBCEOL20/2PT is identical to the product V33 TRAITEMENT MULTI USAGES. Only the following leaching study was submitted:

- Wood preservative 06LBCEOL 20/2PT Estimation of emission from wood preservative – treated wood to the environment: For wood held in storage after treatment and for wooden commodities that are not covered and are not in contact with ground (NT build 509). Test report #402/12/1074F-e from May 18, 2016. FCBA Institut Technologique.

### 2.1.8.2 Access to documentation

**Identity, physico-chemical and analytical method data**

V33 has access to analytical methods on the active substance Cypermethrin with a Letter of Access of Agriphar.
V33 has access to analytical methods on the active substance Propiconazole with a Letter of Access of Lanxess.
V33 has access to analytical methods on the active substance Tebuconazole with a Letter of Access of Lanxess.

## 2.2 Assessment of the biocidal product

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

**Table 2.2-1. Intended use # 1 – Preventive use**

| | |
|---|---|
| Product Type(s) | 8 – Wood preservatives |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood on use classes 1, 2 and 3 |
| Target organism (including development stage) | Wood rotting fungi (brown rot and white rot)<br><br>Wood boring beetles<br>- House longhorn beetle (*Hylotrupes bajulus*)<br>- Common furniture beetle (*Anobium punctatum*)<br>- Powder post beetles (*Lyctus brunneus*)<br><br>Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| Field of use | Preventive treatment for wood on use classes 1, 2 and 3 |
| Application method(s) | Superficial application / brush<br>Superficial application / spray |
| Application rate(s) and frequency | Preventive treatment by superficial application (Brush or Spray)<br>- 200 g product/m² (or 200 mL/m²) |
| Category(ies) of user(s) | Professional and non-profesional users |
| Pack sizes and packaging material | The product is packaged in 0.5, 1, 5, 6, 25 or 30 L steel cans with polyethylene closure systems. |

**Table 2.2-2. Intended use # 2 – Curative use**

| | |
|---|---|
| Product Type(s) | 8 – Wood preservatives |

| | |
|---|---|
| Where relevant, an exact description of the authorised use | Curative treatment for wood in service (indoor and outdoor) |
| Target organism (including development stage) | Wood rotting fungi (brown rot and white rot)<br><br>Wood boring beetles<br>- House longhorn beetle (*Hylotrupes bajulus*)<br>- Common furniture beetle (*Anobium punctatum*)<br>- Powder post beetles (*Lyctus brunneus*)<br><br>Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| Field of use | Indoor and outdoor |
| Application method(s) | Superficial application / brush<br>Superficial application / spray<br>Injection (combined with a superficial application) |
| Application rate(s) and frequency | Curative treatment by superficial application (Brush or Spray)<br>- 300 g product/m² (or 300 mL/m²)<br><br>Curative treatment by injection (combined with superficial application)<br>The application rate is :<br>- 150 g of product / m² of wood (+ 300g of product / m² of wood) |
| Category(ies) of user(s) | Professional and non-profesional users |
| Pack sizes and packaging material | The product is packaged in 0.5, 1, 5, 6, 25 or 30 L steel cans with polyethylene closure systems. |

## *2.2.2 Physico, chemical and technical properties*

### 2.2.2.1 Active ingredient

The sources of the active substances Cypermethrin, Propiconazole and Tebuconazole are recognized at EU level.

### 2.2.2.2 Biocidal product

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. In terms of pure substance active content, the product contains 0.17% of pure cypermethrin (cis:trans/ 40:60); 0.14% of pure tebuconazole; 0.13% of pure propiconazole.

The biocidal product 06LBCEOL20/2PT is a translucent pale yellow liquid with a characteristic odour of linseed oil. The pH of the pure product is about 6.9 at 20°C and its density is about 1.00. The product forms and maintains a stable uniform emulsion, without free oil, cream or solid matter.

| Trade Name | V33 TRAITEMENT MULTI USAGES | | |
|---|---|---|---|
| Manufacturer's development code number | 06LBCEOL20/PT | | |
| Ingredient of product | Function | Content of pure substance (% w/w) | Content of technical substance (% w/w) |
| Cypermethrin (CAS n°52315-07-8) | Active substance | 0.17 | 0.18 |
| Tebuconazole (CAS n°107534-96-3) | Active substance | 0.14 | 0.15 |
| Propiconazole (CAS n°60207-90-1) | Active substance | 0.13 | 0.14 |
| Formulants | Details on confidential PAR | | |
| Physical state of product | Liquid | | |

| | |
|---|---|
| Nature of the product | EW (emulsion oil in water) |

The preservatives in the biocidal product are in the review program for TP6.

The tested product is V33 TRAITEMENT MULTI USAGES (code 06LBCEOL20/2PT).
The used batch is 16011520/2PT.
The product is an emulsion oil in water, ready to use.

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
|---|---|---|---|---|---|
| Physical state at 20 °C and 101.3 kPa<br>Colour at 20 °C and 101.3 kPa<br>Odour at 20 °C and 101.3 kPa | visual method | [redacted] | Translucent pale yellow liquid, with no deposit no phase partition. | Acceptable | Legay S. 2015, final report No.402/14/1207F/abcde-e |
| Acidity / alkalinity | CIPAC MT 75.3 | [redacted] | pH of the pure test item : 6.86 at 20°C<br><br>acidity is not required since pH of the test item is > 4 and < 10 | Acceptable | Legay S. 2015, final report No.402/14/1207F/abcde-e |
| Relative density / bulk density | EEC A.3 | [redacted] | 1.003 at 20°C and 101.3kPa | Acceptable | Legay S. 2015, final report No.402/14/1207F/abcde-e |

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr><td>Storage stability test – accelerated storage 14 days at 54°C</td><td>Analytical methods validated in section 2.3.2.4<br>CIPAC MT 46.3<br>CIPAC MT 75.3<br>CIPAC MT 36.3</td><td>[redacted]</td><td>Packaging: 1 L steel can with epoxy varnish
<table>
<tr><th></th><th>Initial</th><th>After 14 days at 54°C</th></tr>
<tr><td>Appearance</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td><td>No change</td></tr>
<tr><td>Appearance of packaging</td><td>No sign of corrosion, or degradation</td><td>No change</td></tr>
<tr><td>Content of tebuconazole (% w/w)</td><td>0.138</td><td>0.135</td></tr>
<tr><td>% variation</td><td>/</td><td>-2.2%</td></tr>
<tr><td>Content of Cypermethrin (% w/w)</td><td>0.168</td><td>0.164</td></tr>
<tr><td>% variation</td><td>/</td><td>-2.4%</td></tr>
<tr><td>Content of propiconazole (% w/w)</td><td>0.129</td><td>0.131</td></tr>
<tr><td>% variation</td><td>/</td><td>+1.6%</td></tr>
<tr><td>Weight</td><td>580.46</td><td>580.3</td></tr>
<tr><td>Variation of weight</td><td>/</td><td>-0.028%</td></tr>
</table></td><td>Acceptable,<br><br>The product is stable 14 days at 54°C.</td><td>Legay S. 2015, final report No.402/14/1207F/abcde-e</td></tr>
</table>

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
|---|---|---|---|---|---|
| | | | pH undiluted: 6.86 at 20 °C / 6.29 at 20 °C<br>Emulsion stability of the pure test item<br>initially<br>after 30 minutes: Homogeneous / Homogeneous<br>after 2 hours: Homogeneous / Homogeneous<br>after 24 hours: Homogeneous / Homogeneous<br>after re-emulsification: Homogeneous / Homogeneous<br>after 24 h: Homogeneous / Homogeneous<br>30 minutes after the re-emulsification: Homogeneous / Homogeneous | | |

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Technical Monograph 17<br>Analytical methods validated in section 2.3.2.4</td>
<td>[redacted]</td>
<td>Storage in commercial 1L packaging material (steel can with epoxy varnish). Study has been performed with formulation 06LBCEOL20PT. The product 06LBCEOL20/2PT and 06LBCEOL20PT have very close compositions, with the following difference: 06LBCEOL20PT contains 0.16% w/w additional cypermethrin replaced by water in 06LBCEOL20/2PT.
<table>
<tr><td></td><td>Initial</td><td>After 1 year</td><td>After 3 years</td><td>After 4 years</td></tr>
<tr><td>Appearance</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td><td>Deposit 0.01%<br>No phase partition</td><td>Deposit 0.01%<br>No phase partition</td><td>Deposit 0.01%<br>No phase partition</td></tr>
<tr><td>Appearance of packaging</td><td>No sign of corrosion, or degradation</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Content of tebuconazole (% w/w)</td><td>0.14</td><td>0.13</td><td>0.15</td><td>0.129</td></tr>
<tr><td>% variation</td><td>/</td><td>-7.1%</td><td>+7.1%</td><td>-7.9%</td></tr>
<tr><td>Content of Cypermethrin (% w/w)</td><td>0.33</td><td>0.32</td><td>0.32</td><td>0.294</td></tr>
<tr><td>% variation</td><td>/</td><td>-3.0%</td><td>-3.0%</td><td>-10.9%</td></tr>
<tr><td>Content of propiconazole (% w/w)</td><td>0.15</td><td>0.14</td><td>0.14</td><td>0.127</td></tr>
<tr><td>% variation</td><td>/</td><td>-6.7%</td><td>-6.7%</td><td>-15.3%</td></tr>
<tr><td>Weight</td><td>1131.4</td><td>/</td><td>1131.1</td><td>1131.6</td></tr>
<tr><td>Variation of weight</td><td>/</td><td>-0.028%</td><td></td><td></td></tr>
</table>
</td>
<td>Study has been performed with 06LBCEOL20PT, which is also acceptable for 06LBCEOL20/2PT regarding the composition.<br>The product is stable 3 years in commercial packaging. After 4 years the loss of content of propiconazole and cypermethrin is higher than 10%.<br>The acceptable self-life is 3 years at ambient temperature.</td>
<td>Legay S. 2015, final report No.402/09/1046F/a + Legay S. 2015, final report No.402/09/1046F/b-e</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Technical Monograph 17<br>Analytical methods validated in section 2.3.2.4</td>
<td>[redacted]</td>
<td>Packaging: 1L steel can with epoxy varnish.
<table>
<tr><td></td><td>Initial</td><td>After 1 year</td><td>After 3 years</td><td>After 4 years</td></tr>
<tr><td>Appearance</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td><td>Translucent pale yellow liquid, with no deposit no phase partition.</td></tr>
<tr><td>Appearance of packaging</td><td>No sign of corrosion, or degradation</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Content of tebuconazole (% w/w)</td><td>0.141</td><td>0.138</td><td>0.135</td><td>0.140</td></tr>
<tr><td>% variation</td><td>/</td><td>-2.1</td><td>-4.3</td><td>-0.7</td></tr>
<tr><td>Content of Cypermethrin (% w/w)</td><td>0.167</td><td>0.162</td><td>0.164</td><td>0.162</td></tr>
<tr><td>% variation</td><td>/</td><td>-3</td><td>-1.8</td><td>-3</td></tr>
<tr><td>Content of propiconazole (% w/w)</td><td>0.129</td><td>0.133</td><td>0.129</td><td>0.129</td></tr>
<tr><td>% variation</td><td>/</td><td>+3.1</td><td>0</td><td>0</td></tr>
<tr><td>Variation of weight</td><td>/</td><td>+0.009%</td><td>No variation</td><td>-0.004%</td></tr>
</table>
</td>
<td>Acceptable. The product is stable after storage 3 years at ambient temperature in commercial packaging.</td>
<td>Legay S. 2013, final report No.402/13/1030F/a-e</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 75.3<br>CIPAC MT 36.3</td><td>[redacted]</td><td>Storage in closed glass bottle.
<table>
<tr><td></td><td>Initial</td><td>After 7days at 0°C</td></tr>
<tr><td>Appearance</td><td>Homogeneous transparent clear yellow liquid, with a chemical odour.</td><td>No change</td></tr>
<tr><td>Emulsion stability in pure test item<br>initially<br>after 30 minutes<br>after 2 hours<br>after 24 hours<br>after re-emulsification after 24 h<br>30 minutes after the re-emulsification</td><td><br><br>Homogeneous<br>Homogeneous<br>Homogeneous<br>Homogeneous<br>Homogeneous<br><br>Homogeneous</td><td><br><br>Homogeneous<br>Homogeneous<br>Homogeneous<br>Homogeneous<br>Homogeneous<br><br>Homogeneous</td></tr>
</table></td><td>Acceptable<br>The product is stable at low temperature.</td><td>Legay S. 2015, final report No.402/14/ 1207F/ fgh-e+<br>Legay S. 2015, final report No.402/14/ 1207F/ b-e</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td></td><td></td><td></td><td>Since the packagings are barrier to light and since the active substances are sensitive to light, no data are required.</td><td></td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product – temperature and</td><td></td><td></td><td></td><td>The product is stable at 54°C for 14 days.<br>Therefore, no mitigation on temperature</td><td></td></tr>
</table>

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
|---|---|---|---|---|---|
| **humidity** | | | | applied. | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | | | | The product is stable in commercial packaging. It has been demonstrated with the shelf life study. | |
| Wettability | | | | Not applicable | |
| Suspensibility, spontaneity and dispersion stability | | | | Not applicable | |
| Wet sieve analysis and dry sieve test | | | | Not applicable | |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | [redacted] | Undiluted<br>initially: Homogeneous<br>after 30 minutes: Homogeneous<br>after 2 hours: Homogeneous<br>after 24 hours: Homogeneous<br>after re-emulsification after 24 h: Homogeneous<br>30 minutes after the re-emulsification: Homogeneous | Acceptable | Legay S. 2015, final report No.402/14/1207F/abcde-e + Legay S. 2015, final report No.402/14/1207F/fgh-e |
| Disintegration time | | | | Not applicable | |
| Particle size distribution, content of dust/fines, attrition, friability | | | | Not applicable | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
|---|---|---|---|---|---|
| Persistent foaming | | | The product 06LBCEOL20/2PT is a ready to use product and is not intended to be diluted in water before using. Therefore no formation of foam is expected.<br>Moreover, emulsion tests have been performed with the product before and after storage 14 days at 4°C. During this test, the product is shaking 10 times and no foam has been noticed. Therefore, the product is not expected to be a foaming product | Acceptable | |
| Flowability/Pourability/ Dustability | | | | Not applicable | |
| Burning rate — smoke generators | | | | Not applicable | |
| Burning completeness — smoke generators | | | | Not applicable | |
| Composition of smoke — smoke generators | | | | Not applicable | |
| Spraying pattern — aerosols | | | | Not applicable | |
| Physical compatibility | | | | Not applicable | |
| Chemical compatibility | | | | Not applicable | |
| Degree of dissolution and dilution stability | | | | Not applicable | |
| Surface tension | OECD Guideline 115 (Surface Tension of Aqueous Solutions) | [redacted] | On neat test item<br>Temperature : 20°C ± 0.5°C: 31.48 mN/m | Acceptable<br>The product is surface active. | Legay S. 2015, final report No.402/14/ 1207F/fgh-e |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
|---|---|---|---|---|---|
| | | [redacted] | | | |
| Viscosity | OECD Test Guideline 114 (Viscosity of Liquids) | [redacted] | Temperature: 20°C ± 0.5°C < 6.62 mm²/s<br>40°C ± 0.5°C < 6.62 mm²/s | The product is a non-Newtonian liquid. Acceptable | Legay S. 2015, final report No.402/14/1207F/fgh-e |

### *2.2.3 Physical hazards and respective characteristics*

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Explosives | Statement | - | The product 06LBCEOL20/2PT is not explosive. Test is not required as 06LBCEOL20/2PT contains more than 95% w/w water and as no ingredient is classified as explosive. | - |
| Flammable gases | - | - | Not required as the product is a liquid product. | - |
| Flammable aerosols | - | - | Not required as the product is a liquid product. | - |
| Oxidising gases | - | - | Not required as the product is a liquid product. | - |
| Gases under pressure | - | - | Not required as the product is a liquid product. | - |
| Flammable liquids | Statement | - | The product 06LBCEOL20/2PT is not flammable. Test is not required as 06LBCEOL20/2PT contains more than 95% w/w water and as no ingredient is classified as flammable. | |
| Flammable solids | - | - | Not required as the product is a liquid product. | - |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Self-reactive substances and mixtures | - | - | Not required as the product is a liquid product. | - |
| Pyrophoric liquids | - | - | Not required as the product is a liquid product. | - |
| Pyrophoric solids | - | - | Not required as the product is a liquid product. | - |
| Self-heating substances and mixtures | - | - | Not required as the product is a liquid product. | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | Not required as the product is a liquid product. | - |
| Oxidising liquids | Statement | - | The product 06LBCEOL20/2PT is not oxidising. Test is not required as 06LBCEOL20/2PT contains more than 95% w/w water and as no ingredient is classified as oxidising liquid or solid. | Legay S. 2015, final report No.402/14/1207F/abcde-e |
| Oxidising solids | - | - | Not required as the product is a liquid product. | - |
| Organic peroxides | - | - | Not required as the product is a liquid product. | - |
| Corrosive to metals | Statement | - | One co-formulant is corrosive to metals, but it is in very low quantity so the product is not corrosive to metals. Moreover, no sign of corrosion has been noticed during the accelerated and ambient storage stability study. | |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | The product 06LBCEOL20/2PT is not expected to present a significant hazard for auto-flammability. Test is not required as 06LBCEOL20/2PT contains more than 95% w/w water and as no ingredient is considered to be auto-flammable based on available data found in safety data sheets.<br>The product is not flammable at ambient temperature. | Legay S. 2015, final report No.402/14/1207F/abcde-e |
| Relative self-ignition temperature for solids | - | - | Not required as the product is a liquid product. | - |
| Dust explosion hazard | - | - | Not required as the product is a liquid product. | - |

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

The product 06LBCEOL20/2PT is a translucent pale yellow liquid, ready to use product. It is not explosive and has no oxidising properties. It is not highly flammable and is not expected to be auto-flammable in the conditions of use. It has a pH (pure) of 6.86 at 20°C. Its density is 1.003g/mL. The surface tension of the neat formulation is 31.48mN/m, therefore, the product is considered as surface active. The product is a non-Newtonian liquid (kinematic viscosity < 6.62 mm²/s at 20°C and 40°C). The product is stable after 14 days at 54°C, 7 days at 0°C and after 3 years at ambient temperature in steel can with epoxy varnish. The product forms stable

emulsion. Effect of light has not been investigated. Nevertheless, packagings are light barrier and the active substances are not sensitive.

### *2.2.4 Methods for detection and identification*

#### 2.2.4.1 Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient

The applicant has letters of access to the data provided at EU level for each active substance.

**Summary for Cypermethrin:**

| | Principle of method |
|---|---|
| Technical active substance as manufactured: | HPLC-UV at 210 nm |
| Impurities in technical active substance: | HPLC-FID at 260°C |

**Summary for Propiconazole:**

| | Principle of method |
|---|---|
| Technical active substance as manufactured: | GC-FID packed column, internal standardization |
| Impurities in technical active substance: | GC-FID |

**Summary for tebuconazole:**

| | Principle of method |
|---|---|
| Technical active substance as manufactured: | GC-FID |
| Impurities in technical active substance: | GC-FID |

#### 2.2.4.2 Analytical method for determining the active substance and relevant component in the biocidal product

**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.**

Test item: 06LBCEOL20/2PT; Batch 16011520/2PT
Blank matrix: 69168920M; batch 080116M
Nominal content in pure active substances: 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 and 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**
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.

### 2.2.4.3 Analytical methods for determining relevant components and/or residues in different matrices

- **Summary for Cypermethrin:**

| Analytical methods for monitoring | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Matrix** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | | Range | Mean | RSD | | |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | 0.05 to 1.5 mg/Ln N=5, $r^2$>0.98 | the mean concentrations of the interfering components in the control samples did not exceed 30% of the LOQ | 80-94 | 89 | 6.6 | 0.05 | Wimbush, J (2003); 40/037-D2149 |
| | | | 0.5 mg/kg / 5 | | | 80-91 | 85 | 5.7 | | |
| | Oilseed rape (oil) | | 0.05 mg/kg / 5 | | | 87-94 | 89 | 3.0 | | |
| | | | 0.5 mg/kg / 5 | | | 76-82 | 79 | 3.4 | | |
| cypermethrin | Wheat grain | GC-ECD | 0.025 mg/kg / 5 | | | 71-93 | 84 | 9.7 | 0.025 | |
| | | | 0.25 mg/kg / 5 | | | *79-92* | *87* | *5.6* | | |
| | Wheat straw | | 0.025 mg/kg / 5 | | | *104-117* | *110* | *4.3* | | |
| | | | 0.25 mg/kg / 5 | | | *84-95* | *90* | *4.8* | | |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | | | *75-85* | *79* | *4.8* | 0.05 | *ILV Devine H., 2003 ; CLE 0040/037-03RO* |
| | | | 0.5 mg/kg / 5 | | | *78-88* | *85* | *5.1* | | |
| | Oilseed rape (oil) | | 0.05 mg/kg / 5 | | | *87-113* | *100* | *11.4* | | |
| | | | 0.5 mg/kg / 5 | | | *69-88* | *78* | *9.5* | | |
| | Wheat grain | | 0.025 mg/kg / 5 | | | *69-80* | *77* | *6.0* | 0.025 | |
| | | | 0.25 mg/kg / 5 | | | *64-80* | *72* | *9.1* | | |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | | | *93-106* | *98* | *5.9* | 0.05 | Confirmatory method of Wimbush, J (2003) by column replacement |
| | | | 0.5 mg/kg / 5 | | | *88-97* | *92* | *5.2* | | |
| | Oilseed rape (oil) | | 0.05 mg/kg / 5 | | | *73-80* | *75* | *3.8* | | |
| | | | 0.5 mg/kg / 5 | | | *76-82* | *78* | *3.4* | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Wheat grain | | 0.025 mg/kg / 5 | | | *101-106* | *105* | *2.0* | 0.025 | |
| | | | 0.25 mg/kg / 5 | | | *87-102* | *98* | *6.5* | | |
| | Wheat straw | | 0.025 mg/kg / 5 | | | *90-98* | *94* | *3.4* | | |
| | | | 0.25 mg/kg / 5 | | | *93-105* | *97* | *5.3* | | |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/L N=6 $R^2$>0.98 | No interference > 30% of LOQ in the control matrices. | *86-91* | *87* | *2.5* | *0.05* | Wimbush, J (2003); 40/041-D2149 Ion m/z 207 |
| | | | 0.5 mg/kg / 5 | | | *80-84* | *81* | *2.2* | | |
| | Bovine kidney | | 0.05 mg/kg / 5 | | | *95-103* | *100* | *3.0* | | |
| | | | 0.5 mg/kg / 5 | | | *84-89* | *87* | *2.3* | | |
| | Bovine liver | | 0.05 mg/kg / 5 | | | *83-87* | *85* | *2.1* | | |
| | | | 0.5 mg/kg / 5 | | | *81-90* | *86* | *4.5* | | |
| | Bovine fat | | 0.05 mg/kg / 5 | | | *78-84* | *82* | *3.5* | | |
| | | | 0.5 mg/kg / 5 | | | *93-101* | *97* | *3.7* | | |
| | Eggs | | 0.01 mg/kg / 5 | | | *80-87* | *83* | *3.9* | *0.01* | |
| | | | 0.1 mg/kg / 5 | | | *87-94* | *91* | *3.1* | | |
| | Milk | | 0.005 mg/kg / 5 | | | *84-106* | *92* | *9.7* | *0.005* | |
| | | | 0.05 mg/kg / 5 | | | *62-90* | *77* | *15.1* | | |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/L N=6 $R^2$>0.98 | No interference > 30% of LOQ in the control matrices. | *82-85* | *83* | *1.3* | *0.05* | *ILV Devine H., 2003 ; CLE 0040/041-03R* |
| | | | 0.5 mg/kg / 5 | | | *78-89* | *85* | *5.2* | | |
| | Bovine fat | | 0.05 mg/kg / 5 | | | *92-101* | *96* | *4.1* | | |
| | | | 0.5 mg/kg / 5 | | | *72-86* | *79* | *6.5* | | |
| | Eggs | | 0.01 mg/kg / 5 | | | *98-102* | *101* | *1.9* | *0.01* | |
| | | | 0.1 mg/kg / 5 | | | *84-86* | *85* | *1.1* | | |
| | Milk | | 0.005 mg/kg / 5 | | | *73-88* | *82* | *6.8* | *0.005* | |
| | | | 0.05 mg/kg / 5 | | | *91-101* | *96* | *4.3* | | |
| cypermethrin | Bovine | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 | No | *87-92* | *89* | *2.6* | *0.05* | Wimbush, J |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | muscle | | 0.5 mg/kg / 5 | mg/L N=6 $R^2$>0.98 | interference > 30% of LOQ in the control matrices. | *79-84* | *81* | *2.5* | | (2003); 40/041-D2149 Ion m/z 209 |
| | Bovine kidney | | 0.05 mg/kg / 5 | | | *97-106* | *103* | *3.3* | | |
| | | | 0.5 mg/kg / 5 | | | *85-89* | *87* | *2.1* | | |
| | Bovine liver | | 0.05 mg/kg / 5 | | | *83-104* | *92* | *9.2* | | |
| | | | 0.5 mg/kg / 5 | | | *87-91* | *89* | *1.8* | | |
| | Bovine fat | | 0.05 mg/kg / 5 | | | *80-88* | *83* | *3.7* | | |
| | | | 0.5 mg/kg / 5 | | | *91-99* | *95* | *5.2* | | |
| | Eggs | | 0.01 mg/kg / 5 | | | *80-84* | *82* | *2.5* | *0.01* | |
| | | | 0.1 mg/kg / 5 | | | *85-97* | *91* | *5.2* | | |
| | Milk | | 0.005 mg/kg / 5 | | | *82-105* | *90* | *10.8* | *0.005* | |
| | | | 0.05 mg/kg / 5 | | | *62-88* | *76* | *14.5* | | |

| **Analytical methods for soil** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| cypermethrin | GC-MSD Ion m/z 207 | 0.05 mg/kg / 5 | 0.005 to 1.0 mg/L, n=6, $r^2$>0.999 | No significant matrix interference (control values < 30% LOQ) | 99-105 | 101 | 2.3 | 0.05 | Wimbush, J (2003); 40/039-D2149 |
| | | 0.5 mg/kg / 5 | | | 99-101 | 100 | 1.0 | | |
| | GC-MSD Ion m/z 209 | 0.05 mg/kg / 5 | | | 98-104 | 101 | 2.4 | | |
| | | 0.5 mg/kg / 5 | | | *98-101* | *100* | *1.3* | | |

| **Analytical methods for water** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| cypermethrin | GC-ECD | 0.01 µg/L / 5 | 0.005 to 0.5 mg/L, n=6, $r^2$>0.99 | No significant matrix interference (control values < 30% LOQ) | 94-116 | 101 | 8.4 | 0.01 µg/L | Wimbush, J (2002); 40/040-D2149 |
| | | 0.1 µg/L / 5 | | | 84-94 | 89 | 4.6 | | |
| | GC-MSD | 0.01 µg/L / 5 | | | 89-108 | 93 | 7.6 | | |
| | | 0.1 µg/L / 5 | | | 79-97 | 88 | 7.8 | | |

| **Analytical methods for air** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| cypermethrin | GC-MSD (Ambient conditions) | 0.375 µg/$m^3$ | 0.01 to 0.3 µg/mL, n=6, $r^2$≥0.98 | No significant matrix interference (control values < 30% LOQ) | - | 80 | 8.6 | 0.375 µg/$m^3$ | Wimbush, J (2005); 1669/016-D2149 |
| | | 3.75 µg/$m^3$ | | | - | 110 | 12.0 | | |
| | GC-MSD (Elevated conditions) | 0.375 µg/$m^3$ | | | - | 89 | 11.0 | | |
| | | 3.75 µg/$m^3$ | | | - | 99 | 3.9 | | |

| **Analytical methods for animal and human body fluids and tissues** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Not required | | | | | | | | | |

Methods for body fluids and tissues and food and feeding stuffs of plant origin are not required since cypermethrin is not classified as toxic or highly toxic and as the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

- **Summary for Propiconazole:**

| Sample | Test substance | Analytical method | Fortification range / number of measurements altogether | Specificity | Recovery rate (%) | | | Limit of determination | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Range | Mean | St. dev % | | |
| soil | parent compound | REM 130.02/REM 11/81 GLC, P/N detector | 0.04 – 0.4 mg/kg N=35 | Parent compound | 78 - 88 | 86 | 12 | 0.02 mg/kg | A4.2 / 01 Forrer, K., 1991 |
| soil | parent compound | RUE 8-86 GLC, P/N detector | 0.05 – 2.0 mg/kg N>12 | Parent compound | 75 - 112 | | 4-20 | 0.02 mg/kg | A4.2 / 02 Anonymous, 1986 |
| soil | parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole) | AG-677, separation HPLC, detection LC/MS-MS | 5-50 ng/kg N= 10<br>N= 10 | Parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole) | 86 – 110<br>88 - 105 | 94<br>94 | 8<br>5.4 | 0.005 mg/kg | A4.2 / 17A Vargo J.D., 1997<br>A4.2 / 17B Cassidy P., 2004 |
| soil | total 2.4-DCBA moiety | AG 465 Capillary GLC (ECD) | 0.05 – 0.5 mg/kg N=8 | DCBA | Not determined | 85 | 15 | 0.05 mg/kg | A4.2 / 04 Perez, R., 1985 |
| soil | free 1.2.4-triazole | REM 130.03 HPLC, 2-column switch;UV detection | 0.02 – 0.1 mg/kg N=18 | 1,2,4-triazole | 82 - 83 | 82 | 10 | 0.01 mg/kg | A4.2 / 05 Formica, G., 1991 |
| soil | free 1.2.4-triazole | REM 130.04, HPLC, 2 column switch, UV | 0.02 – 0.1 mg/kg N=8 | 1,2,4-triazole | Identical for different | 74 | 11 | 0.01 mg/kg | A4.2 / 06 Formica, G., 1992 |

| Sample | Test substance | Analytical method | Fortification range / number of measurements altogether | Specificity | Recovery rate (%) | | | Limit of determination | Reference |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | Range | Mean | St. dev % | | |
| | | detection | | | fortification levels | | | | |
| soil | CGA 118 244 | REM 130.10, LC-LC-ESI/MS/MS | 0.005 – 0.05 (sandy loam and silty clay) N=20 | CGA 118 244 | 98 - 118 | 103 | 6 | 0.005 mg/kg | A4.2 / 08 Tribolet, R., 2001 |
| potable water | Parent compound | REM 10/86 GLC, electron capture detector (ECD) | 0.1 / 0.5 / 2.0 µg /L N=28 | Parent compound | 70 – 110 | 90 | 7 | 0.05 µg/L | A4.2 / 09 Formica, G.; 1986 |
| potable water & surface water | parent compound | GC-MS, confirmatory method to REM 10/86 | 0.05 – 0.5 µg /L N=20 | Parent compound | 76-108 | Within 70 - 110 | < 20% | 0.05 µg/L | A4.2 / 10B Pointurier R. – Duchêne P., 2000 |
| air | parent compound | REM 130.07 GLC; N/P detector | 10/20/100 µg/m$^3$ N=6 | Parent compound | 70 - 110 | 96 | 10 | 10 µg/m$^3$ | A4.2 / 11 Tribolet, R., 1992 |
| air | parent compound | GC-MS, confirmatory method to REM 130.07 | 10 – 100 µg/m$^3$ N=2 | Parent compound | 70 - 110 | Within 70 - 110 | - | 10 µg/m$^3$ | A4.2 / 11B Pointurier R. – Duchêne P., 2000 |
| sediment | Parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735 | AG-630, separation HPLC, detection LC/MS-MS | 10/25/100/250 ng/kg N = 9 | Parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735 | 84-107 | 96 | 6.8 | 10 µg/kg | A4.2 / 18 Vargo J.P., 1994 |

Methods for body fluids and tissues and food and feeding stuffs of plant origin are not required since propiconazole is not classified as toxic or highly toxic and as the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

- **Summary for tebuconazole:**

| Sample | Test substance | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of determination | Reference |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Range | Mean | Relative standard deviation | | |
| **Soil** | Tebu-conazole | DFG Method S19 (extended and revised): GC with nitrogen/phos-phorus detector (NPD) and mass selective detector mass selective detector (MSD). | Fortification experiments were performed at 0.01 and 0.1 mg/kg. Fortified specimen were analysed in quintuple for each fortification level. For confirmation analysis one fortified specimen for each level was analysed. | Single measurement of nine concentrations ranging from 0.100 to 2.01 µg/ml. Correlation coefficient: 1.0000. | No significant interferences from the sample matrix were detected at the retention time corresponding to tebuconazole in any of the control samples. | Mean recoveries were 100% for 0.01 mg/kg with single values ranging from 94 – 105%, and 94% for 0.10 mg/kg with single values ranging from 92 – 95%. Relative standard deviations: 4.3% for 0.01 mg/kg and 1.2% for 0.1 mg/kg.<br>Confirmation analysis: the recoveries obtained were 98% for 0.01 mg/kg and 101% for 0.10 mg/kg. | | | Limit of determination: 0.01 mg/kg; limit of detection: 0.002 mg/kg. | Weeren and Pelz, 2000a |

| Sample | Test substance | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of determination | Reference |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Range | Mean | Relative standard deviation | | |
| **Air** | Tebuco-nazole | GC with nitrogen and phosphorous detection (NPD).<br>For confirmation GC with mass selective detection (MSD) was used | GC-NPD:<br>Fortification experiments were performed over the range from 0.0011 to 0.142 mg a.s. /m³.<br>Results were obtained from four tests for each fortification level.<br>GC-MSD:<br>Two fortification experiments were performed at 0.0021 mg a.s. /m³ | GC-NPD:<br>Single measurement of nine concentrations ranging from 0.017 to 1.701 mg/l.<br>Coefficient of determination: 0.998640.<br>GC-MSD:<br>Single measurement of five concentrations ranging from 0.0872 to 0.8715 mg/l.<br>Correlation coefficient: 0.9920. | GC-NPD:<br>No significant interferences found.<br>GC-MSD:<br>Blank values of control samples were about 1% of the LOQ level. | GC-NPD:<br>Recovery rates were determined for two different adsorption materials under defined climatic conditions.<br>Range of mean recoveries: 94 to 104%;<br>Relative standard deviation: 2.0 to 6.3%<br>GC-MSD:<br>The concentration of tebuconazole in the two spiked samples (evaluated against the linearity) could be calculated with 0.3175 and 0.3235 µg/ml, representing a mean recovery of 110% of the spiked amount in theory. | | | 0.0011 mg a.s./m$^3$ air | Riegner, 1992 (GC-NPD) and Hellpointner (GC-MSD), 2000 |

| Sample | Test substance | Analytical method | Fortification range / Number of measurements | Linearity | Specificity | Recovery rate (%) | | | Limit of determination | Reference |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Range | Mean | Relative standard deviation | | |
| **Water** surface water | Tebu-conazole | GC-MSD (DFG W5) | Fortification levels: 0.05 and 0.5 µg/l. Fortified samples were analysed in quintuplet for each fortification level. | Single measurement of eight concentrations ranging from 0.00503 to 0.670 mg/l. Correlation coefficient: r = 0.9994 ($r^2$ = 0.9988) | No significant interferences from the sample matrix were detected at the retention time corresponding to tebuconazole in any of the control samples. | Mean recoveries were 97% for 0.05 µg/l with single values ranging from 85 to 105% and 86% for 0.5 µg/l with single values ranging from 75 to 93%. Relative standard deviations: 8.0% for 0.05 µg/l and 7.8% for 0.5 µg/l. | | | Limit of determination: 0.05 µg/l, limit of detection: 0.02 µg/l. | Weeren, and Pelz, 2000b |
| **Animal and human body fluids and tissues** | Relevant only for toxic substances | | | | | | | | | |

Methods for body fluids and tissues and food and feeding stuffs of plant origin are not required since tebuconazole is not classified as toxic or highly toxic and as the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

### *2.2.5 Risk assessment for Physico-chemical properties*

No risk assessment for physico-chemical properties was performed.

### *2.2.6 Efficacy against target organisms*

#### 2.2.6.1 Function and field of use

MG 02: preservatives
Product Type 08: wood preservative

The product V33 TRAITEMENT MULTI USAGES (development code 06 LBCEOL 20/2 PT) is a water-based wood preservative product ready to use which is intended to be used by superficial application for preventive and curative treatments. For curative treatment, superficial application can be completed by injection.

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

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

The product V33 TRAITEMENT MULTI USAGES (development code 06 LBCEOL 20/2 PT) is intended to be used

- for preventive treatment by superficial application for wood used in use classes 1 to 3 and,
- for curative treatment by superficial application (that could be completed by injection), for wood in service, indoor and outdoor.

The application rates recommended by the applicant are the following:

- Preventive treatments: superficial application at 200 g of product 06LBCEOL20/2PT / m² of wood
- Curative treatment: superficial application at 300 g of product 06LBCEOL20/2PT / m² of wood (+ injection 150 g of product 06LBCEOL20/2PT / m² of wood if need be).

#### 2.2.6.3 Effect on target organisms and efficacy

According to the uses claimed by the applicant, the product V33 TRAITEMENT MULTI USAGES is intended to be used for the preservation of wood in use class 1 to 3 by superficial application against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), wood rotting fungi (*Coniophora puteana, Gloephilum trabeum, Poria Placenta* and *Coriolus versicolor*) and termites (*Reticulitermes spp.* and *Heterotermes spp.*). The termite species *Coptotermes spp*. has been withdrawn during the evaluation.

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*. and *Heterotermes spp*.), indoor and outdoor, by superficial application, completed by injection if need be.
The claim of curative treatment against wood rotting fungi presented in the dossier is not supported by efficacy data. Furthermore, the attack of fungi results in a degradation of the structure of the wood that changes its mechanical properties. This use is therefore not considered as relevant.

The development stages claimed are larvae and adults.

All efficacy studies are presented in annex 9.

### 2.2.6.4 Mode of action including time delay

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon (see AR for Cypermethrin PT08, 12/07/2012).
As other triazole fungicides, tebuconazole and propiconazole are DMIs (DeMethylation Inhibitors). These substances inhibit the C14 demethylation step in the ergosterol biosynthesis of fungi (Fungicide Resistance Action Committee, FRAC2)

There is no time delay between the application of the product and the beginning of the preventive fungicidal and insecticidal activities. The effect is immediate
Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the product demonstrated a slow action on *Hylotrupes bajulus* and a deffered effect on *Anobium punctatum.*

### 2.2.6.5 Occurrence of resistance - resistance management / Unacceptable Effect

Resistance to pyrethroid insecticides such as cypermethrin has been reported for a number of pests both in agriculture and public health. However, no data has been found in the literature regarding resistance occurrence to cypermethrin among wood-boring beetle and termites.

Tebuconazole and Propiconazole are DeMethylation Inhibitor (DMI) fungicides within Sterol Biosynthesis Inhibitor (SBI) Class I. According to the FRAC Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others. It is generally accepted that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium (Resistance management required).
For wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

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.

### 2.2.6.6 Evaluation of the label claim

French competent authorities (FR CA) assessed the product 06LBCEOL20/2PT and concluded that the product shows a sufficient efficacy for the preservation of wood. The product is used:

- for the preventive control of wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), wood rotting fungi (*Coniophora puteana*, *Gloephilum trabeum*, *Poria Placenta* and *Coriolus versicolor*) and termites (*Reticulitermes spp*. and *Heterotermes spp*.), in use class 1 to 3 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.* and *Heterotermes spp.*), indoor and outdoor, by superficial application, completed by injection if need be.

The application rates validated are the following:

- Preventive treatments: superficial application at 200 g of product 06LBCEOL20/2PT / m² of wood
- Curative treatment: superficial application at 300 g of product 06LBCEOL20/2PT / m² of wood (injection 150 g of product 06LBCEOL20/2PT / m² of wood if need be).

### 2.2.6.7 Summary of efficacy assessment

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product V33 TRAITEMENT MULTI USAGES (06 LBCEOL 20/2 PT) according to the uses and the application rates claimed:

- Regarding the claim against wood rotting fungi, according to EN 113 (+EN73/EN84), the product 06LBCEOL20/2PT is efficient, for superficial application, against wood rotting fungi (brown rot and white rot) for use class 2 and 3 at the application rate of 200 g of product 06LBCEOL20/2PT / m² of wood. As for use class 3, the demonstration of the efficacy is based on the EN 113 standard. In that case, the use of a top coat is required according to the EN 599[2] (§5.2.17 & §5.2.18). Consequently, it can be concluded that, for preventive superficial application on wood for use class 3, a top coat has to be applied.
- Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product 06LBCEOL20/2PT is efficient according to respectively EN 46 (+EN73/EN84), EN 49 (+EN73/74) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus* for use class 1 to 3 at the application rate of 200 g of product 06LBCEOL20/2PT / m² of wood.
- Regarding the preventive efficacy claim against termites, for superficial application, the product 06LBCEOL20/2PT is efficient according to EN 118 (+EN73/EN84), against *Reticulitermes spp* and *Heterotermes spp*., for use class 1 to 3, at the application rate of 200 g of product 06LBCEOL20/2PT / m² of wood.
- Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product 06LBCEOL20/2PT is efficient according to respectively EN 1390 and EN 370 (+EN73) against *Hylotrupes bajulus* with a slow action activity and against *Anobium punctatum* with a differed activity, at the application rate of 300 g of product 06LBCEOL20/2PT / m² of wood. According to EN 141428[3], if curative treatment against Lyctus brunneus is demanded, a curative wood preservative "for *Hylotrupes* and *Anobium*" should be applied. The curative efficacy against wood boring beetles is then validated.
- Regarding the curative efficacy claim against termites (*Reticulitermes spp.* and *Heterotermes spp.*), no curative efficacy standard are available against termites. However, the objective of curative products are, as for the preventive treatments against termites (tested following the standard EN 118 + EN73/84), to protect wood against termites and to eliminate termites in the wood. Their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application.
- Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection and in combination with a superficial treatment, at the application rate of 150 g of product 06LBCEOL20/2PT / m² of wood prior a superficial treatment at 300g/m² is validated.

[2] Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class.

3 Performance criteria for curative wood preservatives as determined by biological tests (2004)

## *2.2.7 Risk assessment for human health*

### 2.2.7.1 Assessment of effects on Human Health

#### *2.2.7.1.1 Toxicology of the active substance*

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 “Toxicology and metabolism” must be taken into consideration.

- ***Cypermethrin***

**ADME**

Absorption of cypermethrin cis:trans/40:60 from the gastro-intestinal tract of the rat is rapid but incomplete. Urinary and faecal excretion was similar at the low dose (3 mg/Kg bw) for both the cyclopropyl and phenyl ring radiolabels but at the higher dose (50 mg/Kg bw) faecal excretion predominated, especially in the males. This suggests that the absorption of cypermethrin is being saturated at the high dose. At the low dose 51.3 to 52.8% of the dose was absorbed by the male rats and 43.6 to 57.6% in case of the females. At the high dose level, 28.7 to 31.5% of the dose was adsorbed in male rats and 38.4 to 42.7% in the case of the females. For the estimation of oral absorption, a conservative approach is adopted. Different values were adopted for animals and humans, based on the low dose (3 mg/Kg bw) data of the Needham study (2006). For animals, an oral absorption value of 44% is adopted for deriving systemic NOAELs (PODs for the AELs are closer to the low dose rather than the high dose). For the estimation of human systemic exposure, an oral absorption value of **57%** is adopted.

Distribution. Following repeated daily oral dosing of 3 mg [14C-phenyl]-cypermethrin/Kg bw, the levels of radioactivity in inguinal and peri-renal fat rose by 6-7 times in the female rats, and by >10 times in the males. The lowest levels of radioactivity were seen in the brain and spinal cord. The tissue residues were rapidly cleared following the cessation of dosing, with the levels of radioactivity in the plasma falling by approximately 30 times over a 7 day period (for both males and females), and the levels in the fat falling by 2-7 times: in males in peri-renal fat (2-fold), and in females in brown fat (7-fold).

Excretion. The excretion was rapid being virtually complete by 72 h following a single oral dose of [14C-cyclopropyl]- or [14C-phenyl]-cypermethrin at a dose of 3 or 50 mg/Kg bw. Urinary and faecal excretion was similar at the low dose for both radiolabels, but at the higher dose level faecal excretion predominated, especially in the males.

Metabolism. Hydrolytic cleavage of the ester bond and elimination of the cis- and trans-cyclopropanecarboxylic acid and 3-phenoxybenzyl moieties in the free and conjugated form is known to be a major route of metabolism in mammals, including humans. The cyclopropane carboxylic acid moiety is mainly and rapidly excreted as the glucuronide conjugate, with only limited hydroxylation of the methyl groups attached to the cyclopropane ring. The 3-phenoxybenzyl moiety is mainly converted to 3-phenoxybenzoic acid which is further metabolised to a hydroxyl derivative (3-(4’-hydroxyphenoxy)benzoic acid) and conjugated with glucuronic acid or sulphate. The major route of excretion of metabolites is via the urine. In faeces, most of the radioactivity is unchanged compound. The metabolism of cypermethrin cis:trans/40:60 is stereoselective with a preference for the trans-isomers (human and animal data).

**Acute toxicity**

The oral toxicity of cypermethrin cis:trans/40:60 varies with the type of vehicle used and the isomer ratio. In general, aqueous suspensions were the least toxic and non-polar solutions the most toxic. The acute toxicity of the racemic mixture is also determined by the isomer ratio, with the cis-isomer found the most toxic (WHO, 1989). Oral LD50 values vary from 250 mg/Kg (in oil) to >5000 mg/Kg (in aqueous solutions). Inhalation LC50 = 3281 mg/m3 (4h, aerosol, rat). Nevertheless, the toxic responses in all species were found to be qualitatively similar. The clinical signs observed after oral and inhalation exposure were indicative for an action on the central nervous system and consisted of salivation, ataxia, splayed gait, hyper-excitability to auditory stimuli, tremors, convulsions, choreoathetosis. These neurotoxic signs, better known as CS-syndrome, appear within 1 hour after dosing and survivors recover within 10-12 days. Transient facial sensory symptoms can appear

after cypermethrin exposure. Abnormal facial sensations (burning sensations, tingling, tightness or numbness on the face) are reported in open literature, e.g. in health surveys (workers engaged in packaging cypermethrin), cross sectional surveys (field operators, spraymen). Cypermethrin cis:trans/40:60 was found of low dermal toxicity in the rat with clinical signs characterised by dyspnea, ruffled fur, curved and ventral body position. Dermal LD50 > 2000 mg/Kg bw (rat).
In conclusion, cypermethrin cis:trans/40:60 is of moderate acute oral and inhalation toxicity, but of low dermal toxicity.

**Irritation**
Cypermethrin cis:trans/40:60 is slightly irritant to the rabbit skin and eye, but does not require classification. Acute toxicity and repeated dose toxicity studies performed with rats revealed that cypermethrin cis:trans/40:60 has a respiratory irritation potential. Respiratory tract irritation caused by cypermethrin is characterised by cough, mild dyspnoea, sneezing, and rhinorrhea. This is confirmed with human data. Case reports reported shortness of breath, dyspnea, wheezing, cough, congestion, nasal discharge, burning eyes, after exposure (inhalation) of cypermethrin with the development of significant pulmonary dysfunction (still complaining of cough, congestion, wheezing) 7 months post-exposure.

**Sensitisation**
Cypermethrin cis:trans/40:60 was not found to be a skin sensitizer by animal testing (LLNA). However, there are indications, from both animals and humans, that technical cypermethrin may have a mild skin sensitising potential. Results from preliminary experiments performed with technical cypermethrin (50:50) in rats indicated that technical cypermethrin had a weak skin sensitising potential. In addition, skin sensitisation (contact sensitivity and eczema) in humans is occasionally reported.

**Short/Medium-term toxicity**
The medium-term dermal toxicity of cypermethrin cis:trans/40:60 was studied in a 21-day dermal toxicity study in rabbits. This resulted in irritation of the skin and was associated with systemic effects such as focal liver necrosis. NOAEL = 20 mg/Kg bw/d.

The medium-term oral toxicity of cypermethrin cis:trans/40:60 was studied in rats and dogs. The central nervous system and the liver were detected as the target tissue/organ. Neurotoxicity was characterised by clinical signs including piloerection, nervousness and uncoordinated movements, ataxia, splayed gait and hyperesthesia. In the dog, clinical signs of neurotoxicity were observed at 37.5 mg/Kg bw/d in a 90-day study (NOAEL = 12.5 mg/Kg bw/d). In the rat, clinical signs of neurotoxicity were observed at 80 mg/Kg bw/d in a 90-day study (NOAEL = 20 mg/Kg bw/d). In rats, neurotoxicity was confirmed by histopathology by peripheral nerve damage. (not in dogs). In addition, body weight was reduced, liver weight increased, and rats presented signs of anemia. In the open literature liver toxicity was characterised by inhibition of the rat liver ATPase activity. The oxidative stress induced by cypermethrin cis:trans/40:60 in the cerebral and hepatic tissues was evidenced by enhanced lipid peroxidation. Additionally, a decrease in delayed type hypersensitivity, leucopenia and immunotoxicity were observed when rats were dosed cypermethrin orally for 90 days at doses of 40 mg/Kg bw/d (NOAEL = 10 mg/Kg bw/d.

NOAEL medium-term = NOAEL (90-days, oral, dog) = 12.5 mg/Kg bw/d.

**Long-term toxicity**
The long-term oral toxicity of cypermethrin cis:trans/40:60 was studied in rats. The effects were in line with those observed in the medium-term studies. The central nervous system, liver, and kidneys were detected as the target tissues/organ. Hepatotoxicity was characterised by increased liver weight associated with microsomal enzyme activity induction, but not associated with histological lesions. Increased kidney weight was associated with an increase in blood urea.

NOAEL long-term = NOAEL (2-year, oral, rat) = 5 mg/Kg bw/d.

**Carcinogenicity**

Cypermethrin cis:trans/40:60 was tested in a combined chronic toxicity / carcinogenicity study in the rat. The overall results revealed no effect of cypermethrin cis:trans/40:60 treatment (0.05, 0.5, 5, 50 mg/Kg bw/d, orally) on the number and type of tumours.

**Genotoxicity**
Cypermethrin cis:trans/40:60 was found negative for genotoxic effects in in vitro bacterial and mammalian cell test systems (bacterial reverse gene mutation assay, mammalian gene mutation assay in L5178Y mouse lymphoma cells, mammalian chromosomal aberration study on CHO-cells). In vivo, cypermethrin cis:trans/40:60 did not produce micronuclei in the immature erythrocytes of the mouse bone marrow micronucleus assay (single oral dose), and was, therefore considered negative for mutagenicity.

Overall, the open literature provides inconsistent evidence of genotoxicity in vitro as well as in vivo. The data reported on the genotoxicity of cypermethrin cis:trans/40:60 are rather inconsistent, depending on the genetic system or the assay used. Most of these studies were not performed according to accepted guidelines. Additionally, they lack reliability because of procedural flaws such as deviating route of administration, single versus repeated exposure, other sampling times, no use of positive controls, no 2nd or 3rd confirming experiments, no data about reaching the target organ. Nevertheless, the modest or marginal increases in DNA damage reported in some studies in peripheral lymphocytes or other cells indicate, at least to a limited extent, potential genetic hazards posed by cypermethrin cis:trans/40:60, and emphasize the need and the importance of protective measures and safety regulations to minimize exposure to cypermethrin cis:trans/40:60.

Although the genotoxicity studies on cypermethrin cis:trans/40:60did not exclude a potential for DNA damage, the global weight-of-evidence suggests that cypermethrin cis:trans/40:60 should not be considered a genotoxicant, and thus, no classification as a Category 3 mutagen is warranted. In addition, there was no evidence of carcinogenicity. Also in other repeated-toxicity studies, there was no evidence of proliferative lesions, which would possibly occur if cypermethrin cis:trans/40:60 would display aneuploidogenic or polyploidogenic properties in vivo.

**Reproductive and developmental toxicity**
The teratogenicity studies involving oral administration of cypermethrin cis:trans/40:60 during organogenesis at dosages up to 70 mg/Kg bw/d in rats and up to 120 mg/Kg bw/d in rabbits were without adverse effects upon the progress and outcome of gestation.

A three-generation study involving administration of the substance in the diet of the rat showed that cypermethrin cis:trans/40:60 exerts no effect on the different reproduction parameters or on the survival of the offspring. NOAELparental= 10 mg/Kg bw/d; NOAELreproductive= 50 mg/Kg bw/d; NOAELdevelopmental= 10 mg/Kg bw/d.

According to the open literature, cypermethrin cis:trans/40:60induced functional impairments at the neurotransmitter receptor levels in neonatal rats. However, since the multi-generation reproduction study in rats was without any indication of persistent effects in the offspring, which were also exposed to cypermethrin cis:trans/40:60 neonatally, it is suggested that receptor binding changes are not predictive or causally related to the behavioural changes. Moreover, the most vulnerable phase for humans during the brain growth spurt is prenatal and not post-natal as in rodents. Therefore, exposure of the human fetus will be limited by maternal pharmacokinetics as well as maternal toxicity. The decreased male fertility seen in the rat and rabbit as demonstrated in the open literature appeared to be an indirect effect as it was caused at cypermethrin cis:trans/40:60 doses inducing clear general toxicity.

Based on the available data, it can be concluded that there is no evidence giving rise to concern for an additional risk for the newborn or young humans that should trigger further investigations.

**Neurotoxicity**
Cypermethrin has a neurotoxic potential. Repeated oral dosing of adult laying hens with 1000 mg/Kg cypermethrin cis:trans/40:60 produced no immediate or delayed signs of poisoning, nor any histopathological lesions in the nervous system. However, the hen sciatic nerve is not suitable for studying pyrethroid-induced

nerve damage. In contrast with hens, rats treated with a single dose of cypermethrin cis:trans/40:60 (60 mg/Kg bw) showed behavioral changes indicating a broad neurological activity of cypermethrin. A NOAEL was observed at 20 mg/Kg bw. The clinical signs observed are characteristic for the acute poisoning with a type II pyrethroid: choreoathetosis accompanied by salivation (CS syndrome). In the rat, cypermethrin cis:trans/40:60 also produces epileptic activity during repeated administration. The neurotoxic effect of cypermethrin cis:trans/40:60 on peripheral nerves (axons, endoneurium) was highly correlated with exposure time. Cypermethrin cis:trans/40:60 exerts its toxicity by opening the voltage-gated sodium channel slowly for extended times, leading to a prolonged sodium current in the target neurons. Furthermore, the decrease in the Na+, K+-ATPase pump activity is involved in the paroxysmal epileptic activity induced by cypermethrin cis:trans/40:60. Cypermethrin cis:trans/40:60 also inhibits GABAA receptors.

**Other: Immunotoxicity**
Cypermethrin cis:trans/40:60 causes immunosuppression: both the humoral and cell-mediated immune response are impaired by cypermethrin.

**Other: Endocrine disruption activity**
The estrogenic potential of cypermethrin cis:trans/40:60 based on ER-mediated mechanisms remains equivocal. Contradictory results were revealed in different studies. In summary, the estrogenic and antiandrogenic effect of cypermethrin cis:trans/40:60 (and pyrethroids in general) depend on the assays or cells used. Results indicate that data obtained with high concentrations (> 10 µM) should be interpreted carefully (solubility of test chemical, cell toxicity). Possibly, cypermethrin cis:trans/40:60 is an oestrogen-like chemical that might act through signalling pathways other than direct ER binding, and as such, might function as an endocrine modulator. However, at present no definite conclusions can be drawn.

The relevant critical endpoints of cypermethrin cis:trans/40:60 in the toxicological studies are identified as the effect on the central nervous system, characterised by clinical signs (CS syndrome) and peripheral nerve damage; a decrease in delayed type hypersensitivity; and the effect on the liver, characterised by increase in organ weight associated with increased microsomal enzyme activity. The NOAELs have been derived from the studies in the most sensitive species showing these effects. It is suggested to consider these effects in the risk assessment. The following AEL were proposed:

| Reference dose | Value (mg/kg bw/day) | Study | NOAEL (mg/kg bw/day) | Uncertainty Factor | Oral absorption |
|---|---|---|---|---|---|
| Long-term AEL | 0.022 | 2-year rat study | 5 | 100 | 44% |
| Medium-term AEL | 0.055 | 90-days dog | 12.5 | 100 | 44% |
| Short-term AEL | 0.088 | Acute delayed neurotoxicity in rat | 20 | 100 | 44% |

- ***Propiconazole***

Propiconazole is moderately toxic with an oral acute LD50 of 1500 mg/kg bw/day and it is as skin sensitizer. Based on the test results propiconazole is a moderate sensitizer according to the potency categorisation described in the Guidance on the Application of the CLP Criteria, 2011.

The liver is the main target organ of propiconazole toxicity. Increased liver weights and slight histopathological changes in the liver were seen already in short term studies. Mice were more sensitive than rats to the liver toxicity elicited by propiconazole; male mice were particularly susceptible to hepatotoxicity. Long-term feeding

studies in mice, including re-examination of tissue samples of the original study and additional testing in male mice only, showed neoplastic changes of the liver in male mice.

Mechanistic studies, including liver enzyme induction and hepatic cell proliferation properties, indicate that propiconazole is only to a certain degree comparable to phenobarbital as a hepatotoxic substance. Propiconazole is a strong inducer of xenobiotic metabolism and a tumour promoter in rodents which probably explains the induction of tumours in male mice. It may be presumed that rodents are more susceptible than humans to the hepatotoxicity of propiconazole. The overall chronic NOAEL in mice, based on hepatoxicity, was 10 mg/kg bw/day. The NOEL for hepatotoxicity in the 2-year rat study was 18 mg/kg bw/day, and the NOAEL was 3.6 mg/kg bw/day, based on changes in body weight and food conversion, changes in hematology and blood glucose, and adrenal weight changes. The overall NOAEL for chronic effects, 3.6 mg/kg bw/day in the 2-year rat study, covers liver toxicity in both rats and mice.

Propiconazole was not genotoxic in vitro or in vivo in the supplied tests.

A slight increase in the incidence of cleft palate was observed in rat teratogenicity studies. The low incidences of this rare malformation were not clearly treatment-related and occurred at dose levels causing marked maternal toxicity. It was therefore concluded that the effect seen in rats is probably occasional. The lowest relevant NOAEL for developmental effects was 30 mg/kg bw/day in rats, based on a slight increase in cleft palate and increased visceral and skeletal variations in a teratology study in rat.

Results of a two-generation study in rats included, in addition to hepatotoxicity in parental animals at low dose levels, slight reproductive effects at a high dose (reduced litter sizes and pup weights, reductions in testes/epididymides weights). The lowest relevant NOAEL in the 2-generation study was 8 mg/kg bw/day, based on liver toxicity in parental animals.

Three reference doses for the systemic toxicity of propiconazole can be defined, with relevance to the assessment of risks associated with exposure to a preservative for polymerized materials. The risks are related to the length of exposure and take into account the most relevant adverse health effects expected on the basis of animal studies.

The reference values are applicable both to primary (direct) exposure in professional and non-professional use, as well as secondary (indirect) exposure with intentional or unintentional exposure to the treated products. The reference values are based on systemic NOAELs from oral dosage studies in experimental animals; factors contributing to the determination of the systemic dose at different exposure routes (e.g. oral, dermal and pulmonary absorption) should therefore be considered at risk assessment. Toxicokinetic studies in rat show that 86% is absorbed within 48 h after oral administration. Correction for bioavailability is therefore not considered necessary.

The reference doses and the relevant NOAEL-values from which they are derived are summarised in the following table:

| **Reference dose** | **Value (mg/kg bw/day)** | **Study** | **NOAEL (mg/kg bw/day)** | **Uncertainty Factor** | **Relevance for risk assessment** |
|---|---|---|---|---|---|
| Long-term AEL | 0.04 | 2-year rat study | 3.6 | 100 | long-term exposure |
| Medium-term AEL | 0.08 | 2-generation rat study | 8 | 100 | repeated exposure (few weeks per year or frequent exposure) |
| Short-term AEL | 0.3 | developmental toxicity study in rat | 30 | 100 | acute exposure (single dose or a few days of exposure) |

- ***Tebuconazole***

The **ADME** studies show that oral administration of tebuconazole is followed by a rapid and extensive absorption in the rat. Thus no correction for incomplete oral absorption is necessary in the risk assessment. The substance is quickly distributed throughout the body tissues with the highest level found in the liver. The majority of the administered dose is excreted in the faeces and enterohepatic circulation is expected. There are no indications of accumulation in any tissue. The metabolic study revealed sex differences for example in the excretion of the toxicologically relevant metabolite 1H-1,2,4-triazole amounting 5% in the urine of the male and 1.5% in that of the female. There are no toxicokinetic studies available in other animal species used in the toxicological studies that is dogs, cats, mice, guinea pigs and rabbits nor studies using the dermal route of exposure.

In a dermal absorption study in the rat around 50% of the test substance was absorbed within 8 hours.

In **acute toxicity studies,** tebuconazole was found to be of rather low toxicity by the oral route and of low toxicity by inhalation and dermal application when the rat is used as the test species.

Tebuconazole has no potential for **skin or eye irritation** and is not **sensitising** to the skin in the Magnusson-Kligmann maximisation test or in the Buehler Patch test.

Several **short-term and long-term tests** were submitted and the dog was again found to be the most sensitive animal tested and the only species showing potential for opacities of the eye lenses. Other effects observed in both rats and dogs were minor effects in the liver in the form of slightly increased weights, enzyme induction and decreased plasma glyceride levels as well as vacuolisation of the *zona fasciculata* cells of the adrenals.

No evidence for **genotoxic** potential as no indication of gene mutations, chromosome anomalies or increases in DNA-repair activity were noted in an adequate battery of *in-vitro* and *in-vivo* assays with various endpoints including both prokaryotes and eukaryotes.

Two 21-months combined chronic toxicity/carcinogenicity studies were conducted in mice. At the highest dose, pronounced liver toxicity and an increased incidence of liver tumours were seen. This tumorigenic potential is not considered relevant to humans as it is only found in a sensitive mouse strain and at very high dose levels above the maximum tolerated dose.

In a two-year combined chronic toxicity/carcinogenicity study in rats there was no evidence for carcinogenicity with relevance to humans.

In the **developmental toxicity studies** foetotoxic effects were revealed in all three animal species tested. The developmental toxicity occurred at doses that are associated with some maternal toxicity, however, the toxicity to the dams could not in all cases be categorised in severity to a degree that would influence the development of the offspring via non-specific secondary mechanisms to effects such as malformations (e.g. peromelia in rabbits).

Impaired spatial cognitive learning was observed during development but no corresponding neuropathology could be found in a developmental neurotoxicity study in rats.

The AOEL was derived from the one-year study in dogs where unspecific effects like histopathological alterations in the adrenal cortex were found. The NOAEL for this effect was 3 mg/kg bw/day. An uncertainty factor of 100 will be applied to the NOAEL for these nonspecific toxicological effects.

Therefore the values that will be used as basis for the risk characterisation is:

**NOAEL = 3 mg/kg bw/day** and **AOEL** = **0.03 mg/kg bw/day**

#### *2.2.7.1.2 Toxicology of the substance(s) of concern*

Active substances acting as co-formulants in the product, have been identified in V33 TRAITEMENT MULTI USAGES: 2-methyl-3(2H)-isothiazolone (MIT) and 1,2 benzisothiazol-3(2H)-one (BIT). However, these substances have not been considered SoC since they are present in the biocidal product at a concentration below 0.1% (0.0025% for MIT and BIT).

#### *2.2.7.1.3 Toxicology of the biocidal product*

The toxicology of the biocidal product was considered appropriately according to standard requirements.
The basis for the health assessment of the biocidal product is laid out in Annex 5 “Toxicology – biocidal product”.

#### *2.2.7.1.4 Percutaneous absorption*

The ability of cypermethrin, propiconazole and tebuconazole to penetrate the skin was examined *in vitro* with the 06LBCEOL20/2PT formulation (code name for V33 TRAITEMENT MULTI USAGES) containing 14C-cypermethrin at 1.7 g/L, 14C-propiconazole at 1.3g/L and 14C-tebuconazole at 1.4 g/L.
For the three active substances, over 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, all tape strips were excluded from absorption calculation.
The mean *in vitro* dermal absorption in the 06LBCEOL20/2PT formulation was 1.7 ± 0.52%, 1.78 ± 1.09% and 4.7 ± 1.55% for cypermethrin, propiconazole and tebuconazole respectively.
According to the EFSA guidance on dermal absorption (2012), as the standard deviation is larger than 25% of the mean of the absorption, the dermal absorption value has to be the addition of the mean value to the standard deviation. Therefore, the *in vitro* dermal absorption in the 06LBCEOL20/2PT formulation was 2.2%, 2.87% and 6.25%, rounded to 2%, 3% and 6% (according to EFSA guidance) for cypermethrin, propiconazole and tebuconazole respectively.

| Guideline/test method | Species | Route of administration | Endpoint/type of test | Results (dermal absorption) |
|---|---|---|---|---|
| OECD 428<br>*In vitro*<br>Washing at 8 h /<br>Exposure for 24 h | Human skin | Dermal | Dermal absorption of Cypermethrin | 2% |
| | | | Dermal absorption of Propiconazole | 3% |
| | | | Dermal absorption of Tebuconazole | 6% |

2.2.7.1.4.1 Acute toxicity

No acute toxicity study (oral, dermal or inhalation) has been submitted for the product V33 TRAITEMENT MULTI USAGES. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product.
Regarding the content of active substances and co-formulants, no classification is required.

2.2.7.1.4.2 Irritation and corrosivity

No skin irritation study has been submitted for the product V33 TRAITEMENT MULTI USAGES. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint.

An eye irritation study in rabbits has been performed on V33 TRAITEMENT MULTI USAGES according to the OECD Guideline 405.

0.1 mL of the test item was instilled, as supplied, into the conjunctival sac of one eye of three male albino New Zealand rabbit. Ocular examinations were performed on both right and left eyes 1 hour, 24, 48 and 72 hours following treatment.
The conjunctivae ocular reactions observed during the study have been slight to moderate and totally reversible: a slight to moderate redness noted 1 hour after the test item instillation and totally reversible between days 2 and 3, associated with a slight to moderate chemosis noted 1 hour after the test item instillation and totally reversible on day 1.
The individual and mean scores are presented in the following table (see below).

The results obtained, under these experimental conditions, enable to conclude that in accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, V33 TRAITEMENT MULTI USAGES is not classified for eye irritation.

**Table 2.2-3: Individual and mean scores of conjunctivae, iris and cornea**

| Animal n° Weight *(kg)* | Time after treatment | CONJUNCTIVAE | | IRIS | CORNEA |
|---|---|---|---|---|---|
| | | CHEMOSIS (A) | REDNESS (C) | LESION (D) | OPACITY (E) |
| A4106 | 24 hours | 0 | 1 | 0 | 0 |
| | 48 hours | 0 | 1 | 0 | 0 |
| | 72 hours | 0 | 0 | 0 | 0 |
| Start: 2.78 | TOTAL | 0 | 2 | 0 | 0 |
| End: 2.80 | Mean | 0.0 | 0.7 | 0.0 | 0.0 |
| A4156 | 24 hours | 0 | 2 | 0 | 0 |
| | 48 hours | 0 | 0 | 0 | 0 |
| | 72 hours | 0 | 0 | 0 | 0 |
| Start: 1.91 | TOTAL | 0 | 2 | 0 | 0 |
| End: 1.95 | Mean | 0.0 | 0.7 | 0.0 | 0.0 |
| A4154 | 24 hours | 0 | 1 | 0 | 0 |
| | 48 hours | 0 | 0 | 0 | 0 |
| | 72 hours | 0 | 0 | 0 | 0 |
| Start: 1.94 | TOTAL | 0 | 1 | 0 | 0 |
| End: 2.00 | Mean | 0.0 | 0.3 | 0.0 | 0.0 |

2.2.7.1.4.3 Sensitisation

A skin sensitization study in mice has been performed on V33 TRAITEMENT MULTI USAGES according to the OECD Guideline 442-B (LLNA: BrdU).
The test was performed to assess the skin sensitisation potential of the product in the CBA/J strain mouse following topical applications to the dorsal surface of the ear.
The basic principle underlying the LLNA:BrdU is that sensitizers induce proliferation of lymphocytes in the lymph nodes draining the site of test item application.

Three groups of four animals were treated for three consecutive days (D1, D2, D3) with 50 µL (25 µL per ear) of the test item undiluted and diluted in Acetone/Olive Oil (4:1, v/v) at concentrations of 25% and 50%. A further group of four animals was treated with Acetone/Olive Oil (4:1, v/v).
On D5, 0.5 mL of BrdU solution (10 mg/ml) was injected by intra-peritoneally route.
On D6, the proliferation of lymphocytes in the draining auricular lymph nodes was determined by measurement of BrdU content in DNA of lymphocyte with kit ELISA. The experimental protocol was

established according to *the OECD Guideline n°442-B,* and test method B.51 of Council regulation No 640/2012 of 30 May 2012.

No mortality and no signs of systemic toxicity were noted in the test and control animals during the test. No significant increase in ear thickness and in ear weight was noted in animals treated at 25%, 50% and 100%. Therefore, the test item must be considered as not excessively irritant at these concentrations.
The Stimulation Index (**SI**) calculated by pooled approach was **0.92**, **1.43** and **1.07** for the treated groups at **25%, 50%** and **100%,** respectively. The $EC_{1.6}$ cannot be determined in this study.

**Table 2.2-4: BrdU index, Stimulation index and calculation of $EC_{1.6}$**

| Groups | Test item | BrdU-index (mean) | Stimulation Index S.I. | Result | $EC_{1.6}$ value |
|---|---|---|---|---|---|
| 1 | AOO | 1.133 | n.a | n.a | n.a. |
| 2 | 25% | 1.045 | 0.92 | negative | n.a. |
| 3 | 50% | 1.625 | 1.43 | negative | |
| 4 | 100% | 1.213 | 1.07 | negative | |

In view of these results, under these experimental conditions, the product V33 TRAITEMENT MULTI USAGES is not classified as a skin sensitizer, in accordance with the Regulation (EC) No. 1272/2008.
However, in accordance with the Regulation (EC) No. 1272/2008, the sentence EUH 208: Contains propiconazole and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction should be mentioned on labelling.

Moreover, the presence of 1,2-benzisothiazolin-3-one (BIT), skin sensitizer, has been identified in the product at 0.0025%. The threshold value for classification H317 of BIT is 0.05% leading to a threshold value for elicitation at 0.005%. The content of BIT is below this SCL, so no specific labeling is required. However, BIT is a well known skin sensitizer that may induce skin reactions at concentration below the threshold value. Therefore, FR proposes to mention the presence of BIT on the label.

2.2.7.1.4.4 Other studies

No other study has been submitted.

### 2.2.7.2 Human exposure assessment

The product is a ready-to-use (RTU) water-based wood preservative for both professional and non-professional uses. It contains 0.18% w/w cypermethrin, 0.15% w/w tebuconazole, and 0.14% w/w propiconazole (technical contents are considered for the 3 active substances).

The product is intended to be used for the preventive and curative treatment of interior woods and exterior woods.
These preventive and curative treatments are done by brush application, spray application or injection.

With a density of 1.0 g/mL, the application doses are, respectively, 200 mL/m² (= 200 g/$m^2$) for preventive treatment and 300 mL/m² (= 300 g/$m^2$) for curative treatment. For curative treatment, an application dose of 150 mL/$m^2$ can be added by injection, in combination with a superficial treatment (brush or spray).

#### *2.2.7.2.1 Identification of main paths of human exposure towards active substance 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 mixing and loading, 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).

**Table 2.2-5: Summary of main paths of human exposure**

| Exposure path | Industrial use | Professional use | General public | *via* the environment |
|---|---|---|---|---|
| Inhalation | Not appropriate | yes | Yes | Not appropriate |
| Dermal | Not appropriate | yes | Yes | Not appropriate |
| Oral | Not appropriate | Not appropriate | yes | Not appropriate |

Physico-chemical and toxicological data of cypermethrine, tebuconazole and propiconazole used for the risk assessment are summarized in the following table.

| Active Substance | Concentration (% w/w)* | Molecular weight (g/mol) | Vapor Pressure (Pa) | Log Pow | Inhalation absorption | Dermal absorption | Oral absorption |
|---|---|---|---|---|---|---|---|
| **Cypermethrin** | 0.18 | 416 | $6*10^{-7}$ | 5.45 | 100% | 2% | 57% |
| **Tebuconazole** | 0.15 | 308 | $1.7*10^{-6}$ | 3.49 | 100% | 6% | 100% |
| **Propiconazole** | 0.14 | 342 | $5.6*10^{-5}$ | 3.72 | 100% | 3% | 100% |

* Since the toxicological reference values derived for the active substances are set from animal studies in which animal are exposed to technical contents and not pure active substance; the technical contents of a.s. have been used for exposure calculations.

#### *2.2.7.2.2 Direct exposure as a result of use of the active substance in biocidal product*

V33 TRAITEMENT MULTI USAGES is a RTU product that can be applied by brushing or spraying. An application dose of 150 mL/$m^2$ 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 is presented below. It covers the preventive treatment.

2.2.7.2.2.1 Exposure of professional users

*In Annex 6 "Safety for professional operators", the results of the exposure calculations for the active substances for the professional user are laid out.*

***Brush application***

Professional exposure during the application phase has been considered 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[4]. The mixing and loading phase is not considered since the product is a RTU that can be applied directly with a brush.
Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[5].

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Dermal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Brushing 300g/m$^2$ – without PPE**[6] | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 2.45 x $10^{-4}$ | 8.31 x $10^{-4}$ | 1.08 x $10^{-3}$ |
| | Propiconazole | 1.16 x $10^{-3}$ | 9.69 x $10^{-4}$ | 1.16 x $10^{-3}$ |
| | Tébuconazole | 2.28 x $10^{-3}$ | 2.08 x $10^{-3}$ | 2.28 x $10^{-3}$ |
| Brush cleaning phase | Cyperméthrine | negligible | 3.09 x $10^{-4}$ | 3.09 x $10^{-4}$ |
| | Propiconazole | negligible - | 3.22 x $10^{-4}$ | 3.22 x $10^{-4}$ |
| | Tébuconazole | negligible | 4.23 x $10^{-4}$ | 4.23 x $10^{-4}$ |
| Application + cleaning | Cyperméthrine | 2.45 x $10^{-4}$ | 11.4 x $10^{-4}$ | 1.38 x $10^{-3}$ |
| | Propiconazole | 1.16 x $10^{-3}$ | 12.91 x $10^{-4}$ | 1.48 x $10^{-3}$ |
| | Tébuconazole | 2.28 x $10^{-3}$ | 2.5 x $10^{-3}$ | 2.7 x $10^{-3}$ |

***Brush application + injection***

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.
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.

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Brushing 300 g/m$^2$ + injection 150 g/m$^2$ – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 4.89 x $10^{-4}$ | 1.66 x $10^{-3}$ | 2.15 x $10^{-3}$ |
| | Propiconazole | 3.8 x $10^{-4}$ | 1.94 x $10^{-3}$ | 2.32 x $10^{-3}$ |
| | Tébuconazole | 4.08 x $10^{-4}$ | 4.15 x $10^{-3}$ | 4.56 x $10^{-3}$ |
| Cleaning phase | Cyperméthrine | negligible | 6.4 x $10^{-4}$ | 6.4 x $10^{-4}$ |
| | Propiconazole | negligible - | 7.08 x $10^{-4}$ | 7.08 x $10^{-4}$ |
| | Tébuconazole | negligible | 1.25 x $10^{-3}$ | 1.25 x $10^{-3}$ |
| Appli + cleaning | Cyperméthrine | 4.89 x $10^{-4}$ | 2.3 x $10^{-3}$ | 2.79 x $10^{-3}$ |
| | Propiconazole | 3.8 x $10^{-4}$ | 2.6 x $10^{-3}$ | 3.03 x $10^{-3}$ |
| | Tébuconazole | 4.08 x $10^{-4}$ | 5.4 x $10^{-3}$ | 5.81 x $10^{-3}$ |

[4] "The most appropriate model to used for the scenario of non-professional application of paints by brushing and rolling", agreed at the HH WG III on 26 May 2016.
[5] 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.
[6] PPE : Personal Protective Equipment

***Spray application***

Professional exposure during the mixing and loading and the application phase has been considered using "*the spraying model 2*" according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[7].
Exposure during the cleaning of equipment has been assessed with the BEAT scenario "*Cleaning of the spray equipment*" from TNsG second version of 2007[8].
For PPE, a protection factor of 90% has been applied for gloves and coated coverall as described in HEEG opinion 9[9].

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 4.28 x $10^{-3}$ | 2.67 x $10^{-2}$ | 3.1 x $10^{-2}$ |
| | Propiconazole | 3.33 x $10^{-3}$ | 3.12 x $10^{-2}$ | 3.45 x $10^{-2}$ |
| | Tébuconazole | 3.56 x $10^{-3}$ | 6.68 x $10^{-2}$ | 7.04 x $10^{-2}$ |
| Cleaning of the spray equipment | Cyperméthrine | negligible | 3.31 x $10^{-4}$ | 3.31 x $10^{-4}$ |
| | Propiconazole | negligible | 3.86 x $10^{-4}$ | 3.86 x $10^{-4}$ |
| | Tébuconazole | negligible | 8.27 x $10^{-4}$ | 8.27 x $10^{-4}$ |
| Appli + cleaning | Cyperméthrine | 4.28 x $10^{-3}$ | 2.9 x $10^{-2}$ | 3.36 x $10^{-2}$ |
| | Propiconazole | 3.33 x $10^{-3}$ | 3.4 x $10^{-2}$ | 3.73 x $10^{-2}$ |
| | Tébuconazole | 3.56 x $10^{-3}$ | 3.2 x $10^{-2}$ | 3.59 x $10^{-2}$ |
| **Spraying 300g/m$^2$ – with PPE during application phase (gloves 90% and coverall 90%)** | | | | |
| M&L | Included in the model | | | |
| Product application phase (gloves and coverall) | Cyperméthrine | 4.28 x $10^{-3}$ | 2.82 x $10^{-3}$ | 7.09 x $10^{-3}$ |
| | Propiconazole | 3.33 x $10^{-3}$ | 2.85 x $10^{-3}$ | 6.17 x $10^{-3}$ |
| | Tébuconazole | 3.56 x $10^{-3}$ | 6.1 x $10^{-3}$ | 9.66 x $10^{-3}$ |
| Cleaning of the spray equipment | Cyperméthrine | negligible | 3.31 x $10^{-4}$ | 3.31 x $10^{-4}$ |
| | Propiconazole | negligible | 3.86 x $10^{-4}$ | 3.86 x $10^{-4}$ |
| | Tébuconazole | negligible | 8.27 x $10^{-4}$ | 8.27 x $10^{-4}$ |
| Application (PPE) + cleaning | Cyperméthrine | 4.28 x $10^{-3}$ | 3.1 x $10^{-3}$ | 7.42 x $10^{-3}$ |
| | Propiconazole | 3.33 x $10^{-3}$ | 3.2 x $10^{-3}$ | 6.56 x $10^{-3}$ |
| | Tébuconazole | 3.56 x $10^{-3}$ | 6.9 x $10^{-3}$ | 1.05 x $10^{-2}$ |

***Spray application + injection***

For this scenario, the exposure values of the exposure models (application + cleaning) taken for the spray application have been multiplied by two in order to simulate an application by spray followed by an application by injection.

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ + injection 150g/m2 – with PPE during application (gloves 90% and coverall 90%)** | | | | |

[7] "Methods and models to assess exposureto biocidal product in different product types" version 2, June 2016.
[8] Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007).
[9] HEEG opinion 9 on Default protecion factors for preventive clothing and gloves. Agreed at TM I 2010.

| | | | | |
|---|---|---|---|---|
| M&L | n.a | | | |
| Product application phase (gloves and coverall) | Cyperméthrine | 8.55 x $10^{-3}$ | 5.64 x $10^{-3}$ | 1.42 x $10^{-2}$ |
| | Propiconazole | 6.65 x $10^{-3}$ | 5.69 x $10^{-3}$ | 1.23 x $10^{-2}$ |
| | Tébuconazole | 7.13 x $10^{-3}$ | 1.22 x $10^{-2}$ | 1.93 x $10^{-2}$ |
| Cleaning phase | Cyperméthrine | negligible | 6.62 x $10^{-4}$ | 6.62 x $10^{-4}$ |
| | Propiconazole | negligible | 7.72 x $10^{-4}$ | 7.72 x $10^{-4}$ |
| | Tébuconazole | negligible | 1.65 x $10^{-3}$ | 1.65 x $10^{-3}$ |
| Application (PPE) + cleaning | Cyperméthrine | 8.55 x $10^{-3}$ | 6.2 x $10^{-3}$ | 1.48 x $10^{-2}$ |
| | Propiconazole | 6.65 x $10^{-3}$ | 6.4 x $10^{-3}$ | 1.31 x $10^{-2}$ |
| | Tébuconazole | 7.13 x $10^{-3}$ | 1.4 x $10^{-2}$ | 2.1 x $10^{-2}$ |

2.2.7.2.2.2 Exposure of non-professional users

*In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substances for the non-professional user and the general public are laid out.*

***Brush application***

Non-professional exposure during the application phase has been considered 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[10]. The mixing and loading phase is not considered since the product is a RTU that can be applied directly with a brush.
Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[11].

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Dermal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Brushing 300g/m$^2$** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 2.45 x $10^{-4}$ | 8.31 x $10^{-4}$ | 1.08 x $10^{-3}$ |
| | Propiconazole | 1.16 x $10^{-3}$ | 9.69 x $10^{-4}$ | 1.16 x $10^{-3}$ |
| | Tébuconazole | 2.28 x $10^{-3}$ | 2.08 x $10^{-3}$ | 2.28 x $10^{-3}$ |
| Brush cleaning phase | Cyperméthrine | negligible | 3.09 x $10^{-4}$ | 3.09 x $10^{-4}$ |
| | Propiconazole | negligible | 3.22 x $10^{-4}$ | 3.22 x $10^{-4}$ |
| | Tébuconazole | negligible | 4.23 x $10^{-4}$ | 4.23 x $10^{-4}$ |
| Appli + cleaning | Cyperméthrine | 2.45 x $10^{-4}$ | 11.4 x $10^{-4}$ | 1.38 x $10^{-3}$ |
| | Propiconazole | 1.16 x $10^{-3}$ | 12.91 x $10^{-4}$ | 1.48 x $10^{-3}$ |
| | Tébuconazole | 2.28 x $10^{-3}$ | 2.5 x $10^{-3}$ | 2.7 x $10^{-3}$ |

***Brush application + injection***

No specific exposure 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, considering that the task duration is the same for injection and for brushing. .

[10] "The most appropriate model to used for the scenario of non-professional application of paints by brushing and rolling", agreed at the HH WG III on 26 May 2016.
[11] 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.

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.

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Brushing 300 g/m$^2$ + injection 150 g/m$^2$** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 4.89 x $10^{-4}$ | 1.66 x $10^{-3}$ | 2.15 x $10^{-3}$ |
| | Propiconazole | 3.8 x $10^{-4}$ | 1.94 x $10^{-3}$ | 2.32 x $10^{-3}$ |
| | Tébuconazole | 4.08 x $10^{-4}$ | 4.15 x $10^{-3}$ | 4.56 x $10^{-3}$ |
| Cleaning phase | Cyperméthrine | negligible | 6.4 x $10^{-4}$ | 6.4 x $10^{-4}$ |
| | Propiconazole | negligible - | 7.08 x $10^{-4}$ | 7.08 x $10^{-4}$ |
| | Tébuconazole | negligible | 1.25 x $10^{-3}$ | 1.25 x $10^{-3}$ |
| Appli + cleaning | Cyperméthrine | 4.89 x $10^{-4}$ | 2.3 x $10^{-3}$ | 2.79 x $10^{-3}$ |
| | Propiconazole | 3.8 x $10^{-4}$ | 2.6 x $10^{-3}$ | 3.03 x $10^{-3}$ |
| | Tébuconazole | 4.08 x $10^{-4}$ | 5.4 x $10^{-3}$ | 5.81 x $10^{-3}$ |

***Spray application***

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.
Exposure during the cleaning of equipment has been assessed with the BEAT scenario "*Cleaning of the spray equipment*" from TNsG second version of 2007[12].

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.63 x $10^{-4}$ | 5.47 x $10^{-3}$ | 5.63 x $10^{-3}$ |
| | Propiconazole | 1.48 x $10^{-3}$ | 6.38 x $10^{-3}$ | 7.86 x $10^{-3}$ |
| | Tébuconazole | 1.35 x $10^{-4}$ | 1.37 x $10^{-2}$ | 1.38 x $10^{-2}$ |
| Cleaning of the spray equipment | Cyperméthrine | negligible | 3.31 x $10^{-4}$ | 3.31 x $10^{-4}$ |
| | Propiconazole | negligible - | 3.86 x $10^{-4}$ | 3.86 x $10^{-4}$ |
| | Tébuconazole | negligible | 8.27 x $10^{-4}$ | 8.27 x $10^{-4}$ |
| Appli + cleaning | Cyperméthrine | 1.63 x $10^{-4}$ | 5.8 x $10^{-3}$ | 5.97 x $10^{-3}$ |
| | Propiconazole | 1.48 x $10^{-3}$ | 6.8 x $10^{-3}$ | 8.25 x $10^{-3}$ |
| | Tébuconazole | 1.35 x $10^{-4}$ | 1.45 x $10^{-2}$ | 1.46 x $10^{-2}$ |

***Spray application + injection***

For this scenario, the exposure values of the exposure models (application + cleaning) taken for the spray application have been multiplied by two in order to simulate an application by spray followed by an application by injection.

[12] Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007).

| Scenario | Active substance | Inhalation Exposure (mg/kg bw/d) | Demal Exposure (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ + injection 150g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 3.25 x $10^{-4}$ | 1.09 x $10^{-2}$ | 1.13 x $10^{-2}$ |
| | Propiconazole | 2.53 x $10^{-4}$ | 1.28 x $10^{-2}$ | 1.30 x $10^{-2}$ |
| | Tébuconazole | 2.71 x $10^{-4}$ | 2.74x $10^{-2}$ | 2.76 x $10^{-2}$ |
| Cleaning phase | Cyperméthrine | negligible | 6.62 x $10^{-4}$ | 6.62 x $10^{-4}$ |
| | Propiconazole | negligible | 7.72 x $10^{-4}$ | 7.72 x $10^{-4}$ |
| | Tébuconazole | negligible | 1.65 x $10^{-3}$ | 1.65 x $10^{-3}$ |
| Appli + cleaning | Cyperméthrine | 3.25 x $10^{-4}$ | 1.16 x $10^{-12}$ | 1.19 x $10^{-2}$ |
| | Propiconazole | 2.53 x $10^{-4}$ | 1.35 x $10^{-2}$ | 1.38 x $10^{-2}$ |
| | Tébuconazole | 2.71 x $10^{-4}$ | 2.91 x $10^{-2}$ | 2.93 x $10^{-2}$ |

#### *2.2.7.2.3 Indirect exposure as a result of use of the active substance in biocidal product*

For secondary exposure, as described in TNsG for Human Exposure (2002 and 2007), it was considered as 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 volatilizing residues indoors (adult and infant), of child playing on playground structure outdoors and infant playing on weathered (playground) structure and mouthing.

These scenarios which have to be considered for wood preservative treatments are summarised below.

| Secondary scenario | Exposure situation | Routes of exposure | Exposed population | |
|---|---|---|---|---|
| | | | Adult | Infant/child |
| **Sanding treated wood** | Acute | Dermal, inhalation | yes | - |
| **Chewing treated wood offcuts** | Acute | Ingestion | - | Yes |
| **Sanding treated wood** | Chronic | Dermal, inhalation | yes | - |
| **Inhalation of volatilising residues indoors** | Chronic | Inhalation | Yes | Yes |
| **Child playing on playground structure outdoors** | Chronic | Dermal | - | Yes |
| **Infant playing on weathered (playground) structure and mouthing** | Chronic | Dermal, ingestion | - | Yes |

***Acute secondary exposure scenario***

Two application rates were considered for the treated wood:

- Dose of 450 g/m$^2$ corresponding to a curative treatment by injection and brushing or spraying.

- Dose of 300 g/m$^2$ corresponding to a superficial curative treatment.

| Scenario | Substances | Dermal Exposure (mg/kg bw/d) | Inhalation Exposure (mg/kg bw/d | Oral Exposure (mg/kg bw/d | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|---|
| **Adult amateur sanding/processing of treated wood composites (450g/m$^2$)** | Cyperméthrine | 3.40 x $10^{-4}$ | 2.83 x $10^{-5}$ | - | 3.68 x $10^{-4}$ |
| | Propiconazole | 3.97 x $10^{-4}$ | 2.20 x $10^{-5}$ | - | 4.19 x $10^{-4}$ |
| | Tébuconazole | 8.51 x $10^{-4}$ | 2.36 x $10^{-5}$ | - | 8.74 x $10^{-4}$ |
| **Infant chewing wood composites chips (450g/m$^2$)** | Cyperméthrine | - | - | 0.015 | 0.015 |
| | Propiconazole | - | - | 0.02 | 0.02 |
| | Tébuconazole | - | - | 0.02 | 0.02 |
| **Infant chewing wood composites chips (300g/m$^2$)** | Cyperméthrine | - | - | 0.015 | 0.015 |
| | Propiconazole | - | - | 0.02 | 0.02 |
| | Tébuconazole | - | - | 0.02 | 0.02 |

***Chronic secondary exposure scenario***

Two application rates were considered for the treated wood:

- Dose of 450 g/m$^2$ corresponding to a curative treatment by injection and brushing or spraying.
- Dose of 300 g/m$^2$ corresponding to a superficial curative treatment

| Scenario | Substances | Dermal Exposure (mg/kg bw/d) | Inhalation Exposure (mg/kg bw/d | Oral Exposure (mg/kg bw/d | Total Exposure (mg/kg bw/d) |
|---|---|---|---|---|---|
| **Adult professional sanding/processing of treated wood composites (450g/m$^2$)** | Cyperméthrine | 3.40 x $10^{-5}$ | 1.70 x $10^{-4}$ | - | 2.04 x $10^{-4}$ |
| | Propiconazole | 3.97 x $10^{-5}$ | 1.32 x $10^{-4}$ | - | 1.72 x $10^{-4}$ |
| | Tébuconazole | 8.51 x $10^{-5}$ | 1.41 x $10^{-4}$ | - | 2.26 x $10^{-4}$ |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine | - | 2.74 x $10^{-5}$ | - | 2.74 x $10^{-5}$ |
| | Propiconazole | - | 2.1 x $10^{-3}$ | - | 2.1 x $10^{-3}$ |
| | Tébuconazole | - | 5.73 x $10^{-5}$ | - | 5.73 x $10^{-5}$ |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine | - | 5.54 x $10^{-5}$ | - | 5.54 x $10^{-5}$ |
| | Propiconazole | - | 4.25 x $10^{-3}$ | - | 4.25 x $10^{-3}$ |
| | Tébuconazole | - | 1.16 x $10^{-4}$ | - | 1.16 x $10^{-4}$ |
| **Child playing on playground structure outdoors** | Cyperméthrine | 1.30 x $10^{-4}$ | - | - | 1.30 x $10^{-4}$ |
| | Propiconazole | 1.51 x $10^{-4}$ | - | - | 1.51 x $10^{-4}$ |
| | Tébuconazole | 3.24 x $10^{-4}$ | - | - | 3.24 x $10^{-4}$ |
| **Infant playing on weathered (playground) structure and mouthing (450** | Cyperméthrine | 1.94 x $10^{-4}$ | - | 1.22 x $10^{-2}$ | 1.23 x $10^{-2}$ |
| | Propiconazole | 2.27 x $10^{-4}$ | - | 9.45 x $10^{-3}$ | 9.7 x $10^{-3}$ |
| | Tébuconazole | 4.86 x $10^{-4}$ | - | 1.3 x $10^{-2}$ | 1.06 x $10^{-2}$ |

| | | | | | |
|---|---|---|---|---|---|
| **g/m2)** | | | | | |
| **Infant playing on weathered (playground) structure and mouthing (300 g/m2)** | Cyperméthrine | 1.3x $10^{-4}$ | - | 8.1 x $10^{-3}$ | 8.23 x $10^{-3}$ |
| | Propiconazole | 1.51 x $10^{-4}$ | - | 3.6 x $10^{-3}$ | 6.45 x $10^{-3}$ |
| | Tébuconazole | 3.24 x $10^{-4}$ | - | 6.75 x $10^{-3}$ | 7.07 x $10^{-3}$ |

#### *2.2.7.2.4 Exposure to residues in food*

In Annex 8 “Residue behaviour”, the results of the residue assessment are laid out.

#### *2.2.7.2.5 Combined exposure*

A combined exposure is also considered for an adult (professional exposure + inhalation of volatilizing residues) and an infant (playing on weathered (playground) structure and mouthing + inhalation of volatilizing residues).
These scenarios which have to be considered for wood preservative treatments are summarized below.

| **Secondary scenario** | **Exposure situation** | **Routes of exposure** | **Exposed population** | |
|---|---|---|---|---|
| | | | **Non-professionals** | |
| | | | **Adult** | **Infant** |
| **Combined exposure (pro exposure + inhalation of volatilizing residues)** | Chronic | Dermal, inhalation | Yes | - |
| **Combined exposure (Infant playing on weathered structure and mouthing + inhalation of volatilizing residues)** | Chronic | Dermal, ingestion, inhalation | - | Yes |

***Adult combined exposure (chronic exposure scenario)***

| **Scenario** | **Active substance** | **Professional exposure (mg/kg bw/d)** | **Secondary exposure (inhalation of volatilzed residues) (mg/kg bw/d)** | **Total exposure (mg/kg bw/d)** |
|---|---|---|---|---|
| Brushing | Cyperméthrine | 1.08 x $10^{-3}$ | 2.74 x $10^{-5}$ | 1.1 x $10^{-3}$ |
| | Propiconazole | 1.16 x $10^{-3}$ | 2.10 x $10^{-3}$ | 3.26 x $10^{-3}$ |
| | Tébuconazole | 2.28 x $10^{-3}$ | 5.73 x $10^{-5}$ | 2.34 x $10^{-3}$ |
| Spraying (gloves + coverall 20%) | Cyperméthrine | 7.09 x $10^{-3}$ | 2.74 x $10^{-5}$ | 7.12 x $10^{-3}$ |
| | Propiconazole | 6.17 x $10^{-3}$ | 2.10 x $10^{-3}$ | 8.27 x $10^{-3}$ |
| | Tébuconazole | 9.66 x $10^{-3}$ | 5.73 x $10^{-5}$ | 9.72 x $10^{-3}$ |

| | | | | |
|---|---|---|---|---|
| Brushing + injecting | Cyperméthrine | $2.15 \times 10^{-3}$ | $2.74 \times 10^{-5}$ | $2.18 \times 10^{-3}$ |
| | Propiconazole | $2.32 \times 10^{-3}$ | $2.10 \times 10^{-3}$ | $4.42 \times 10^{-3}$ |
| | Tébuconazole | $4.56 \times 10^{-3}$ | $5.73 \times 10^{-5}$ | $4.62 \times 10^{-3}$ |
| Spraying + injecting | Cyperméthrine | $1.42 \times 10^{-2}$ | $2.74 \times 10^{-5}$ | $1.42 \times 10^{-2}$ |
| | Propiconazole | $1.23 \times 10^{-2}$ | $2.10 \times 10^{-3}$ | $1.44 \times 10^{-2}$ |
| | Tébuconazole | $1.93 \times 10^{-2}$ | $5.73 \times 10^{-5}$ | $1.94 \times 10^{-2}$ |

**Infant combined exposure (chronic exposure scenario)**

| Active substance | Infant playing on a wood strucure + mouthing (mg/kg bw/d)* | Secondary exposure (inhalation of volatilzed residues) (mg/kg bw/d) | Total exposure (mg/kg bw/d) |
|---|---|---|---|
| Cyperméthrine | $6.45 \times 10^{-3}$ | $5.54 \times 10^{-5}$ | $8.23 \times 10^{-3}$ |
| Propiconazole | $4.3 \times 10^{-3}$ | $4.25 \times 10^{-3}$ | $1.07 \times 10^{-2}$ |
| Tébuconazole | $7.07 \times 10^{-3}$ | $1.16 \times 10^{-4}$ | $7.2 \times 10^{-3}$ |

* wood treated by spraying with a dose of 300 g/m$^2$

## 2.2.7.3 Risk assessment for human health

### *2.2.7.3.1 Risk for direct exposure*

2.2.7.3.1.1 Professional users

The exposure values are compared to long term AEL of each active substance.

| | Cyperméthrine | Tébuconazole | Propiconazole |
|---|---|---|---|
| **Long term AEL (mg/kg bw/d)** | 0.022 | 0.03 | 0.04 |

The product contains 3 different active substances; therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, Part B of 2015[13].
The first step (Tier 1) of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL.

In a Tier 2, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).
**If HI ≤ 1** the risk related to use of the mixture will be considered acceptable;
**If HI > 1** the risk related to use of the mixture will be considered unacceptable; a refinement is needed.

In a Tier 3, the confirmation of concentration (dose) addition in the mixture/product is presented.
As a first step, target organs/mode of action for each substance are listed, corresponding to a Tier 3A.
Substances are then grouped related to their common target organs or MoA. When a target organ or MoA is observed for only one substance, there is no need to perform a Tier 3A.

If general AELs are not established on the same organs/MoA, it is necessary to determine specific AELs for each identified target organ/MoA and each active substance. This step corresponds to a Tier 3B.

[13] Guidance on the Biocidal product Regulation, Volume III Human Health – Part B risk assessment, 2015.

***Brush application***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Brushing 300g/m$^2$ – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine 0.022 | 1.08 x $10^{-3}$ | 4.89 | Acceptable |
| | Propiconazole : 0.04 | 1.16 x $10^{-3}$ | 2.9 | Acceptable |
| | Tébuconazole : 0.03 | 2.28 x $10^{-3}$ | 7.60 | Acceptable |
| Brush cleaning phase | Cyperméthrine 0.022 | 3.09 x $10^{-4}$ | 1.41 | Acceptable |
| | Propiconazole : 0.04 | 3.22 x $10^{-4}$ | 0.8 | Acceptable |
| | Tébuconazole : 0.03 | 4.23 x $10^{-4}$ | 1.41 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.022 | 1.38 x $10^{-3}$ | 6.29 | Acceptable |
| | Propiconazole : 0.04 | 1.48 x $10^{-3}$ | 3.7 | Acceptable |
| | Tébuconazole : 0.03 | 2.7 x $10^{-3}$ | 9.01 | Acceptable |

➔ The risk is acceptable for brush application by a professional without PPE.

*Tier 2 (additivity)*

| Cyperméthrine | Propiconazole | Tébuconazole | HI (∑ HQ a.s) | Risk |
|---|---|---|---|---|
| HQ (Exposure/AEL) | | | | |
| 0.063 | 0.04 | 0.09 | **0.19** | **Acceptable** |

➔ HI < 1, the risk is acceptable for brush application by a professional without PPE.

***Spray application***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ – no PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine 0.022 | 3.1 x $10^{-2}$ | 140.93 | **Unacceptable** |
| | Propiconazole : 0.04 | 3.45 x $10^{-2}$ | 86.28 | Acceptable |
| | Tébuconazole : 0.03 | 7.04 x $10^{-2}$ | 234.63 | **Unacceptable** |
| Cleaning spray equipment | Cyperméthrine 0.022 | 3.31 x $10^{-4}$ | 1.5 | Acceptable |
| | Propiconazole : | 3.86 x $10^{-4}$ | 0.97 | Acceptable |

| | | | | |
|---|---|---|---|---|
| | 0.04 | | | |
| | Tébuconazole : 0.03 | $8.27 \times 10^{-4}$ | 2.76 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.022 | $3.36 \times 10^{-2}$ | 152.9 | **Unacceptable** |
| | Propiconazole : 0.04 | $3.73 \times 10^{-2}$ | 87.25 | Acceptable |
| | Tébuconazole : 0.03 | $3.59 \times 10^{-2}$ | 252.98 | **Unacceptable** |
| **Spraying 300g/m$^2$ – PPE during application phase (gloves 90% and coverall 90%)** | | | | |
| M&L | Included in the model | | | |
| Application phase (gloves + coverall) | Cyperméthrine 0.022 | $7.09 \times 10^{-3}$ | 32.24 | Acceptable |
| | Propiconazole : 0.04 | $6.17 \times 10^{-3}$ | 15.43 | Acceptable |
| | Tébuconazole : 0.03 | $9.66 \times 10^{-3}$ | 32.21 | Acceptable |
| Cleaining equipement (no PPE) | Cyperméthrine 0.022 | $3.31 \times 10^{-4}$ | 1.5 | Acceptable |
| | Propiconazole : 0.04 | $3.86 \times 10^{-4}$ | 0.97 | Acceptable |
| | Tébuconazole : 0.03 | $8.27 \times 10^{-4}$ | 2.76 | Acceptable |
| Appli + cleaning (gloves + coverall during application) | Cyperméthrine 0.022 | $7.42 \times 10^{-3}$ | 33.75 | Acceptable |
| | Propiconazole : 0.04 | $6.56 \times 10^{-3}$ | 16.4 | Acceptable |
| | Tébuconazole : 0.03 | $1.05 \times 10^{-2}$ | 34.96 | Acceptable |

➔ The risk is acceptable for spray application by a professional with PPE (gloves and cotton coverall) during application phase.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| 0.33 | 0.16 | 0.35 | **0.84** | **Acceptable** |

➔ HI < 1, the risk is acceptable for spray application by a professional with PPE (gloves and cotton coverall) during application phase.

***Brush application + injection***

*Tier 1 (acceptability of each substance)*

| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
|---|---|---|---|---|
| **Brushing 300g/m$^2$ and Injecting 150g/m$^2$ – without PPE** | | | | |
| M&L | n.a | | | |
| Application phase | Cyperméthrine 0.022 | $2.15 \times 10^{-3}$ | 9.78 | Acceptable |

| | | | | |
|---|---|---|---|---|
| | Propiconazole : 0.04 | $2.32 \times 10^{-3}$ | 5.8 | Acceptable |
| | Tébuconazole : 0.03 | $4.56 \times 10^{-3}$ | 15.21 | Acceptable |
| Brush and injector cleaning | Cyperméthrine 0.022 | $6.4 \times 10^{-4}$ | 2.91 | Acceptable |
| | Propiconazole : 0.04 | $7.08 \times 10^{-4}$ | 1.77 | Acceptable |
| | Tébuconazole : 0.03 | $1.25 \times 10^{-3}$ | 4.17 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.022 | $2.79 \times 10^{-3}$ | 12.69 | Acceptable |
| | Propiconazole : 0.04 | $3.03 \times 10^{-3}$ | 7.57 | Acceptable |
| | Tébuconazole : 0.03 | $5.81 \times 10^{-3}$ | 19.37 | Acceptable |

➔ The risk is acceptable for brush + injection application (curative treatment) by a professional without PPE.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| 0.13 | 0.08 | 0.19 | **0.4** | **Acceptable** |

➔ HI < 1, the risk is acceptable for brush + injection application (curative treatment) by a professional without PPE.

***Spray application + injection***

*Tier 1 (acceptability of each substance)*

| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
|---|---|---|---|---|
| **Spraying 300g/m² + injecting 150 mg/m² – PPE during application phase (gloves 90% and coverall 90%)** | | | | |
| M&L | Including in the model | | | |
| Application phase (gloves + coverall) | Cyperméthrine 0.022 | $1.42 \times 10^{-2}$ | 64.49 | Acceptable |
| | Propiconazole : 0.04 | $1.23 \times 10^{-2}$ | 30.86 | Acceptable |
| | Tébuconazole : 0.03 | $1.93 \times 10^{-2}$ | 64.41 | Acceptable |
| Cleaning equipment (no PPE) | Cyperméthrine 0.022 | $6.62 \times 10^{-4}$ | 3.01 | Acceptable |
| | Propiconazole : 0.04 | $7.72 \times 10^{-4}$ | 1.93 | Acceptable |
| | Tébuconazole : 0.03 | $1.65 \times 10^{-3}$ | 5.52 | Acceptable |
| Appli + cleaning (gloves + coverall during application) | Cyperméthrine 0.022 | $1.48 \times 10^{-2}$ | 67.5 | Acceptable |
| | Propiconazole : 0.04 | $1.31 \times 10^{-2}$ | 32.79 | Acceptable |

| | | | | |
|---|---|---|---|---|
| | Tébuconazole : 0.03 | 2.1 x $10^{-2}$ | 69.93 | Acceptable |

➔ The risk is acceptable for spray + injection application (curative treatment) by a professional with PPE (gloves and cotton coverall) during the application phase.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| 0.7 | 0.3 | 0.7 | **1.7** | **Unacceptable** |

➔ HI > 1, a refinement is needed.

A Tier 3B approach is considered since the 3 active substances have a target organ in common.
The liver is a target organ common to cypermethrine, propiconazole and tebuconazole. A specific target organ AEL can be derived for each active substance.

According to the datapackage available in the CAR of Cypermethrin, liver effects are observed in a 3-week rat study. A NOAEL of 31.5 mg/kg bw/d has been set for these effects, corrected by an AF of 100 and the oral absorption of 57%, leading to a specific AEL of 0.18 mg/kg bw/d.

According to the datapackage available in the CAR of Tebuconazole, liver effects are observed in a 2-year mice study. A NOAEL of 5.9 mg/kg bw/d has been set for these effects, corrected by an AF of 100 and the oral absorption of 100%, leading to a specific AEL of 0.06 mg/kg bw/d.

According to the datapackage available in the CAR of Propiconazole, liver effects are observed in a 2-generation mice study. A NOAEL of 8 mg/kg bw/d has been set for these effects, corrected by an AF of 100 and the oral absorption of 86%, leading to a specific AEL of 0.08 mg/kg bw/d.

| | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** |
|---|---|---|---|
| **General long term AEL** | 0.022 | 0.03 | 0.04 |
| **Specific AEL: liver** | 0.18 | 0.06 | 0.08 |

The comparison of the exposure values during the application and the cleaning with the specific liver AELs leads to the following results:

| **Scenario** | **$AEL_{specific}$ (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% $AEL_{specific}$** | **Risk** |
|---|---|---|---|---|
| **Spraying 300g/$m^2$ + injecting 150 mg/$m^2$ – PPE during application phase (gloves 90% and coverall 90%)** | | | | |
| Appli + cleaning (gloves + coverall during application) | Cyperméthrine 0.18 | 1.48 x $10^{-2}$ | 8.25 | Acceptable |
| | Propiconazole : 0.08 | 1.31 x $10^{-2}$ | 16.39 | Acceptable |
| | Tébuconazole : 0.06 | 2.1 x $10^{-2}$ | 34.96 | Acceptable |

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |

| | | | | |
|---|---|---|---|---|
| 0.08 | 0.16 | 0.35 | **0.59** | **Acceptable** |

➔ In Tier 3, HI < 1, the risk is then considered acceptable for spray + injection application by a professional with PPE (gloves + coated coverall ) during the application phase.

2.2.7.3.1.2 Non-professional users

The exposure values are compared to short term AEL of each active substance.

| | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** |
|---|---|---|---|
| **Short term AEL (mg/kg bw/d)** | 0.088 | 0.03 | 0.3 |

As for professional application, a risk for combined exposure to several substances is performed for non-professionals.

***Brush application***

*Tier 1 (acceptability of each substance)*

| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
|---|---|---|---|---|
| **Brushing 300g/m$^2$** | | | | |
| M&L | n.a | | | |
| Application phase | Cyperméthrine 0.088 | $1.08 \times 10^{-3}$ | 1.22 | Acceptable |
| | Propiconazole : 0.3 | $1.16 \times 10^{-3}$ | 0.39 | Acceptable |
| | Tébuconazole : 0.03 | $2.28 \times 10^{-3}$ | 7.60 | Acceptable |
| Brush cleaning | Cyperméthrine 0.088 | $3.09 \times 10^{-4}$ | 0.35 | Acceptable |
| | Propiconazole : 0.3 | $3.22 \times 10^{-4}$ | 0.11 | Acceptable |
| | Tébuconazole : 0.03 | $4.23 \times 10^{-4}$ | 1.41 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.088 | $1.38 \times 10^{-3}$ | 1.57 | Acceptable |
| | Propiconazole : 0.3 | $1.48 \times 10^{-3}$ | 0.5 | Acceptable |
| | Tébuconazole : 0.03 | $2.7 \times 10^{-3}$ | 9.01 | Acceptable |

➔ The risk is acceptable for brush application by non-professionals.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| 0.02 | 0.005 | 0.09 | **0.11** | **Acceptable** |

➔ HI < 1, the risk is acceptable.

***Spray application application***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Spraying 300g/m$^2$** | | | | |
| M&L | Included in the model | | | |
| Application phase | Cyperméthrine 0.088 | 5.63 x $10^{-3}$ | 6.4 | Acceptable |
| | Propiconazole : 0.3 | 7.86 x $10^{-3}$ | 2.62 | Acceptable |
| | Tébuconazole : 0.03 | 1.38 x $10^{-2}$ | 46.05 | Acceptable |
| Cleaning spray equipment | Cyperméthrine 0.088 | 3.31 x $10^{-4}$ | 0.38 | Acceptable |
| | Propiconazole : 0.3 | 3.86 x $10^{-4}$ | 0.13 | Acceptable |
| | Tébuconazole : 0.03 | 8.27 x $10^{-4}$ | 2.76 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.088 | 5.97 x $10^{-3}$ | 6.78 | Acceptable |
| | Propiconazole : 0.3 | 8.25 x $10^{-3}$ | 2.75 | Acceptable |
| | Tébuconazole : 0.03 | 1.46 x $10^{-2}$ | 48.81 | Acceptable |

➔ The risk is acceptable for spray application by non-professionals.

*Tier 2 (additivity)*

| Cyperméthrine | Propiconazole | Tébuconazole | HI (∑ HQ a.s) | Risk |
|---|---|---|---|---|
| HQ (Exposure/AEL) | | | | |
| 0.07 | 0.03 | 0.5 | **0.6** | **Acceptable** |

➔ HI < 1, the risk is acceptable.

***Brush application + injection***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Brushing 300g/m$^2$ et Injecting 150g/m$^2$** | | | | |
| M&L | n.a | | | |
| Application phase | Cyperméthrine 0,088 | 2.15 x $10^{-3}$ | 2.44 | Acceptable |
| | Propiconazole : 0.3 | 2.32 x $10^{-3}$ | 2.9 | Acceptable |
| | Tébuconazole : 0,03 | 4.56 x $10^{-3}$ | 15.21 | Acceptable |
| Brush and injector cleaning | Cyperméthrine 0,088 | 6.4 x $10^{-4}$ | 0.77 | Acceptable |
| | Propiconazole : 0.3 | 7.08 x $10^{-4}$ | 0.26 | Acceptable |

| | | | | |
|---|---|---|---|---|
| | Tébuconazole : 0.03 | 1.25 x $10^{-3}$ | 4.17 | Acceptable |
| Appli + cleaning | Cyperméthrine 0,088 | 2.79 x $10^{-3}$ | 3.21 | Acceptable |
| | Propiconazole : 0.3 | 3.03 x $10^{-3}$ | 3.16 | Acceptable |
| | Tébuconazole : 0.03 | 5.81 x $10^{-3}$ | 19.37 | Acceptable |

➔ The risk is acceptable for brush + injection application by non-professionals.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| 0.03 | 0.03 | 0.2 | **0.26** | **Acceptable** |

➔ HI < 1, the risk is acceptable.

***Spray application + injection***

*Tier 1 (acceptability of each substance)*

| **Scenario** | **AEL (mg/kg bw/d)** | **Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ + injecting 150 mg/m$^2$** | | | | |
| M&L | Included in the model | | | |
| Application phase | Cyperméthrine 0,088 | 1.13 x $10^{-2}$ | 12.81 | Acceptable |
| | Propiconazole : 0.3 | 1.30 x $10^{-2}$ | 4.34 | Acceptable |
| | Tébuconazole : 0.03 | 2.76 x $10^{-2}$ | 92.10 | Acceptable |
| Cleaning spray equipment | Cyperméthrine 0.088 | 6.62 x $10^{-4}$ | 0.75 | Acceptable |
| | Propiconazole : 0.3 | 7.72 x $10^{-4}$ | 0.26 | Acceptable |
| | Tébuconazole : 0.03 | 1.65 x $10^{-3}$ | 5.52 | Acceptable |
| Appli + cleaning | Cyperméthrine 0.088 | 1.19 x $10^{-2}$ | 13.56 | Acceptable |
| | Propiconazole : 0.3 | 1.38 x $10^{-2}$ | 4.6 | Acceptable |
| | Tébuconazole : 0.03 | 2.93 x $10^{-2}$ | 97.62 | Acceptable |

➔ The risk is acceptable for spray + injection application by non-professionals.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |

| | | | | |
|---|---|---|---|---|
| 0.13 | 0.05 | 0.98 | **1.16** | **Unacceptable** |

➔ HI > 1, a refinement is needed.

A Tier 3B approach is considered since the 3 active substances have a target organ in common.
The liver is a target organ common to cypermethrine, propiconazole and tebuconazole. A specific target organ AEL can be derived for each active substance.

| | Cyperméthrine | Tébuconazole | Propiconazole |
|---|---|---|---|
| **General short term AEL** | 0.088 | 0.03 | 0.03 |
| **Specific AEL: liver** | 0.18 | 0.06 | 0.08 |

The comparison of the exposure values during the application and the cleaning with the specific liver AELs leads to the following results:

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Spraying 300g/m$^2$ + injecting 150 mg/m$^2$** | | | | |
| Appli + cleaning | Cyperméthrine 0,18 | 1.19 x $10^{-2}$ | 6.63 | Acceptable |
| | Propiconazole : 0.08 | 1.38 x $10^{-2}$ | 17.24 | Acceptable |
| | Tébuconazole : 0.06 | 2.93 x $10^{-2}$ | 48.81 | Acceptable |

| Cyperméthrine | Propiconazole | Tébuconazole | HI (∑ HQ a.s) | Risk |
|---|---|---|---|---|
| HQ (Exposure/AEL) | | | | |
| 0.07 | 0.17 | 0.49 | **0.73** | **Acceptable** |

➔ HI < 1, the risk is then acceptable for spray + injection application by non-professionals.

#### *2.2.7.3.2 Risk for indirect exposure*

The exposure values are compared to AELs of each active substance.

| | Cyperméthrine | Tébuconazole | Propiconazole |
|---|---|---|---|
| **Long term AEL (mg/kg bw/d)** | 0.022 | 0.03 | 0.04 |
| **Short term AEL (mg/kg bw/d)** | 0.088 | 0.03 | 0.3 |

***Acute Exposure***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Adult amateur sanding/processing** | Cyperméthrine 0,088 | 3.68 x $10^{-4}$ | 0.42 | Acceptable |

| | | | | |
|---|---|---|---|---|
| **of treated wood composites (450 g/m²)** | Propiconazole : 0.3 | $4.19 \times 10^{-4}$ | 0.14 | Acceptable |
| | Tébuconazole : 0,03 | $8.74 \times 10^{-4}$ | 2.91 | Acceptable |
| **Infant chewing wood composites chips (450 g/m²)** | Cyperméthrine 0,088 | 0.015 | 25.18 | Acceptable |
| | Propiconazole : 0.3 | 0.02 | 10.08 | Acceptable |
| | Tébuconazole : 0,03 | 0.02 | 108 | **Unacceptable** |

➔ An unacceptable risk is identified for the scenario "infant chewing wood composites chips" considering a wood treated with a curative treatment (450 g/m$^2$).

With an application dose of 300 g/m$^2$ for the treated wood, the risk assessment is as follows:

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Infant chewing wood composites chips (300 g/m²)** | Cyperméthrine 0,022 | 0.015 | 16.79 | Acceptable |
| | Propiconazole : 0.08 | 0.02 | 6.72 | Acceptable |
| | Tébuconazole : 0.03 | 0.021 | 72 | Acceptable |

*Tier 2 (additivity)*

| Cyperméthrine | Propiconazole | Tébuconazole | HI (∑ HQ a.s) | Risk |
|---|---|---|---|---|
| HQ (Exposure/AEL) | | | | |
| 0.17 | 0.07 | 0.72 | **0.96** | **Acceptable** |

➔ HI < 1, the risk is then acceptable.

Due to an unacceptable risk observed with wood treated at the application dose intended for curative treatment (450 g/m$^2$), this type of wood treatment should be limited to inaccessible woods (construction wood).

***Chronic Exposure***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Adult professional sanding/processing of treated wood composites** | Cyperméthrine 0.022 | $5.1 \times 10^{-4}$ | 2.32 | Acceptable |
| | Propiconazole : 0.04 | $5.29 \times 10^{-4}$ | 1.32 | Acceptable |
| | Tébuconazole : 0.03 | $9.92 \times 10^{-4}$ | 3.31 | Acceptable |
| **Adult: inhalation of volatilised residues, indoors** | Cyperméthrine 0.022 | $2.74 \times 10^{-5}$ | 0.12 | Acceptable |
| | Propiconazole : 0.04 | $2.1 \times 10^{-3}$ | 5.25 | Acceptable |
| | Tébuconazole : 0.03 | $5.73 \times 10^{-5}$ | 0.19 | Acceptable |

| | | | | |
|---|---|---|---|---|
| **Infant: inhalation of volatilised residues, indoors** | Cyperméthrine 0.022 | $5.54 \times 10^{-5}$ | 0.25 | Acceptable |
| | Propiconazole : 0.04 | $4.25 \times 10^{-3}$ | 10.63 | Acceptable |
| | Tébuconazole : 0.03 | $1.16 \times 10^{-4}$ | 0.39 | Acceptable |
| **Child playing on playground structure outdoors** | Cyperméthrine 0.022 | $1.30 \times 10^{-4}$ | 0.6 | Acceptable |
| | Propiconazole : 0.04 | $1.51 \times 10^{-4}$ | 0.4 | Acceptable |
| | Tébuconazole : 0.03 | $3.24 \times 10^{-4}$ | 1.1 | Acceptable |
| **Infant playing on playground structure outdoors and mouthing (wood treated at 300 g/m2)** | Cyperméthrine 0.022 | $8.2 \times 10^{-3}$ | 37.4 | Acceptable |
| | Propiconazole : 0.04 | $6.45 \times 10^{-3}$ | 16.13 | Acceptable |
| | Tébuconazole : 0.03 | $7.07 \times 10^{-3}$ | 23.6 | Acceptable |

➔ The risk is acceptable for chronic exposure scenarios.

*Tier 2 (additivity)*

| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **HI (∑ HQ a.s)** | **Risk** |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| **Adult professional sanding/processing of treated wood composites** | | | | |
| 0.0232 | 0.01.32 | 0.0331 | **0.0695** | **Acceptable** |
| **Adult: inhalation of volatilised residues, indoors** | | | | |
| 0.0012 | 0.053 | 0.0019 | **0.06** | **Acceptable** |
| **Infant: inhalation of volatilised residues, indoors** | | | | |
| 0.0025 | 0.11 | 0.004 | **0.11** | **Acceptable** |
| **Child playing on playground structure outdoors** | | | | |
| 0.006 | 0.004 | 0.011 | **0.021** | **Acceptable** |
| **Infant playing on playground structure outdoors and mouthing (wood treated at 200 g/m2)** | | | | |
| 0.4 | 0.16 | 0.24 | **0.8** | **Acceptable** |

➔ HI < 1, the risk is acceptable for chronic exposure scenarios

#### *2.2.7.3.3 Risk 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 TRAITEMENT MULTI USAGES must contain label restrictions against use in contact with livestock, food and feed.

#### *2.2.7.3.4 Risk for combined exposure*

The exposure values are compared to AELs of each active substance.

| | Cyperméthrine | Tébuconazole | Propiconazole |
|---|---|---|---|
| **Long term AEL (mg/kg bw/d)** | 0.022 | 0.03 | 0.04 |

***Adult combined exposure (chronic exposure scenario)***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| **Adult combined expo : Brushing** | Cyperméthrine 0.022 | $1.1 \times 10^{-3}$ | 5.01 | Acceptable |
| | Propiconazole : 0.04 | $3.26 \times 10^{-3}$ | 8.15 | Acceptable |
| | Tébuconazole : 0.03 | $2.34 \times 10^{-3}$ | 7.79 | Acceptable |
| **Adult combined expo: spraying (gloves +coverall 20%)** | Cyperméthrine 0.022 | $7.12 \times 10^{-3}$ | 32.37 | Acceptable |
| | Propiconazole : 0.04 | $8.27 \times 10^{-3}$ | 20.68 | Acceptable |
| | Tébuconazole : 0.03 | $9.72 \times 10^{-3}$ | 32.4 | Acceptable |
| **Adult combined expo : Brushing + injecting** | Cyperméthrine 0.022 | $2.18 \times 10^{-3}$ | 9.9 | Acceptable |
| | Propiconazole : 0.04 | $4.42 \times 10^{-3}$ | 11.04 | Acceptable |
| | Tébuconazole : 0.03 | $4.62 \times 10^{-3}$ | 15.4 | Acceptable |
| **Adult combined expo : spraying (gloves +coverall 20%) + injecting** | Cyperméthrine 0.022 | $1.42 \times 10^{-2}$ | 7.9 | Acceptable |
| | Propiconazole : 0.04 | $1.44 \times 10^{-2}$ | 36.10 | Acceptable |
| | Tébuconazole : 0.03 | $1.94 \times 10^{-2}$ | 32.3 | Acceptable |

➔ The risk is acceptable for combined chronic exposure scenarios (adult).

*Tier 2 (additivity)*

| Cyperméthrine | Propiconazole | Tébuconazole | HI (∑ HQ a.s) | Risk |
|---|---|---|---|---|
| **HQ (Exposure/AEL)** | | | | |
| **Adult combined expo : Brushing** | | | | |
| 0.05 | 0.08 | 0.08 | **0.21** | **Acceptable** |
| **Adult combined expo : spraying (gloves +coverall)** | | | | |
| 0.32 | 0.2 | 0.3 | **0.82** | **Acceptable** |
| **Adult combined expo : Brushing + injecting** | | | | |
| 0.01 | 0.12 | 0.15 | **0.28** | **Acceptable** |
| **Adult combined expo : spraying (gloves +coverall) + injecting** | | | | |

| | | | | |
|---|---|---|---|---|
| 0.08 | 0.36 | 0.3 | **0.74** | **Acceptable** |

➔ HI < 1, the risk is acceptable for combined chronic exposure scenarios (adult)

***Infant combined exposure (chronic exposure scenario)***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL (mg/kg bw/d) | Exposure (mg/kg bw/d) | % AEL | Risk |
|---|---|---|---|---|
| Infant combined exposure | Cyperméthrine 0.022 | $8.23 \times 10^{-3}$ | 37.7 | Acceptable |
| | Propiconazole : 0.04 | $1.07 \times 10^{-2}$ | 26.75 | Acceptable |
| | Tébuconazole : 0.03 | $7.2 \times 10^{-3}$ | 24 | Acceptable |

➔ The risk is acceptable for combined chronic exposure scenarios (infant).

*Tier 2 (additivity)*

| Cyperméthrine | Propiconazole | Tébuconazole | HI | Risk |
|---|---|---|---|---|
| HQ (Exposure/AEL) | | | (∑ HQ a.s) | |
| 0.38 | 0.26 | 0.24 | **0.88** | **Acceptable** |

➔ HI < 1, the risk is acceptable for combined chronic exposure scenarios (infant).

### *2.2.7.3.5 Summary of risks characterisation of the product for human health*

Risks related to the use of V33 TRAITEMENT MULTI USAGE by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

Risks related to a secondary exposure to treated wood are considered acceptable except in the case of chewing of a piece of treated wood by an infant, considering a curative treatment (spraying or brushing combined with injection) with an application dose of 450 g/m$^2$. Therefore, the curative treatments with the highest application doses and combining a superficial treatment and injection should be restricted to inaccessible woods (construction wood).

### *2.2.8 Risk assessment for the environment*

**FR-CA box 1**

Please notice that the environmental risk assessment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in green evaluation boxes.

According to the composition provided by the applicant and the SDSs, no ingredient with an environmental classification and present at a concentration leading to the classification of the product, or showing a potential hazard for environment are contained in the product.

Nonetheless, the product contains 2 preservatives, both under review as active substance in PT06:
- 2-methyl-2H-isothiazol-3-one (MIT, CAS N°2682-20-4);
- 1,2-benzisothiazol-3(2H)-one (BIT, CAS N°2634-33-5).

These 2 substances should therefore be considered as substances of concern for the mixture toxicity assessment. However, as both active substances are under review as PT06, they cannot be currently taking into account for the risk assessment of the product, without approved PT06-assessment report.

#### 2.2.8.1 Fate and distribution in the environment of the active substance AAA

The environmental fate and behaviour of the product 06LBCEOL20/2PT is presented in IUCLID, in Section 10. Based on the intended uses of the product and on the nature of the substances, on its physico-chemical properties and on the relation structure/function, the main foreseen route of entry in the environment is the soil.
For the assessment of the environmental fate and behaviour of each active substances contained in the biocidal product 06LBCEOL20/2PT, please refer to the chapters on fate and distribution in the environment (see Assessment Reports, cypermethrin *cis:trans* / 40:60 PT08, 12/07/2013; IPBC PT06 27/09/2013, tebuconazole PT10, 27/09/2013; propiconazole PT09, 12/07/2013) and environmental effects assessment of each active substances in Document II-A (see Letter of Access from Agriphar and Lanxess).
A summary of the environmental behaviour of the active substances cypermethrin, tebuconazole and propiconazole and their relevant metabolites is presented below. All the data are coming from Assessment Report of the active substances.

- **Environmental behaviour of cypermethrin**

Degradation

- Hydrolysis

In acidic conditions and at pH 7, cypermethrin is relatively stable ($DT_{50}$ > 29 days at pH 7, 25°C and $DT_{50}$ > 1 year and of 4.73 days respectively at pH 4 and 7, 50°C). It is degraded under alkaline conditions at pH 9 ($DT_{50}$ of 1.9 hours at 50°C). The increase in temperature increases the degradation rate of cypermethrin.
At 12°C (environmental conditions), the derived $DT_{50}$ of cypermethrin are > 7630 days, 98.9 days and 39.71 hours at pH 4, 7 and 9 respectively.

- Photolysis

*In water*

Cypermethrin is degraded by photolysis in water. The half-lives for net photolysis were calculated to be 14.7 days for $^{14}C$ phenoxy label and 12.4 days for $^{14}C$ cyclopropane label. The main photolytic degradates were DCVC acid (18% of

Applied Radioactivity, AR), 3-phenoxybenzoic acid (15% of AR) and 3-phenoxybenzaldehyde (3% of AR).

*In soil* Light accelerates the degradation of cypermethrin on a soil surface. However, soil photolysis is a minor route of degradation of the active substance as shown by data on distribution of radioactivity and $DT_{50}$ for cis- and trans isomers.

*In air* EPIWIN AOP model gives an indirect half-life of 18h for the photolysis in air (OH) of cypermethrin.

- Biodegradation — Cypermethrin is not readily biodegradable, not inherently biodegradable, not ultimately biodegradable.

*In water /sediment* Cypermethrin is degradable in a water/sediment compartment. Degradation of cypermethrin was effective in both water-sediment systems. At 12°C, $DT_{50}$ values were calculated to be between 6.6 and 18.5 days in the whole system, 0.95 days in the water phase and between 20.7 and 27 days in sediments. The significant metabolites were 3-phenoxybenzoic acid (21% AR in water and 11% in sediment), TDCVC (44% AR in water and 20% in sediment) and CDCVC (22% AR in water and 15% in sediment). A further unknown metabolite was identified up to 14% of AR in the units dosed with the cyclopropyl label.
The two main degradation products TDCVC and CDCVC have to be considered as persistent with typical $DT_{50}$ values > 40 days.

*In soil* In soil in aerobic conditions, cypermethrin is metabolised to three significant metabolites: 3-phenoxybenzoic acid (10.2% AR at day 7), TDCVC (13.6% of AR at day 7) and CDCVC (3.9% of AR at day 7). Further metabolism of cypermethrin and/or these metabolites lead to bound residues and mineralisation to carbon dioxide. The $DT_{50}$ values for the degradation of cypermethrin is within the range 6 to 24 days following incubation at 20 ± 2°C (mean $DT_{50}$ = 13.5 days at 20°C). In soil PT 102, incubated at 10 ± 2°C, the $DT_{50}$ value for the degradation of cypermethrin is 52 days. The corresponding $DT_{50}$ at 12°C is calculated to be 17.2 days, based on the geometric mean. Cis cypermethrin degrades at lower rates in comparison to trans cypermethrin.
In anaerobic conditions, cypermethrin is metabolised to three extractable metabolites: 3-PBA (max. 35.1% AR), CDCVC (max. 22.8% AR), TDCVC (max. 31.2% AR) and carbon dioxide (max. 22.8% AR) in the total flooded soil system. The $DT_{50}$ is estimated to 46 days at 20°C, corresponding to 87.2 days at 12°C.

Distribution

- Adsorption desorption — Results of the soil adsorption/desorption study provided minimum $K_{oc}$ values ranging from 80 653 to 574 360. $K_{oc}$ for the sediment is minimum 527 972.
These values are indicative of a strong adsorption to the soil particles and sediment.

- Volatilisation — Due to its low vapour pressure ($2.3*10^{-7}$ at 20°C), volatilisation of cypermethrin is not expected.

- Bioaccumulation — Cypermethrin tends to bioaccumulate in water organisms with a typical bioaccumulation factor (fish) of 417 L/kg.

- **Environmental behaviour of tebuconazole**

Degradation

- Hydrolysis — Tebuconazole is stable to hydrolysis.

- Photolysis

*In water* Direct photo-degradation of tebuconazole in water is low and the substance may

be considered photolytically stable in water. However, indirect photolysis of tebuconazole may occur in water.

*In soil* The substance may be considered photolytically stable in soil.

*In air* The calculated $DT_{50}$ of tebuconazole in air is more than 2 days. It is therefore considered persistent in air.

- Biodegradation Based on the modified MITI test, tebuconazole is considered as not readily biodegradable.

*In water /sediment* The biodegradation half-life in surface water is estimated to be about 198 days. However, tebuconazole will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days based on a water/sediment study.
The dissipation half-life in sediment is one year.
No major metabolites were found in water/sediment systems.

*In soil* Tebuconazole is not metabolized rapidly in soil in laboratory experiments; the half-life for primary degradation is greater than one year. In field studies the dissipation half-life is 77 days.
1,2,4-triazole is the primary metabolite from the aerobic degradation of tebuconazole (max. 9% of applied radioactivity). However it appears to breakdown more rapidly in soil than tebuconazole. The dissipation half-life of this metabolite in aerobic soil is estimated to be about 10 days.

Distribution

- Adsorption desorption Tebuconazole has a low mobility potential with a $K_{oc}$ = 992 L/kg (arithmetic mean value).
The triazole metabolite has a high mobility potential, the $K_{oc}$ values are on average 89 L/kg.

- Volatilisation Air will not be an environmental compartment of concern for tebuconazole used in wood preservatives because of the very low vapour pressure of this compound.

- Bioaccumulation The BCF for fish varies from 31 to 93. However, the higher value includes the metabolites as well. For the risk assessment, a BCF of 78 is used since this value seems to be the highest reliable value found.

- **Environmental behaviour of propiconazole**

Degradation

- Hydrolysis Propiconazole is hydrolytically stable

- Photolysis Propiconazole is photolytically stable

- Biodegradation Propiconazole is not readily biodegradable.

*In water /sediment* The dissipation half-life of propiconazole is around 6.4 days in water and the degradation half-life in whole water/sediment system is 636 days at 20°C corresponding to 1206 days at 12°C. There is no simulation test of the biodegradation of propiconazole in surface water without sediment available and due to adsorption onto sediment in the water-sediment study the biodegradation half-life of propiconazole in water has not been determined.
There was no metabolite accounting > 10% of the active substance found in the water/sediment key study.

*In soil* In the laboratory studies the geometric mean $DT_{50}$ of propiconazole was determined to be 43 days at 20 °C, corresponding to 82 days at 12°C.

From field studies, the maximum dissipation half-life of 129 days in soil is used as the worst-case in the risk assessment.
In the soil laboratory studies there were two degradation products of propiconazole accounting for more than 10% of the active substance: 1,2,4-triazole (accounting for 24 - 43% of applied radioactivity) and CGA 118 245 (accounting for 22% of applied radioactivity). Both are degraded in soil faster than the parent substance, 1,2,4-triazole having $DT_{50}$ of around 9.3 days and CGA 118 245 having $DT_{50}$ of around 1 day at 20 °C.

Distribution

- Adsorption desorption: With an arithmetic mean value of $K_{oc}$ = 944 mL/g, propiconazole is regarded as slightly mobile in soil. The two degradation products of propiconazole accounting for more than 10% in the soil degradation studies are considered mobile in soil (more mobile than parent). Arithmetic mean values of $K_{oc}$ for 1,2,4-triazole and CGA 118 245 are 69 mL/g and 129 mL/g, respectively.

- Volatilisation: Propiconazole is very slightly volatile. With the estimated half-life less than 2 days (between 10.2 and 42 hours) in troposphere it is not regarded as a persistent contaminant in the air.

- Bioaccumulation: Propiconazole is slightly bioaccumulative to fish with a BCF of 180 and a depuration half-life of 0.48 days for the whole fish.
The estimated BCF for earthworms was 64 (determined by calculation). Based on this estimation, propiconazole is not bioaccumulative in terrestrial organisms.

The physico-chemical and fate and behaviour data on the 3 active substances are summarised in the following table:

**Table 3-1: Physical-chemical and fate and behaviour data on active substances and relevant metabolites**

| Physical-chemical and fate and behaviour data | Cypermethrin *cis:trans* / 40:60 and relevant metabolites | Tebuconazole and relevant metabolites | Propiconazole and relevant metabolites |
|---|---|---|---|
| Molecular weight [g/mol] | 416.3 | 307.8 | 342.2 |
| Melting point [°C] | Onset: 41.2<br>Peak: 47.3 | 105 | no data |
| Boiling point [°C] | Not measurable, decomposes | Not measurable, decomposes | > 250 |
| Vapour pressure [Pa] | $2.3*10^{-7}$ at 20°C<br>$6*10^{-7}$ at 25°C | $1.7*10^{-6}$ at 20°C | $5.6*10^{-5}$ at 25°C |
| Henry's law constant [$Pa.m^3.mol^{-1}$] | 0.024 at 20°C | $1*10^{-5}$ | $9.2*10^{-5}$ |
| Solubility in water [mg/L] | $4*10^{-3}$ at 20°C | 29 at 20°C, pH = 7 | 100 at 20°C |
| Partition coefficient (log $P_{ow}$) | 5.45 at 25°C<br>TDCVC: 2.672 (calculated)<br>CDCVC: 2.672 (calculated) | 3.49 at 20°C | 3.72 at 25°C |
| Hydrolysis $DT_{50}$ [d] | 12°C, pH 4: $DT_{50}$ = 7 631 d<br>12°C, pH 7: $DT_{50}$ = 98.9 d<br>12°C, pH 9: $DT_{50}$ = 1.65 d | Stable at 25°C after 28 days | Stable at 70°C after 28 days |
| Photolytic / photo-oxidative | At 20°C, pH 4: | Stable at pH 7 | Stable at 25°C after 30 |

| Physical-chemical and fate and behaviour data | Cypermethrin *cis:trans* / 40:60 and relevant metabolites | Tebuconazole and relevant metabolites | Propiconazole and relevant metabolites |
|---|---|---|---|
| degradation in water ($DT_{50}$) [d] | $DT_{50}$ = 12.4 - 14.7 d | | days |
| Degradation in water/sediment ($DT_{50}$) [d] | **In water:**<br>0.95 d at 12°C<br>**In sediment:**<br>20.7 – 27 d at 12°C<br>**In whole system**:<br>6.6 - 18.5 d at 12°C<br><br>3-PBA: 24.5 d at 12°C<br>(whole system)<br>TDCVC: 152 – 274 d at 12°C (whole system)<br>CDCVC: 118 – 356 d at 12°C (whole system) | **In water:**<br>198 d (degradation); 43 d (dissipation)<br><br>**In sediment:**<br>365 d (dissipation)<br>**In whole system:**<br>46 d (dissipation) | **In water:**<br>6.4 d at 20°C (dissipation)<br>$DT_{50}$ degradation has not been determined<br><br>**In whole system:**<br>1206 d at 12°C (degradation) |
| Degradation in soil ($DT_{50}$) [d] | **In aerobic conditions:**<br>17.2 at 12°C (geometric mean)<br>**In anaerobic conditions:**<br>87.2 at 12°C | **Laboratory study:**<br>> 365 d at 20°C<br>**Field study:**<br>77 d at 12°C (dissipation)<br><br>1,2,4-triazole: 10 d (dissipation) | 129 (dissipation) (maximal $DT_{50}$ in field studies)<br><br>1,2,4-triazole: 9.3 d at 20°C<br>CGA 118 245: 1 d at 20°C |
| Soil photolysis ($DT_{50}$) [d] | 29.6<br>(soil photolysis is considered as a minor route of degradation) | Stable | Stable |
| Photo-oxidative degradation in air ($DT_{50}$) | 18 h | > 2 days (3.8 days) | < 2 days |
| Adsorption / desorption $K_{oc}$ [L/kg] | 574 360 | 992 (arithmetic mean value)<br><br>1,2,4-triazole: 89 (source: AR for PT10) | 944 (arithmetic mean value)<br><br>1,2,4-triazole: 69<br>(arithmetic mean value)<br>CGA 118 245: 129 (arithmetic mean value) |
| BCF in fish | 417<br><br>TDCVC: 37.25 (calculated)<br>CDCVC: 37.25 (calculated) | 78 | 180 |
| Depuration rate constant (fish) [$d^{-1}$] | $1.58*10^{-3}$ L/h | 0.44 | 0.48 |
| BCF in earthworms | - | 28 (estimated) | 64 (calculated with TGD, formula 82d) |

**FR-CA box 2 – Summary of the physico-chemical, environmental fate and behavior parameters for each active substance and their relevant metabolites used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level**

| Parameter / Variable | Unit | Cypermethrin | Tebuconazole | Propiconazole | 1,2,4-triazole(*) |
|---|---|---|---|---|---|
| Molar mass | [g/mol] | 416.3 | 307.8 | 342.2 | 69.1 |
| Vapour pressure - Vp | [Pa] | 6.00E-07 | 1.70E-06 | 5.6E-05 | 0.220 |
| Water solubility – WS | [$mg.L^{-1}$] | 4.00E-03 | 29 | 100 | 700 |
| $K_{oc}$ | [$L.kg^{-1}$] | 575 000 | 992 | 944 | 89 |
| $DT_{50}$ (soil) | [d at 12°C] | 17.2 | 77 | 82 | 114.7 (**) |
| $DT_{50}$ (surface water – degradation + dissipation) | [d at 12°C] | 0.95 | 43 | 12 | n.r. |
| $DT_{50}$ (aquatic – degradation only) | [d at 12°C] | 18.5 (whole system) | 198 (degradation in water) | 1206 (whole system) | n.r. |
| BCF in fish | [$L.kg^{-1}$] | 417 | n.r. | n.r. | n.r. |
| BCF in earthworm | [$L.kg^{-1}$] | 3380 | n.r. | n.r. | n.r. |
| STP fraction | | | | | |
| $F_{STP, water}$ | [-] | 0.091 | 0.89 | 0.9 | n.r. |
| $F_{STP, sludge}$ | [-] | 0.909 | 0.109 | 0.1 | n.r. |

n.r. – Not relevant for the environmental risk assessement of the product
(*) – Relevant metabolite of tebuconazole and propiconazole in soil with a maximum of 9% and 43.23 % of applied radioactivity, respectively.
(**) – Calculated according to the arrehnius equation with a $DT_{50}$ at 20°C of 60.5 days.

### 2.2.8.2 Effects on environmental organisms for active substance

#### *2.2.8.2.1 Aquatic compartment (including water, sediment and STP)*

A summary and evaluation of effect data for the active substances with relevance to the aquatic compartment can be found in Document II-A of the active substance dossier (see Letters of Access from Agriphar and Lanxess).
The relevant ecotoxicological data and the calculated PNECs (see Assessment Report) are summarised in the following Table:

**Table 5.1-1: Ecotoxicological data on active substances and relevant metabolites for the aquatic compartment**

| Ecotoxicity on aquatic organisms | Cypermethrin *cis:trans* / 40:60 | Tebuconazole and relevant metabolite | Propiconazole |
|---|---|---|---|
| $LC_{50}$ fish [mg/L] | *Mortality (96 h):* $2.83*10^{-3}$ | *Mortality (96 h):* 4.4<br>1,2,4-triazole: 498 | *Mortality (96 h)* 2.6 |
| NOEC fish [mg/L] | *Fry survival, body length/weight (28 d):* **1*10$^{-5}$**(1) | *(21 d semi-static)* **0.010**<br>*(83 d ELS, flow-through)* 0.012 | *(100 d)* **0.068** |
| $EC_{50}$ aquatic invertebrates [mg/L] | *Immobilisation (48 h):* $4.71*10^{-3}$ | *Immobilisation (48 h):* 2.8<br>*Mortality (48 h):* 4.2<br>1,2,4-triazole: > 100 | *Mortality (96 h)* 0.51 |

| | | | |
|---|---|---|---|
| NOEC aquatic invertebrates [mg/L] | *Immobilisation (21 d):* $4*10^{-5}$ | *Immobilisation (21 d):* 0.01 | *Immobilisation (28 d)* 0.11 |
| $ErC_{50}$ algae [mg/L] | *Growth rate (96 h):* > $33*10^{-3}$ | *Growth rate (72 h):* 5.3<br>1,2,4-triazole: > 31 | *Growth rate (72 h)* 9.0 |
| $EbC_{50}$ algae [mg/L] | *Biomass (96 h):* > $33*10^{-3}$ | *Biomass (72 h):* 1.96 | no data |
| NOEC algae [mg/L] | *Biomass (96 h):* > $33*10^{-3}$ | *(72h)* 0.56 | *Biomass (72 h)* 0.46 |
| **$PNEC_{water}$ [mg/L]** | **$1.10^{-6}$ (AF = 10)** | **$1*10^{-3}$ (AF=10)** | **$6.8*10^{-3}$ (AF=10)** |
| NOEC Sediment dwelling organism | - | *(28 d)* **54.5 mg/kg** | *Emergence (28 d)* **5.4 mg/$kg_{wwt}$** (= 25 mg/$kg_{dwt}$) *Development (28 d)* 10.8 mg/$kg_{wwt}$ (= 50 mg/$kg_{dwt}$) |
| **$PNEC_{sediment}$ [mg/$kg_{wwt}$]** | **0.125 (equilibrium partitioning method[(2)])** | **0.55 (AF=100)** | **0.054 (AF=100)** |
| $EC_{50}$ Microorganisms [mg/L] | *Respiration inhibition (3 h):* **163** | *Respiration inhibition (30 min):* **> 32** | *Respiration inhibition (3 h)* **> 100** |
| **$PNEC_{STP}$ [mg/L]** | **1.63 (AF = 100)** | **0.32 (AF=100)** | **100 [(3)]** |

(1) A new study has been commissioned by the applicant to further address the chronic toxicity to fish. The result of the new study will be available for the PT18 Annex I inclusion. A conservative approach decided at TM level sets the overall NOEC for the chronic toxicity to fish to 0.01 µg/L.

(2) The $PNEC_{sediment}$ was calculated using the equilibrium partitioning method and a value of $K_{oc}$ of 575 000 (to calculate $K_{sup\text{-}water}$),

(3) Water solubility of the active substance without any Assessment Factor.

The values in red are the lowest values used for the determination of PNEC for each compartment.

#### *2.2.8.2.2 Atmosphere*

A summary and evaluation of effect data for the active substances with regard to effects in the atmospheric compartment can be found in Document II-A of the active substance dossier (see Letter of Access from Agriphar and Lanxess).

- Data on cypermethrin

The vapour pressure of cypermethrin is such that emissions to air are very limited. The result of EPIWIN model indicates that cypermethrin is photolysed in air and should not tends to accumulate. Therefore, no data are available for cypermethrin.

- Data on tebuconazole

No data is available because based on the Henry's Law constant, no significant volatilisation of tebuconazole is to be expected and air is therefore not a compartment of concern.

- Data on propiconazole

Propiconazole is very slightly volatile. With the estimated half-life less than 2 days (between 10.2 and 42 hours) in troposphere, propiconazole is not regarded as a persistent contaminant in the air.

#### *2.2.8.2.3 Terrestrial compartment*

A summary and evaluation of effect data for the active substances with relevance to the terrestrial compartment can be found in Document II-A of the active substance dossier (see Letters of Access from Agriphar and Lanxess).
The relevant ecotoxicological data and the PNEC (see Assessment Report) are presented in the following Table:

**Table 5.3-1: Ecotoxicological data on active substances for the terrestrial compartment**

| Ecotoxicity on terrestrial organisms | Cypermethrin *cis:trans* / 40:60 | Tebuconazole | Propiconazole and relevant metabolites |
|---|---|---|---|
| $EC_{50}$ earthworm [mg/kg] | *(14 d)* > 100 $mg/kg_{dwt}$ | *Mortality (14 d):* 470 $mg/kg_{dwt}$ | *Mortality (14 d):* 205 $mg/kg_{wwt}$ (= 686 $mg/kg_{dwt}$)<br><br>1,2,4-triazole: > 299 $mg/kg_{wwt}$ (> 1000 $mg/kg_{dwt}$)<br>CGA 118 245: > 299 $mg/kg_{wwt}$ (> 1000 $mg/kg_{dwt}$) |
| NOEC earthworm [mg/kg] | *Mortality (56 d):* > 100 $mg/kg_{dwt}$<br>*Biomass (56 d):* 30.8 $mg/kg_{dwt}$<br>*Reproduction (56 d):* **5.20 $mg/kg_{dwt}$** | *Reproduction (56 d):* **5.70 $mg/kg_{dwt}$** | *Reproduction (56 d):* **0.998 $mg/kg_{wwt}$** |
| $LC_{50}$ plants [mg/kg] | Not expected to be phytotoxic | *Emergence (14 d):* > 100 $mg/kg_{dwt}$ | no data |
| $EC_{50}$ plants [mg/kg] | Not expected to be phytotoxic | *Growth (14 d):* 24 $mg/kg_{dwt}$ | *Seedling emergence and survival:* 4.32 $mg/kg_{wwt}$ |
| NOEC plants [mg/kg] | Not expected to be phytotoxic | no data | *Reproduction:* 1.69 $mg/kg_{wwt}$ (0.96 $mg/kg_{dwt}$) |
| $EC_{50}$ Mineralization [mg/kg] | - | *Nitrogen and carbon mineralisation (28 d):* > 8.30 $mg/kg_{dwt}$ | *Nitrogen mineralisation:* > 2.16 $mg/kg_{wwt}$ (> 1.67 $mg/kg_{dwt}$)<br><br>1,2,4-triazole: > 0.82 $mg/kg_{wwt}$ (> 0.33 $mg/kg_{dwt}$) |
| NOEC Mineralization [mg/kg] | *Nitrogen mineralisation:* 52 $mg/kg_{dwt}$ | *Nitrogen and carbon mineralisation (28 d):* 8.30 $mg/kg_{dwt}$ | *Nitrogen mineralisation:* 2.16 $mg/kg_{wwt}$ (1.67 $mg/kg_{dwt}$)<br><br>1,2,4-triazole: 0.82 $mg/kg_{wwt}$ (0.33 $mg/kg_{dwt}$) |
| **PNECsoil** | **0.0918 $mg/kg_{wwt}$ (AF = 50)** (0.104 $mg/kg_{dwt}$) | **0.1 $mg/kg_{wwt}$ (AF=50)** (0.114 $mg/kg_{dwt}$) | **0.1 $mg/kg_{wwt}$ (AF=10)** |
| $LD_{50}$ bird [mg/kg b.w.] (acute) | Not determined. | 1988 | - |
| $LC_{50}$ bird [mg/kg feed] (dietary) | *(5 d)* > 5620 mg/kg feed equivalent to > 1376 mg/kg b.w./d | *(5 d)* > 4816 | - |
| NOEC bird [mg/kg feed] | *(21 d)* 1000 mg/kg feed equivalent to 92.0 mg/kg b.w./d | no data | - |
| $LD_{50}$ mammal [mg/kg b.w.] (acute) | 1945 | 1700 (female)<br>4000 (male) | - |

The values in red are the lowest values used for the determination of PNEC for each compartment.

#### *2.2.8.2.4 Non compartment specific effect relevant to the food chain*

**- Data on cypermethrin**

As cypermethrin has a log $K_{ow}$ > 3 (log $K_{ow}$ = 5.45) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm estimated in EUSES as 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

$PNEC_{oral, bird}$ and $PNEC_{oral, small\ mammal}$ are not available in the Assessment Report of cypermethrin. These PNEC are therefore calculated based on available toxicity data according to the guidance on BPR, Volume IV, Part B risk assessment (active substances), v1.0, April 2015, section 3.8.3.5.

* A chronic dietary study on birds has been performed and the NOEC reported in the Assessment Report is 1000 $mg/kg_{food}$. The $PNEC_{oral, bird}$ is then derived from this NOEC according to formula 79 of the guidance:

$PNEC_{oral, bird} = NOEC_{bird} / AF_{oral}$.

According to the Table 26 of the guidance, the assessment factor ($AF_{oral}$) is equal to 30 because a chronic study on birds is available.
$PNEC_{oral,bird}$ = 1000 / 30
**$PNEC_{oral,bird}$ = 33.3 $mg/kg_{food}$**

* A 2 years study on rats *via* oral route has been performed and the NOAEL reported in the Assessment Report is 5 $mg/kg_{bw}$/d. This NOAEL is converted in NOEC expressed in $mg/kg_{food}$ according to the formula 78 of the guidance:
$NOEC_{mammal} = NOAEL_{mammal, oral} * CONV_{mammal}$
where $CONV_{mammal}$ is a conversion factor from NOAEL to NOEC. For rats, when a study of more of 6 weeks is available, the conversion factor is equal to 20 according to the Table 25 of the guidance.
$NOEC_{mammal}$ = 5 * 20 = 100 $mg/kg_{food}$.

Then, the $PNEC_{oral, small\ mammal}$ is derived from this NOEC according to formula 79 of the guidance:

$PNEC_{oral, small\ mammal} = NOEC_{mammal}$ / AForal.

According to the Table 26 of the guidance, the assessment factor (AForal) is equal to 30 because a chronic study (2 years) on rats is available.
$PNEC_{oral,small\ mammal}$ = 100 / 30
**$PNEC_{oral,small\ mammal}$ = 3.33 $mg/kg_{food}$**

**- Data on tebuconazole**

Tebuconazole showed a low bioconcentration potential in aquatic and terrestrial organisms ($BCF_{fish}$ < 100) and it did not undergo biomagnification through the food chain. Moreover, tebuconazole did not represent a real risk to birds due to the low toxicity of the active substance.

**- Data on propiconazole**

In the bioaccumulation study the mean steady-state BCF of propiconazole was 180 and depuration half-life 0.48 days for the whole fish. The estimated BCF of propiconazole for bioconcentration to soil dwelling species is 64.
For mammals, a NOAEC of 100 mg a.s./kg feed (lowest average intake 8.0 mg/kg b.w./day) was obtained from a two generation reproduction study with rats. The $PNEC_{oral}$ of 3.33 mg a.s./kg food is derived by dividing the NOAEC by an assessment factor, which is 30 in case of a chronic study with mammals.

Based on the above information from the AR, secondary poisoning is not considered a problem for this product.

**FR-CA box 3 – Summary of the PNEC values for each active substance and their relevant metabolites used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level**

| PNEC | Unit | Cypermethrin | Tebuconazole | Propiconazole | 1,2,4-triazole |
|---|---|---|---|---|---|
| $PNEC_{STP}$ | [mg/L] | 1.63E+00 | 3.20E-01 | 1.00E+02 | n.r. |
| $PNEC_{water}$ | [mg/L] | 1.00E-06 | 1.00E-03 | 6.80E-03 | n.r. |
| $PNEC_{sediment}$ | [$mg/kg_{wwt}$] | 1.25E-01 | 5.50E-01 | 5.40E-02 | n.r. |
| $PNEC_{soil}$ | [$mg/kg_{wwt}$] | 9.18E-02 | 1.00E-01 | 1.00E-01 | 8.2E-03 |
| $PNEC_{oral,bird}$ | [$mg/kg_{food}$] | 3.33E+01 | n.r. | n.r. | n.r. |
| $PNEC_{oral,mammals}$ | [$mg/kg_{food}$] | 3.33E+00 | n.r. | n.r. | n.r. |

n.r: not relevant

#### *2.2.8.2.5 PBT and ED Assessment*

**FR-CA box 4 – PBT and ED assessment**

**PBT-assessment:**

According to the PT07-AR of tebuconazole (2013), tebuconazole does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance is candidate for substitution, as it fulfils the P and T criteria.

According to the PT07-AR of propiconazole (2013), propiconazole does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance fulfils the P criteria.

According to the PT08-AR of cypermethrin (2013), cypermethrin does not fulfil the PBT nor the vPvB criteria. Nonetheless, the substance fulfils the T criteria.

**ED-assessment:**

According to the PT07-AR of tebuconazole (2013), the PT07-AR of propiconazole (2013), the PT08-AR of cypermethrin (2013), no definite conclusions can be drawn concerning the endocrine disruption activity of each active substance.

### 2.2.8.3 Effects on environmental organisms for biocidal product

**FR-CA box 5**

No data on ecotoxicity of the product has been provided by the applicant.

### 2.2.8.4 Environmental exposure assessment

The environmental exposure assessment has been performed in accordance with the revised Emission Scenario Document for wood preservatives, 27/09/2013 (revised ESD for PT08). In addition, recent agreements published in the Technical agreements of Biocides (TAB, September 2015) were also taken into account to calculate emission values.

The product 06LBCEOL20/2PT is intended to be used:

- indoors for the preventive treatment of woods by professionals and non-professionals especially in wet situation (beams, frames, wood in cellars, basements and bathrooms, Use Class 2) and for the curative treatment on beams and frames only. The preventive treatment is done by brush or spray application at the dose of 200 g/m². The curative treatment can be done by brushing, spraying and injection. By brushing or spraying, the curative treatment is performed at the dose of 300 g/m². The treatment by injection is performed at 150 g/m² and is always followed by a curative surface application by brushing or spraying at 300 g/m².

- outdoors for the preventive and curative treatment of exterior woods (shutters, doors, siding, fences, gates, awnings, roof overhangs, UC 3.1) by professionals and non-professionals. The preventive treatment is done by brush or spray application at the dose of 200 g/m². The curative treatment can be done by brushing, spraying and injection. By brushing or spraying, the curative treatment is performed at the dose of 300 g/m². The curative treatment by injection is done only for large section woods (*i.e.* beams and frames) and performed at 150 g/m². This treatment is always followed by a surface application by brushing or spraying at 300 g/m².

For treatment of interior woods, the potential emissions to the outer environment during application by brushing, spraying or injection and from treated wood in service are considered negligible, according to the revised ESD for PT08.

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

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.

#### *2.2.8.4.1 Emissions estimation during outdoor application*

2.2.8.4.1.1 Emissions into surface *water*

As the product is only used for treating house pieces such as shutters, doors, siding, fences, gates, awnings, roof overhangs and is not used for treating commodities such as bridge over water bodies, the contamination of the surface water during application by brushing, spraying or injection is considered as negligible.
Indeed, as mentioned in the document Technical Agreement of Biocides, when it is not an intended use, the bridge over pond scenario does not need to be evaluated for the application phase:
***"Should the bridge over pond scenario for UC3 be included in the CAR even if this is not proposed as an intended use by the applicant?***
*(TM V 2007, TM IV 2012, TM I 2013)*
*The bridge over pond scenario is not used to evaluate the application phase but the use phase, in order to describe the emission pathway into open water bodies, and should therefore be included in the CAR."*

**FR-CA box 6 – Estimation of emission into surface water during outdoor application.**

FR-CA disagrees with the registrant interpretation of the point ENV58 of the TAB (2015), considering that treatments are intended in PT08 without explicitly excluding application near surface water.

As a consequence, the emissions to surface water during the application phase by brushing for preventive and curative treatment has been performed by FR-CA, by applying the scenario “bridge over pond” described in the ESD-PT08 (2013).

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

According to the intended uses, outdoor injection application is only performed as curative treatment. The treatment by injection is performed at 150 $g.m^{-2}$ of product and is always followed by a curative surface application by brushing or spraying at 300 $g.m^{-2}$ of product.

No scenario is currently described in the PT08-ESD for estimating releases during outdoor application by injection. A worst case approach was considered by FR-CA for estimating releases by applying the scenario used for brushing application by non-professional with an application rate of 150 $g.m^{-2}$.

As injection is always followed by a curative surface application by brushing or spraying at 300 $g.m^{-2}$ of product, emissions have been aggregated, accordingly.

**Outdoor application by brushing**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Treated wood area | $AREA_{bridge}$ | 10 | $[m^2.d^{-1}]$ | D |
| Application rate of the product | $Q_{applic.product}$ | Preventive: 0.2<br>Curative: 0.3 | $[L.m^{-2}]$ | S |
| Content of the active substance | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | [-] | S |
| Density of the product | $RHO_{product}$ | 1 | $[kg.m^{-3}]$ | S |
| Fraction of product lost to water during application | $F_{water,brush}$ | Prof: 0.03<br>Non-prof: 0.05 | [-] | D |
| Water volume under bridge | $V_{water}$ | 1000 | $[m^2]$ | D |

| ***Outputs:***<br>***Preventive treatment*** | | |
|---|---|---|
| Emission of substance to water after application – $E_{water,brush}$ $[kg.d^{-1}]$ (eq. 4.41 of PT08-ESD) | | |
| | Professional | Non professional |
| Tebuconazole | 9.00E-05 | 1.50E-04 |
| Propiconazole | 8.40E-05 | 1.40E-04 |
| Cypermethrine | 1.08E-04 | 1.80E-04 |

| ***Outputs:***<br>***Curative treatment*** | | |
|---|---|---|
| Emission of substance to water after application – $E_{water,brush}$ $[kg.d^{-1}]$ (eq. 4.41 of PT08-ESD) | | |
| | Professional | Non professional |
| Tebuconazole | 1.35E-04 | 2.25E-04 |
| Propiconazole | 1.26E-04 | 2.10E-04 |
| Cypermethrine | 1.62E-04 | 2.70E-04 |

**BRIDGE OVER POND - Outdoor application by spraying**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Treated wood area | $AREA_{bridge}$ | 10 | $[m^2.d^{-1}]$ | D |

| | | | | |
|---|---|---|---|---|
| Application rate of the product | $Q_{applic.product}$ | Preventive: 0.2<br>Curative: 0.3 | [$L.m^{-2}$] | S |
| Content of the active substance | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | [-] | S |
| Density of the product | $RHO_{product}$ | 1 | [$kg.m^{-3}$] | S |
| Fraction of product lost to water during application by drift and by run-off | $F_{water,spray}$ | 0.3 | [-] | (D) |
| Water volume under bridge | $V_{water}$ | 1000 | [m²] | D |

| ***Outputs:***<br>***Preventive treatment*** | |
|---|---|
| Emission of substance to water after application – $E_{water,spray}$ [$kg.d^{-1}$] (modified eq. 4.41 of PT08-ESD) | |
| Tebuconazole | 9.00E-04 |
| Propiconazole | 8.40E-04 |
| Cypermethrine | 1.08E-03 |

| ***Outputs:***<br>***Curative treatment*** | |
|---|---|
| Emission of substance to water after application – $E_{water,spray}$ [$kg.d^{-1}$] (modified eq. 4.41 of PT08-ESD) | |
| Tebuconazole | 1.35E-03 |
| Propiconazole | 1.26E-03 |
| Cypermethrine | 1.62E-03 |

**BRIDGE OVER POND - Outdoor application by injection**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Treated wood area | $AREA_{bridge}$ | 10 | [$m^2.d^{-1}$] | D |
| Application rate of the product | $Q_{applic.product}$ | 0.15 | [$L.m^{-2}$] | S |
| Content of the active substance | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | [-] | S |
| Density of the product | $RHO_{product}$ | 1 | [$kg.m^{-3}$] | S |
| Fraction of product lost to water during application | $F_{water,injection}$ | 0.05 | [-] | D |
| Water volume under bridge | $V_{water}$ | 1000 | [m²] | D |

| ***Outputs:***<br>***Injection treatment*** | |
|---|---|
| Emission of substance to water after application – $E_{water,injection}$ [$kg.d^{-1}$] (modified eq. 4.41 of PT08-ESD) | |
| Tebuconazole | 1.13E-04 |

| | |
|---|---|
| Propiconazole | 1.05E-04 |
| Cypermethrine | 1.35E-04 |

| ***Outputs:*** ***Treatment by injection followed by curative brushing*** | | |
|---|---|---|
| Emission of substance to water after application – $E_{water,injection} + E_{water,brush}$ [$kg.d^{-1}$] | | |
| | Professional | Non professional |
| Tebuconazole | 2.48E-04 | 3.38E-04 |
| Propiconazole | 2.31E-04 | 3.15E-04 |
| Cypermethrine | 2.97E-04 | 4.05E-04 |

| ***Outputs:*** ***Treatment by injection followed by curative spraying*** | |
|---|---|
| Emission of substance to water after application – $E_{water,injection} + E_{water,spray}$ [$kg.d^{-1}$] | |
| Tebuconazole | 1.46E-03 |
| Propiconazole | 1.37E-03 |
| Cypermethrine | 1.76E-03 |

2.2.8.4.1.2 Emissions into the soil

Emissions into the soil are calculated for application by brushing, spraying and injection.

*Emissions into the soil following application by brushing*

During application by brushing, product losses due to spills and drips will end-up in soil, if it is not protected with a plastic foil.

To estimate emissions into the soil following outdoor treatment of UC3.1 woods by brushing, the revised ESD for PT08 describes 2 scenarios: the house and the fence scenarios. The house scenario with amateurs as applicators represents a worst case situation and is therefore used in this risk assessment.

The default values for the size of the receiving soil are: 50 cm distance from the house and a soil depth of 50 cm. This corresponds to a soil volume of 13 $m^3$.

The input parameters for calculating the local emission and the concentration into the soil following an application by brushing by amateurs are presented in the following table.

**Table 3.3.2.1.2-1: Input parameters for calculating the local emission and concentration into the soil – *in situ* brushing**

| Parameter | Nomenclature | | Value | Unit | Origin |
|---|---|---|---|---|---|
| Treated wood area | $AREA_{house}$ | | 125 | [$m^2$/d] | D |
| Application rate of the product | $Q_{applic,product}$ | preventive treatment | 0.2 | [L/m²] | A |
| | | curative treatment | 0.3 | | |
| Content of active substance in the product | $f_{a.i.}$ | cypermethrin | 0.17 | [%] | A |
| | | tebuconazole | 0.14 | | |
| | | propiconazole | 0.13 | | |
| Density of product | $RHO_{product}$ | | 1 | [kg/L] [1] | A |
| Fraction of product lost to soil during application | $F_{soil,brush}$ (amateur) | | 0.05 | [-] | D |
| Volume of (wet) soil | $V_{soil}$ | | 13 | [$m^3$] | D |
| Bulk density of (wet) soil | $RHO_{soil}$ | | 1700 | [$kg_{wwt}/m^3$] | D |

D = default, A = based on information of applicant

[1] In the revised ESD for PT08, the unit for the density is $kg/m^3$ and in the equation to calculate $E_{soil,brush,}$ a factor of $10^{-3}$ must be used. However, in this case, as the density is expressed as kg/L, the factor of $10^{-3}$ is not used in the equation 4.37.

The local emission to soil during the day of application is calculated according to the equation 4.37 from the revised ESD PT08 as following:

$E_{soil,brush} = AREA_{house} * Q_{applic,product} * f_{a.i.} * RHO_{product} * F_{soil,brush}$

The local concentration into the soil at the end of the day of application is calculated according to the equation 4.38 from the revised ESD PT08 as following:

$Clocal_{soil,brush} = E_{soil,brush} / (V_{soil} * RHO_{soil})$

The results are presented in the following tables.

**Table 3.3.2.1.2-2: Resulting local emissions and concentrations into the soil – *in situ* brushing at 200 g/m²**

| Active substance | Local emission ($Elocal_{soil}$) [kg/d] | Local concentration [$kg/kg_{wwt}$] |
|---|---|---|
| Cypermethrin | $2.13*10^{-3}$ | $9.62*10^{-8}$ |
| Tebuconazole | $1.75*10^{-3}$ | $7.92*10^{-8}$ |
| Propiconazole | $1.63*10^{-3}$ | $7.35*10^{-8}$ |

**Table 3.3.2.1.2-3: Resulting local emissions and concentrations into the soil – *in situ* brushing at 300 g/m²**

| Active substance | Local emission ($Elocal_{soil}$) [kg/d] | Local concentration [$kg/kg_{wwt}$] |
|---|---|---|
| Cypermethrin | $3.19*10^{-3}$ | $1.44*10^{-7}$ |
| Tebuconazole | $2.63*10^{-3}$ | $1.19*10^{-7}$ |
| Propiconazole | $2.44*10^{-3}$ | $1.10*10^{-7}$ |

**FR-CA box 7 – Estimation of the emissions into soil during outdoor brushing application.**

FR-CA agrees with the registrant's inputs used for the estimation of releases from brush application of the product according to the "house" scenario described in the PT08-ESD, except for the input "content of active substance in the product", expressed in pure active substance (0.14% w/w, 0.13% w/w, 0.17% w/w, for tebuconazole, propiconazole, and cypermethrin, respectively), instead of technical active substance (0.15% w/w, 0.14% w/w, 0.18% w/w, for tebuconazole, propiconazole, and cypermethrin, respectively). Emission calculations have been revised accordingly.

**HOUSE - Outdoor application by brushing**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Treated wood area | $AREA_{house}$ | 125 | [$m^2.d^{-1}$] | D |
| Application rate of the product | $Q_{applic.product}$ | Preventive: 0.2<br>Curative: 0.3 | [$L.m^{-2}$] | S |
| Content of the active substance | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | [-] | S |
| Density of the product | $RHO_{product}$ | 1 | [$kg.m^{-3}$] | S |
| Fraction of product lost to soil during application | $F_{soil,brush}$ | Professional: 0.03<br><br>Non-professional: 0.05 | [-] | D |
| Wet soil volume | $V_{soil}$ | 13 | [$m^2$] | D |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | [$kg_{wwt}.m^{-3}$] | D |

| ***Outputs:***<br>***Preventive treatment*** | | |
|---|---|---|
| **Emission of substance to soil after application – $E_{soil,brush}$ [$kg.d^{-1}$]** (eq. 4.37 of PT08-ESD) | | |
| | Professional | Non professional |
| Tebuconazole | 1.13E-03 | 1.88E-03 |
| Propiconazole | 1.05E-03 | 1.75E-03 |
| Cypermethrine | 1.35E-03 | 2.25E-03 |

| ***Outputs:***<br>***Curative treatment*** | | |
|---|---|---|
| **Emission of substance to soil after application – $E_{soil,brush}$ [$kg.d^{-1}$]** (eq. 4.37 of PT08-ESD) | | |
| | Professional | Non professional |
| Tebuconazole | 1.69E-03 | 2.81E-03 |
| Propiconazole | 1.58E-03 | 2.63E-03 |
| Cypermethrine | 2.03E-03 | 3.38E-03 |

*Emissions into the soil following application by spraying*

The *in situ* spraying scenario, corresponding to the house scenario is used in this risk assessment.
During outdoor spraying application, product losses are due to run-off and drift. The main receiving compartment by run-off and spray drift is the soil adjacent to the house, if soil is not protected with a plastic foil. By run-off, the wood preservative can be emitted directly from the house to the adjacent soil compartment. By spray drift, a fraction of the droplets formed will not reach the target area but deposit on the soil after drift.

It is assumed, in a tier-1 assessment that 20% of the applied product will reach the soil due to run-off and 10% will deposit on soil due to spray drift. The affected zone by run-off and spray drift is defined as a zone of 50 cm width and 50 cm depth, resulting in an affected soil volume of 13 $m^3$.
A tier-2 assessment is proposed, taking into account the covering of the soil by a plastic sheet assumed to be of 1 m width. In this second tier it is assumed that 0% of applied product will reach the soil due to run-off, since the soil is protected by a plastic foil. It is also assumed that 33% of the total spray drift will deposit on the soil at a distance between 1 m and 1.5 m from house wall, resulting in an affected soil volume of 15 $m^3$.
Releases to the air compartment by drift is considered as negligible since exposure of the air compartment is limited in time and restricted to local scale. Moreover, the estimation of the distribution of the active substances in the different environmental compartments (see Section 10.4 of the IUCLID file) has shown that concentrations of active substances in air compartment represent very small amounts for all the active substances (< 0.5%).
The input parameters for calculating the local emission and concentration into the soil following an application by spraying are presented in the following table.

**Table 3.3.2.1.2-4: Input parameters for calculating the local emission and concentration into the soil – *in situ* spraying**

| Parameters | Nomenclature | | Value | Unit | Origin |
|---|---|---|---|---|---|
| Treated wood area for a house | $AREA_{house}$ | | 125 | [m²/d] | D |
| Application rate of the product | $Q_{applic,product}$ | Preventive treatment | 0.2 | [L/m²] | A |
| | | Curative treatment | 0.3 | | |
| Content of substance in the product | $f_{ai}$ | Cypermethrin | 0.17 | [%] | A |
| | | Tebuconazole | 0.14 | | |
| | | Propiconazole | 0.13 | | |
| Density of product | $RHO_{product}$ | | 1 | [kg/L] [1] | A |
| Fraction of product lost to soil during application by run-off (tier 1) | $F_{runoff}$ | | 0.2 | - | D |
| Fraction of product lost to soil during application by spray drift (tier 1) | $F_{drift}$ | | 0.1 | - | D |
| Fraction of spray drift depositing to a 0.5 m wide soil band 1-1.5 m distant from the house (tier 2) | $F_{dep}$ | | 0.33 | - | D |
| Soil volume adjacent to the treated surface to which run-off and drift deposition occur (tier 1) | $V_{soil,runoff,drift,tier1}$ | | 13 | [$m^3$] | D |
| Soil volume adjacent to the treated surface to which drift deposition occur (tier 2) | $V_{soil,drift,tier2}$ | | 15 | [$m^3$] | D |
| Bulk density of wet soil | $RHO_{soil}$ | | 1700 | [$kg_{wwt}/m^3$] | D |

[1] In the revised ESD for PT08, the unit for the density is kg/$m^3$ and in the equations to calculate the local emissions to soil, a factor of $10^{-3}$ must be used. However, in this case, as the density is expressed as kg/L, the factor of $10^{-3}$ is not used in the equations 4.114, 4.115 and 4.116.

The local emissions into the soil following run off and spray drift are calculated according to the equations 4.114, 4.115 and 4.116 from the revised ESD PT08 as following:
Equation 4.114: $E_{soil,\ runoff} = AREA_{house} * Q_{applic,product} * f_{ai} * RHO_{product} * F_{runoff}$
Equation 4.115: $E_{soil,\ spray\ drift,\ tier1} = AREA_{house} * Q_{applic,product} * f_{ai} * RHO_{product} * F_{drift}$
Equation 4.116: $E_{soil,\ spray\ drift,\ tier2} = AREA_{house} * Q_{applic,product} * f_{ai} * RHO_{product} * F_{drift} * F_{dep}$

The resulting local concentrations in the soil are calculated according to the equations 4.117, 4.118, 4.119, 4.120 and 4.121 from the revised ESD PT08 as following:

Equation 4.117: $Clocal_{soil,\ runoff} = E_{soil,\ runoff} / (V_{soil,\ runoff,\ drift,\ tier1} * RHO_{soil})$
Equation 4.118: $Clocal_{soil,\ spray\ drift,\ tier1} = E_{soil,\ spray\ drift,\ tier1} / (V_{soil,\ runoff,\ drift,\ tier1} * RHO_{soil})$
Equation 4.119: $Clocal_{soil,\ spray\ drift,\ tier2} = E_{soil,\ spray\ drift,\ tier2} / (V_{soil,\ drift,\ tier2} * RHO_{soil})$
Equation 4.120: $Clocal_{soil,\ tier1} = Clocal_{soil,\ runoff} + Clocal_{soil,\ spray\ drift,\ tier1}$
Equation 4.121: $Clocal_{soil,\ tier2} = Clocal_{soil,\ spray\ drift,\ tier2}$

The results are presented in the following tables.

**Table 3.3.2.1.2-5: Local emissions into the soil – *in situ* spraying**

| Active substance | Local emission due to run-off (tier 1) [kg/d] | Local emission due to spray drift (tier 1) [kg/d] | Local emission due to spray drift (tier 2) [kg/d] |
|---|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | | |
| Cypermethrin | $8.50*10^{-3}$ | $4.25*10^{-3}$ | $1.40*10^{-3}$ |
| Tebuconazole | $7.00*10^{-3}$ | $3.50*10^{-3}$ | $1.16*10^{-3}$ |
| Propiconazole | $6.50*10^{-3}$ | $3.25*10^{-3}$ | $1.07*10^{-3}$ |
| **Application dose = 300 g/m² (curative treatment)** | | | |
| Cypermethrin | $1.28*10^{-2}$ | $6.38*10^{-3}$ | $2.10*10^{-3}$ |
| Tebuconazole | $1.05*10^{-2}$ | $5.25*10^{-3}$ | $1.73*10^{-3}$ |
| Propiconazole | $9.75*10^{-3}$ | $4.88*10^{-3}$ | $1.61*10^{-3}$ |

**Table 3.3.2.1.2-6: Local concentrations into the soil – *in situ* spraying due to run-off and spray drift (Tier 1 and Tier 2)**

| Active substance | Local concentration due to run-off (tier 1) [kg/d] | Local concentration due to spray drift (tier 1) [kg/d] | Local concentration due to spray drift (tier 2) [kg/d] |
|---|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | | |
| Cypermethrin | $3.85*10^{-7}$ | $1.29*10^{-7}$ | $5.50*10^{-8}$ |
| Tebuconazole | $3.17*10^{-7}$ | $1.58*10^{-7}$ | $4.53*10^{-8}$ |
| Propiconazole | $2.94*10^{-7}$ | $1.47*10^{-7}$ | $4.21*10^{-8}$ |
| **Application dose = 300 g/m² (curative treatment)** | | | |
| Cypermethrin | $5.77*10^{-7}$ | $2.88*10^{-7}$ | $8.25*10^{-8}$ |
| Tebuconazole | $4.75*10^{-7}$ | $2.38*10^{-7}$ | $6.79*10^{-8}$ |
| Propiconazole | $4.41*10^{-7}$ | $2.21*10^{-7}$ | $6.31*10^{-8}$ |

**Table 3.3.2.1.2-7: Resulting local concentrations into the soil – *in situ* spraying**

| Active substance | Local concentration into a band of soil of 50 cm width adjacent to the house (tier 1) [$kg/kg_{wwt}$] | Local concentration into a band of soil of 50 cm width at a distance between 1 m and 1.5 m from the house wall (tier 2) [$kg/kg_{wwt}$] |
|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | |
| Cypermethrin | $5.77*10^{-7}$ | $5.50*10^{-8}$ |
| Tebuconazole | $4.75*10^{-7}$ | $4.53*10^{-8}$ |
| Propiconazole | $4.41*10^{-7}$ | $4.21*10^{-8}$ |
| **Application dose = 300 g/m² (curative treatment)** | | |
| Cypermethrin | $8.65*10^{-7}$ | $8.25*10^{-8}$ |
| Tebuconazole | $7.13*10^{-7}$ | $6.79*10^{-8}$ |
| Propiconazole | $6.62*10^{-7}$ | $6.31*10^{-8}$ |

**FR-CA box 8 – Estimation of the emissions into soil during outdoor spraying application.**

FR-CA agrees with the registrant's inputs used for the estimation of releases from spray application of the product according to the "house" scenario described in the PT08-ESD, except for the input "content of active substance in the product", expressed in pure active substance (0.14% w/w, 0.13% w/w, 0.17% w/w, for tebuconazole, propiconazole, and cypermethrin, respectively), instead of technical active substance (0.15% w/w, 0.14% w/w, 0.18% w/w, for tebuconazole, propiconazole, and cypermethrin, respectively). Emission calculations have been revised accordingly.

**HOUSE - Outdoor application by spraying**

| ***Inputs :*** | | | | | |
|---|---|---|---|---|---|
| **Parameter / Variable** | **Symbol** | **Value** | | **Unit** | **Origin** |
| | | **Tier 1** | **Tier 2** | | |
| Treated wood area | $AREA_{house}$ | 125 | | $[m^2.d^{-1}]$ | D |
| Application rate of the product | $Q_{applic,product}$ | Preventive: 0.2<br>Curative: 0.3 | | $[l.m^{-2}]$ | S |
| Content of active substance in product | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | | [-] | S |
| Density of product | $RHO_{product}$ | 1 | | $[kg.L^{-1}]$ | S |
| Fraction of product lost to soil during application by spray drift | $F_{drift}$ | 0.1 | | [-] | D |
| Fraction of product lost to soil during application by run-off | $F_{run-off}$ | 0.2 | | [-] | D |
| Fraction of spray drift depositing to a 0.5 m wide soil band 1 – 1.5 m distant from the house (Tier 2) | $F_{dep}$ | | 0.33 | [-] | D |
| Run-off: Soil volume adjacent to treated surface<br>Drift: volume to which deposition occurs in Tier1 | $V_{soil,runoff\ .\ drift-tier1}$ | 13 | | $[m^3]$ | D |
| Drift: volume to which deposition occurs in Tier 2 | $V_{soil,drift-tier2}$ | | 15 | $[m^3]$ | D |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | | $[kg_{wwt}.m^{-3}]$ | D |

| ***Outputs:*** ***Preventive treatment*** | |
|---|---|
| **Emission of substance to soil after application by run-off – $E_{soil,spray\_runnoff}$ [$kg.d^{-1}$] (Eq. 4.114 of PT08-ESD)** | |
| Tebuconazole | 7.50E-03 |
| Propiconazole | 7.00E-03 |
| Cypermethrine | 9.00E-03 |

| **Emission of substance to soil after application by spray drift - $E_{soil,spray\_drift}$ [$kg.d^{-1}$] (Eq. 4.115 and 4.116 of PT08-ESD)** | | |
|---|---|---|
| | **Tier 1** | **Tier 2** |
| Tebuconazole | 3.75E-03 | 1.24E-03 |
| Propiconazole | 3.50E-03 | 1.16E-03 |
| Cypermethrine | 4.50E-03 | 1.49E-03 |

| ***Outputs:*** ***Curative treatment*** | |
|---|---|
| **Emission of substance to soil after application by run-off – $E_{soil,spray\_runnoff}$ [$kg.d^{-1}$] (Eq. 4.114 of PT08-ESD)** | |
| Tebuconazole | 1.13E-02 |
| Propiconazole | 1.05E-02 |
| Cypermethrine | 1.35E-02 |

| **Emission of substance to soil after application by spray drift - $E_{soil,spray\_drift}$ [$kg.d^{-1}$] (Eq. 4.115 and 4.116 of PT08-ESD)** | | |
|---|---|---|
| | **Tier 1** | **Tier 2** |
| Tebuconazole | 5.63E-03 | 1.86E-03 |
| Propiconazole | 5.25E-03 | 1.73E-03 |
| Cypermethrine | 6.75E-03 | 2.23E-03 |

*Emissions into the soil following application by injection*

During application by injection, product losses due to dripping will end-up in soil, if it is not protected with a plastic foil.

For estimating emissions into the soil following outdoor treatment of UC3.1 woods by injection, the emission scenario for injection presented in the revised ESD for PT08 is for a transmission pole with a treated wood area of 0.8 m² and a soil volume of 2.97 $m^3$. This scenario has thus been adapted for the treatment by injection of houses elements. As no scenario relevant for outdoor injection treatment of houses elements (UC 3.1) is available in the revised ESD for PT08, an adapted scenario is therefore proposed below.

It is considered that only heavy sections of wood (as beams and frames) are treated by injection. The most representative wood construction used outdoors and with large sections is a carport. [redacted]

[redacted]

[14] http://www.abris-et-jardin.fr/garages-carports-et-charreterie-en-bois/carport-standard/carport-standard-102.html
http://www.leroymerlin.fr/v3/p/produits/terrasse-jardin/abri-garage-rangement-et-etendage/garage-et-carport/carport-l1308217063
http://www.oogarden.com/cat-728-Carports.html

| | | |
|---|---|---|
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | |
| [redacted] | [redacted] | |
| [redacted] | [redacted] | |
| [redacted] | [redacted] | |
| [redacted] | [redacted] | |
| [redacted] | | |
| [redacted] | [redacted] | [redacted] |
| Depth | 0.5 m | |

The input parameters for calculating the local emission and concentration in the soil following an application by injection are presented in the following table.

**Table 3.3.2.1.2-8: Input parameters for calculating the local emission and concentration into the soil – *in situ* injection**

| Parameter | Nomenclature | | Value | Unit | Origin |
|---|---|---|---|---|---|
| Treated wood area | $AREA_{house, inj}$ | | 15 | [$m^2$/d] | D |
| Application rate of the product | $Q_{applic,product}$ | | 0.15 | [L/m²] | A |
| Content of active substance in the product | $f_{a.i.}$ | cypermethrine | 0.17 | [%] | A |
| | | tebuconazole | 0.14 | | |
| | | propiconnazole | 0.13 | | |
| Density of product | $RHO_{product}$ | | 1 | [kg/L] [1] | A |
| Fraction of product lost to soil during application | $F_{soil,inj}$ | | 0.05 | [-] | D |
| Volume of (wet) soil | $V_{soil, inj}$ | | 10 | [$m^3$] | D |
| Bulk density of (wet) soil | $RHO_{soil}$ | | 1700 | [$kg_{wwt}/m^3$] | D |

D = default, A = based on information of applicant

[1] In the revised ESD for PT08, the unit for the density is kg/$m^3$ and in the equation to calculate the local emissions to soil, a factor of $10^{-3}$ must be used. However, in this case, as the density is expressed as kg/L, the factor of $10^{-3}$ is not used in the equation 4.88.

The local emission to soil is calculated according to the equation 4.88 from the revised ESD PT08 as following:

$E_{soil,inj} = AREA_{house} * Q_{applic,product} * f_{a.i.} * RHO_{product} * F_{soil,inj}$

The local concentration into the soil is calculated according to the equation 4.89 from the revised ESD PT08 as following:

$Clocal_{soil,inj} = E_{soil,inj} / (V_{soil} * RHO_{soil})$

The results are presented in the following table.

**Table 3.3.2.1.2-9: Resulting local emissions and concentrations into the soil – *in situ* injection**

| Active substance | Local emission ($Elocal_{soil,inj}$) [kg/d] | Local concentration ($Clocal_{soil,inj}$) [$kg/kg_{wwt}$] |
|---|---|---|
| Cypermethrin | $1.91\text{-}10^{-4}$ | $1.13*10^{-8}$ |
| Tebuconazole | $1.58*10^{-4}$ | $9.26*10^{-9}$ |
| Propiconazole | $1.46*10^{-4}$ | $8.60*10^{-9}$ |

**FR-CA box 9 – Estimation of the emissions into soil during outdoor injection followed by curative surface application**

According to the applicant's intended uses, outdoor injection application is only performed as curative treatment. The treatment by injection at 150 $g.m^{-2}$ of product is always followed by a curative surface application by brushing or spraying at 300 $g.m^{-2}$ of product.

No scenario is currently described in the PT08-ESD for estimating releases during outdoor application by injection in use class 3. The adapted scenario proposed by the applicant was not considered by FR-CA as a worst case. As outdoor injection application is always followed by a curative surface application by brushing or spraying, FR-CA is of the opinion that emissions from injection and surface application has to be cumulated.

A worst case approach was considered for estimating releases from the outdoor application by injection by applying the house scenario used for brushing application by non-professional with an application rate of 150 $g.m^{-2}$.

As injection is always followed by a curative surface application by brushing or spraying at 300 $g.m^{-2}$ of product, emissions have been cumulated, accordingly.

**HOUSE - Outdoor application by injection**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Treated wood area | $AREA_{house}$ | 125 | $[m^2.d^{-1}]$ | D |
| Application rate of the product | $Q_{applic.product}$ | Injection: 0.15 | $[L.m^{-2}]$ | S |
| Content of the active substance | $f_{ai}$ | Tebuconazole: 0.0015<br>Propiconazole: 0.0014<br>Cypermethrine: 0.0018 | [-] | S |
| Density of the product | $RHO_{product}$ | 1 | $[kg.m^{-3}]$ | S |
| Fraction of product lost to soil during application | $F_{soil,injection}$ | 0.05 | [-] | D |
| Wet soil volume | $V_{soil}$ | 13 | $[m^2]$ | D |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $[kg_{wwt}.m^{-3}]$ | D |

| ***Outputs:***<br>***Injection treatment*** | |
|---|---|
| **Emission of substance to soil during the day of application – $E_{soil,injection}$ [$kg.d^{-1}$]** | |
| Tebuconazole | 1.41E-03 |
| Propiconazole | 1.32E-03 |
| Cypermethrine | 1.69E-03 |

| ***Outputs:*** ***Treatment by injection followed by brushing*** | | |
|---|---|---|
| **Emission of substance to soil during the day of application – $E_{soil,injection}$ + $E_{soil,brush}$ [kg.d$^{-1}$]** | | |
| | Professional | Non professional |
| Tebuconazole | 3.10E-03 | 4.22E-03 |
| Propiconazole | 2.90E-03 | 3.95E-03 |
| Cypermethrine | 3.72E-03 | 5.07E-03 |

| ***Outputs:*** ***Treatment by injection followed by spraying*** | |
|---|---|
| **Emission of substance to soil during the day of application – $E_{soil,injection}$ + $Elocal_{soil,spray,\ Tier\ 1}$ [kg.d$^{-1}$]** | |
| | **Run-off + spray drift (Tier1)** |
| Tebuconazole | 1.83E-02 |
| Propiconazole | 1.71E-02 |
| Cypermethrine | 2.19E-02 |

2.2.8.4.1.3 Emissions estimation during the service life of UC3.1 treated wood

During service life of UC3.1 treated wood, emission into the environment can occur due to leaching of active substances out of the wood due to rainfall.

The leaching values used in the calculation of emissions are derived from a semi-field study conducted according to NT build 509 guidance with the product 06LBCEOL20/2PT applied by brushing at 200 g/m² without and with a top coat ("Lasure Aqua-Stop" supplied by V33).
As recommended on the label, a top coat is always applied following treatment with the product 06LBCEOL20/2PT. Therefore, only leaching values obtained with top coat are considered in the subsequent calculations.
The product was applied on wood by brushing at the dose of 200 g/m² used for preventive treatment. Panels were treated, assembled and placed outdoors without ground contact and exposed to the normal environmental and ecological factors. The test racks were exposed vertically and oriented to south during 694 days from 28/02/2013 to 21/01/2015. The rainwater was retained and the leachate was monitored by chemical analyses of the 3 active substances 8 times during the whole test period. Emission rates in µg/m² are calculated from analytical results.
$Q^*_{leach,\ time}$ values *i.e.* the cumulative quantities leached out of 1 m² of treated wood over 30 days and over 5 years (default value for the duration of service life following an *in situ* application by brushing or by spraying) are calculated based on the leaching study results.
$Q^*_{leach,\ time}$ values are calculated according to the model described in the revised ESD, Appendix 2, *i.e.* by fitting the experimental FLUX (Δt) = f(t) curve using a polynomial regression of second order:

$$\log FLUX(t) = a + b*\log(t) + c*\log(t)^2$$

or, if the goodness of the fit is better, by fitting the cumulative quantities leached versus time plot using a first order decay curve:

$$Q^*_{leach,time} = a*\ln(t) + b)$$

or a linear regression:

$$Q^*_{leach,time} = a*t + b$$

For each active substance the extrapolation with the best goodness of the fit, (with the $r^2$ value closest to 1) has been chosen. This stepwise approach was recommended during the 2nd EU leaching Workshop.

As the cumulative rainfall during the test period was 1 830 mm, leaching values were normalized to correspond to 700 mm rainfall per 365 days, which is the average annual precipitation proposed in the Technical Guidance Document (TGD).

$Q^*_{leach,\ time}$ values obtained from an application by brushing at 200 g/m² with top coat for the three active substances are presented in the following Tables. As recommended during the 2nd EU leaching workshop on wood preservatives, an assessment factor of 2 is applied on the $Q^*_{leach,\ 5\ years}$ values obtained with top coat.

**Table 3.3.2.2-1: $Q^*_{leach,time}$ values obtained with top coat and normalized to 700 mm/year rainfall**

| Active substance | Equation used for calculations | $Q^*_{leach,\ 30d}$ (kg/m²) | $Q^*_{leach,\ 1825d}$ (including AF=2) (kg/m²) |
|---|---|---|---|
| Cypermethrin | $Q^*_{leach,time}$ (µg/m²) = 0.248 * ln(t) + 4.58 ($r^2$ = 0.648) | $5.42*10^{-9}$ | $1.29*10^{-8}$ |
| Tebuconazole | $Q^*_{leach,time}$ (µg/m²) = 3.20 * t + 340.6 ($r^2$ = 0.934) | $4.37*10^{-7}$ | $1.24*10^{-5}$ |
| Propiconazole | $Q^*_{leach,time}$ (µg/m²) = 4.31* t + 237 ($r^2$ = 0.968) | $3.67*10^{-7}$ | $1.62*10^{-5}$ |

The leaching study was performed with an average application rate of 200 g/m$^2$. However, the product 06LBCEOL20/2PT can also be applied at the doses of 300 g/m² and 450 g/m². Therefore, Q*leach values for treatments at 300 g/m² and 450 g/m² have to be extrapolated from the data obtained at the dose of 200 g/m².
Recommendations regarding extrapolation of leaching data from a low to a higher application rate are presented in the report of the leaching Workshop of 13 and 14/06/2005[15] and are reported hereafter:
*"Question 4- issue b. Effect of application rate used (what if this is different to product applied for or efficacy claim?)*
*There was general agreement that the leaching test should be carried out with the maximum application rate based on information from the efficacy testing and the label claim. The question was raised if it is possible to extrapolate from a low application rate used in the leaching test submitted to the maximum application rate?*
*There was general agreement there will be no linear relationship as this depends on the number of binding sites available in the wood. The following scheme was agreed on:*

- *If the application rate is 10 times lower than the maximum application rate: a new leaching test should be submitted using the maximum application rate;*
- *If the application rate is between 2 and 10 times lower than the maximum application rate linear extrapolation and an additional assessment factor shall be applied. The existing information on leaching tests can be used to derive the value for this assessment factor.*
- *If the application rate is less than 2 times the maximum application rate, linear extrapolation can be used.*

*As an alternative approach it was suggested to use an assessment factor of 10 as a first screening. If the risk assessment shows that the PNEC is exceeded, the applicant can carry out a new leaching test."*

Based on these recommendations, Q*leach values for treatment at 300 g/m² are extrapolated from data obtained at the dose of 200 g/m² using a linear extrapolation. Indeed, the application rate of 200 g/m² is less than 2 times the application rate of 300 g/m².
Q*leach values for treatment at 450 g/m² are extrapolated from data obtained at the dose of 200 g/m² using a linear extrapolation and applying an assessment factor of 10. Indeed, the application rate of 200 g/m² is between 2 and 10 times lower than the application rate of 450 g/m².

[15] **REPORT of the LEACHING WORKSHOP (open session)** Arona, Italy, 13 and 14 June 2005.A workshop for technical experts evaluating wood preservatives for the Competent Authorities implementing the Biocidal Products Directive, Directive 98/8/EC, assessing the leaching from treated wood to the environment. Erik van de Plassche and Kirsten Rasmussen.

Q*leach values following treatments at 300 g/m² and 450 g/m² calculated as indicated above are summarised in the following tables.

**Table 3.3.2.2-2: $Q^*_{leach,time}$ values following treatment at 300 g/m² with top coat and normalized to 700 mm/year rainfall**

| Active substance | $Q^*_{leach,\ 30d}$ [kg/m²] | $Q^*_{leach,\ 1825d}$ (including AF=2) [kg/m²] |
|---|---|---|
| Cypermethrin | $8.13*10^{-9}$ | $1.93*10^{-8}$ |
| Tebuconazole | $6.55*10^{-7}$ | $1.85*10^{-5}$ |
| Propiconazole | $5.50*10^{-7}$ | $2.43*10^{-5}$ |

**Table 3.3.2.2-3: $Q^*_{leach,time}$ values following treatment at 450 g/m² with top coat and normalized to 700 mm/year rainfall**

| Active substance | $Q^*_{leach,\ 30d}$ [kg/m²] | $Q^*_{leach,\ 1825d}$ (including AF=2) [kg/m²] |
|---|---|---|
| Cypermethrin | $1.22*10^{-7}$ | $2.90*10^{-7}$ |
| Tebuconazole | $9.82*10^{-6}$ | $2.78*10^{-4}$ |
| Propiconazole | $8.25*10^{-6}$ | $3.64*10^{-4}$ |

**FR-CA box 10 – Calculation of leaching rates from the semi-field leaching study**

The leaching values used in the calculation of emissions are derived from the leaching study results. The results of the semi-field study were recalculated by FR-CA by expressing the leaching in losses per mm rain incident on the panels for the standard rain year, instead of time, as the variability with time is of secondary interest due to the natural variability of rainfall. The results are presented over calendar years and over standard rain years (700 mm rain, in 365 days, *i.e.* 1.92 mm rain per day).

The applicant performed leaching study using the product with and without topcoat. Only results from leaching study with topcoat are presented below, i.e. results used for the environmental risk assessement.

$Q^*_{leach,\ time}$ values are calculated by fitting the experimental FLUX (Δmm) = f(mm) curve using a polynomial regression of second order:

$$\log FLUX(mm) = a + b*\log(mm) + c*\log(mm)^2$$

where “mm” is the accumulated rain ;

or, if the goodness of the fit is better, by fitting the cumulative quantities leached versus cumulative rain fall plot using a first order decay curve:

$$Q^*_{leach,time} = a*\ln(mm) + b)$$

or a linear regression:

$$Q^*_{leach,time} = a*mm + b$$

For each active substance the extrapolation with the best goodness of the fit, (with the $r^2$ value closest to 1) has been chosen.

$Q^*_{leach,\ time}$ values are calculated for:

- TIME1 = 30 days, equivalent to 30 * 1.92 = 57.53 mm of accumulated rain;
- TIME2 = 5 years, equivalent to 1825 * 1.92 = 3500 mm of accumulated rain.

As $Q^*_{leach,\ time}$ values were obtained from an application with top coat for the three active substances, an

assessment factor of 2 is applied for a service-life of 5 years to cover uncertainties linked to the top coat use.

The leaching values obtained from an application by brushing at 200 g/m² with topcoat and normalized to 700 mm per year of rainfall for each active substance are summarized in the following table:

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

| Active substance | Equations used for calculations | Q*leach, TIME1(30d) [mg.m$^{-2}$] | Q*leach, TIME2 (5y) (including AF=2) [mg.m$^{-2}$] |
|---|---|---|---|
| Tebuconazole | $LOG_{10}(FLUX_{(mm)}) = 0.9245 + 0.0423 * LOG_{10}(mm) – 0.1088 * LOG_{10}(mm)^2$ ($r^2 = 0.62$) | | |
| | Q*leach = 702.63E-03 * Ln(mm) – 2592.1E-03 ($r^2 = 0.84$) | | |
| | Q*leach = 1.6682E-03 * mm + 340.68E-03 **($r^2 = 0.93$)** | 4.37E-01 | 1.24E+01 |
| Propiconazole | $LOG_{10}(FLUX_{(mm)}) = 1.3213 - 0.4781 * LOG_{10}(mm) + 0.039 * LOG_{10}(mm)^2$ ($r^2 = 0.46$) | | |
| | Q*leach = 868.33E-03 * Ln(mm) - 3321.3E-03 ($r^2 = 0.81$) | | |
| | Q*leach = 2.1401E-03 * mm + 242.37E-03 **($r^2 = 0.97$)** | 3.65E-01 | 1.55E+01 |
| Cypermethrine | $LOG_{10}(FLUX_{(mm)}) = 3.8123 – 4.4867 * LOG_{10}(mm) + 0.8156 * LOG_{10}(mm)^2$ ($r^2 = 0.96$) | | |
| | Q*leach = 2.2589E-03 * Ln(mm) – 4.1453E-03 ($r^2 = 0.76$) | | |
| | Q*leach = 5.8 * mm + 4.912E-03 **($r^2 = 0.99$)** | 5.25E-03 | 5.04E-02 |

As the product can also be applied at the doses of 300 g/m², Q*leach values for treatment at 300 g/m² are extrapolated from data obtained at the dose of 200 g/m² using a linear extrapolation. Indeed, the application rate of 200 g/m² is less than 2 times the application rate of 300 g/m².

**Extrapolated leaching values for a surface application at 300 g/m² with topcoat**

| Active substance | Q*leach, TIME1(30d) [mg.m$^{-2}$] | Q*leach, TIME2(5y) (including AF=2) [mg.m$^{-2}$] |
|---|---|---|
| Tebuconazole | 6.56E-01 | 1.86E+01 |
| Propiconazole | 5.48E-01 | 2.33E+01 |
| Cypermethrine | 7.88E-03 | 7.56E-02 |

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

| Extrapolated leaching values for a surface application at 450 g/m² with topcoat | | |
|---|---|---|
| Active substance | Q*leach, TIME1(30d) [mg.m$^{-2}$] | Q*leach, TIME2(5y) (including AF=2) [mg.m$^{-2}$] |
| Tebuconazole | 9.83E-01 | 2.79E+01 |
| Propiconazole | 8.21E-01 | 3.49E+01 |
| Cypermethrine | 1.18E-02 | 1.13E-01 |

For 1,2,4-triazole assessment, when necessary, the Q*leach for TIME1 and TIME2 have been recalculated to consider the emission of this metabolite by both tebuconazole and propiconazole. The assessment of 1,2,4-triazol was proposed only for groundwater and soil at the highest level of environmental exposure during service-life, i.e. injection followed by curative surface treatment. The emission calculation for the metabolite takes into account the maximal level of degradation of the substances in soil (9% and 43.23% for tebuconazole and propiconazole respectively) and the molar mass of each component.

| 1,2,4-triazole - Extrapolated leaching values for a surface application at 450 g/m² with topcoat | | |
|---|---|---|
| | Q*leach, TIME1(30d) [mg.m$^{-2}$] | Q*leach, TIME2(5y) (including AF=2) [mg.m$^{-2}$] |
| Equation | (9.83E-01*0.09*69.1/307.8) +(8.21E-01*0.4323*69.1/342.2) | (2.79E+01*0.09*69.1/307.8) +(3.49E+01*0.4323*69.1/342.2) |
| Value | 9.15E-02 | 3.61E+00 |

Emissions due to leaching of the active substances out of the wood may occur into the soil, the surface water and, in urban area, into the Sewage Treatment Plant (STP) after run-off. Emissions to soil may subsequently leach and reach the groundwater.
Emissions into the soil are calculated according to the house scenario.
Emissions into the surface water are calculated according to the bridge over pond scenario.
Emissions into the STP are calculated according to the noise barrier scenario.

Quantities of active substances leached out of treated wood depend on the initial quantities of product applied on the wood. Therefore, emissions during service life are calculated following treatments at the dose of:
- 200 g/m² (preventive treatment by brushing or spraying),
- 300 g/m² (curative treatment by brushing or spraying)
- and 450 g/m² (curative treatment by injection at the dose of 150 g/m² followed by a curative treatment by brushing or spraying at the dose of 300 g/m²)

Consequently to the environmental risk assessment performed for the application phase (see section 3.3.2.1 and 3.3.3.3 of this document and Document IIC, section 2.2.3.1), it is recommended on the label to cover the soil during the application by brushing, spraying or injection. Then, no emission into the environment occurs during the application. Therefore, emissions over 30 days and 5 years are based on emissions due to leaching only and emissions during the application are not taken into account.

Emissions during service life following a treatment at the dose of 200 g/m² are considered to be covered by emissions following a treatment at the dose of 300 and 450 g/m² and are therefore not presented in this document.

#### 2.2.8.4.1.4 Calculations of emissions into the soil according to the house scenario

In the house scenario, the primary receiving compartment is considered to be the soil following leaching due to rainfall. Following surface treatment by brushing or spraying, the default values for the size of the receiving soil are: 50 cm distance from the house and a soil depth of 50 cm. This corresponds to a soil volume of 13 m$^3$. As

explained in section 3.3.2.1.2, following treatment by injection the treated surface is set to 15 m² and the soil volume contaminated is set to 10 $m^3$.
The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

**Table 3.3.2.2.1-1: Input parameters for calculating the local emission and concentration into the soil – service life, house scenario**

| Parameter | Nomenclature | | Value | | Unit | Origin |
|---|---|---|---|---|---|---|
| Treated wood area | $AREA_{house, brush, spray}$ | | 125 | | [$m^2$] | D |
| | $AREA_{house, inj}$ | | 15 | | [$m^2$] | A |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period (30d) | $Q^*_{leach, time 1}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $8.13*10^{-9}$ | $1.22*10^{-7}$ | | |
| | | TBZ | $6.55*10^{-7}$ | $9.82*10^{-6}$ | | |
| | | PPZ | $5.50*10^{-7}$ | $8.25*10^{-6}$ | | |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (1825d) | $Q^*_{leach, time 2}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $1.93*10^{-8}$ | $2.90*10^{-7}$ | | |
| | | TBZ | $1.85*10^{-5}$ | $2.78*10^{-4}$ | | |
| | | PPZ | $2.43*10^{-5}$ | $3.64*10^{-4}$ | | |
| Duration of the initial assessment period | TIME1 | | 30 | | [d] | D |
| Duration of the long-term assessment period | TIME2 | | 1825 | | [d] | D |
| Volume of (wet) soil | $V_{soil, brush, spray}$ | | 13 | | [$m^3$] | D |
| | $V_{soil, inj}$ | | 10 | | [$m^3$] | A |
| Bulk density of (wet) soil | $RHO_{soil}$ | | 1700 | | [$kg_{wwt}/m^3$] | D |

D = default, A = based on information of applicant

The local emissions into the soil (*i.e.* the cumulative quantity of substance leached over 30 days and 5 years, $Q_{leach,time}$) are calculated according to the equations 4.43 and 4.44 from the revised ESD PT08 as following:
Equation 4.43: $Q_{leach, time1} = AREA_{house} * Q^*_{leach, time1}$
Equation 4.44: $Q_{leach, time2} = AREA_{house} * Q^*_{leach, time2}$

The local concentrations into the soil are calculated according to the equations 4.45 and 4.46 from the revised ESD PT08 as following:
Equation 4.45: $Clocal_{soil,leach, time1} = Q_{leach, time1} / (V_{soil} * RHO_{soil})$
Equation 4.46: $Clocal_{soil,leach, time2} = Q_{leach, time2} / (V_{soil} * RHO_{soil})$

The results are presented in the following tables.

**Table 3.3.2.2.1-2: Local emissions into the soil – service life, house scenario**

| Active substance | Local emission in soil due to leaching after 30 days [kg] | Local emission in soil due to leaching after 5 years [kg] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $1.02*10^{-6}$ | $2.41*10^{-6}$ |
| Tebuconazole | $8.19*10^{-5}$ | $2.31*10^{-3}$ |

| | | |
|---|---|---|
| Propiconazole | $6.88*10^{-5}$ | $3.04*10^{-3}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $1.83*10^{-6}$ | $4.35*10^{-6}$ |
| Tebuconazole | $1.47*10^{-4}$ | $4.17*10^{-3}$ |
| Propiconazole | $1.24*10^{-4}$ | $5.46*10^{-3}$ |

**Table 3.3.2.2.1-3: Resulting concentrations into the soil – service life, house scenario**

| Active substance | Local concentration in soil after 30 days [$kg/kg_{wwt}$] | Local concentration in soil after 5 years [$kg/kg_{wwt}$] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $4.60*10^{-11}$ | $1.09*10^{-10}$ |
| Tebuconazole | $3.70*10^{-9}$ | $1.05*10^{-7}$ |
| Propiconazole | $3.11*10^{-9}$ | $1.37*10^{-7}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $1.08*10^{-10}$ | $2.56*10^{-10}$ |
| Tebuconazole | $8.66*10^{-9}$ | $2.45*10^{-7}$ |
| Propiconazole | $7.28*10^{-9}$ | $3.21*10^{-7}$ |

**FR-CA box 11 - Calculations of emissions into the soil according to the house scenario during service life of UC-3 wood**

According to the intended uses and considering the section 4.3 of the PT18-ESD on the emission estimation for treated wood in service, the house scenario has been applied to calculate the emissions into the soil for each active substance by considering emissions due to:

- Preventive treatment (200 g product/m²);
- Curative treatment (300 g product/m²);
- Injection treatment (150 g product/m²) followed by a curative surface treatment (300 g product/m²), which is equivalent as a worst case to a surface application of 450 $g.m^{-2}$.

**HOUSE - Preventive treatment (200 $g.m^{-2}$) – treated wood in service only**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Leachable wood area | $AREA_{house}$ | 125 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 4.37E-01 Propiconazole: 3.65E-01 Cypermethrin: 5.25E-03 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.24E+01 Propiconazole: | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |

| | | | | |
|---|---|---|---|---|
| treated wood over the longer assessment period | | 1.55E+01<br>Cypermethrin: 5.04E-02 | | |

***Outputs:***

| Parameter/variable | Symbol | Value | Unit |
|---|---|---|---|
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 5.46E+01<br>Propiconazole: 4.56E+01<br>Cypermethrin: 6.56E-01 | [mg] |
| Cumulative quantity of substance, leached over a longer assessment period | $Q_{leach,TIME2}$ | Tebuconazole: 1.55E+03<br>Propiconazole: 1.94E+03<br>Cypermethrin: 6.30E+00 | [mg] |

**HOUSE - Curative treatment (300 g.m$^{-2}$) – treated wood in service only**

***Inputs:***

| Parameter/variable | Symbol | Value | Unit | Origin |
|---|---|---|---|---|
| Leachable wood area | $AREA_{house}$ | 125 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 6.56E-01<br>Propiconazole: 5.48E-01<br>Cypermethrin: 7.88E-03 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.86E+01<br>Propiconazole: 2.33E+01<br>Cypermethrin: 7.56E-02 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |

***Outputs:***

| Parameter/variable | Symbol | Value | Unit |
|---|---|---|---|
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 8.20E+01<br>Propiconazole: 6.85E+01<br>Cypermethrin: 9.85E-01 | [mg] |
| Cumulative quantity of | $Q_{leach,TIME2}$ | Tebuconazole: | [mg] |

| | | | |
|---|---|---|---|
| substance, leached over a longer assessment period | | 2.33E+03<br>Propiconazole: 2.91E+03<br>Cypermethrin: 9.45E+00 | |

**HOUSE - Injection treatment (eq. to 450 g.m$^{-2}$) – treated wood in service only**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Leachable wood area | $AREA_{house}$ | 125 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 9.83E-01<br>Propiconazole: 8.21E-01<br>Cypermethrin: 1.18E-02 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 2.79E+01<br>Propiconazole: 3.49E+01<br>Cypermethrin: 1.13E-01 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |

| ***Outputs:*** | | | |
|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 1.23E+02<br>Propiconazole: 1.03E+02<br>Cypermethrin: 1.48E+00 | [mg] |
| Cumulative quantity of substance, leached over a longer assessment period | $Q_{leach,TIME2}$ | Tebuconazole: 3.49E+03<br>Propiconazole: 4.36E+03<br>Cypermethrin: 1.41E+01 | [mg] |

2.2.8.4.1.5 Calculations of emissions into surface water according to the bridge over pond scenario

The bridge over pond scenario describes a wooden bridge which is located over a pond. It is assumed that the emissions of active substance following leaching due to rainfall end up directly in the adjacent static surface water (*i.e.* the pond). The default value for the size of the receiving water body is set to 1000 m$^3$.

The input parameters for calculating the local emission and concentration into the surface water following leaching are presented in the following table.

**Table 3.3.2.2.2-1: Input parameters for calculating the local emission and concentration into the surface water – service life, bridge over pond scenario**

| Parameter | Nomenclature | | Value | | Unit | Origin |
|---|---|---|---|---|---|---|
| Leachable wood area | $AREA_{bridge}$ | | 10 | | [$m^2$] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period (30d) | $Q^*_{leach,\ time\ 1}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $8.13*10^{-9}$ | $1.22*10^{-7}$ | | |
| | | TBZ | $6.55*10^{-7}$ | $9.82*10^{-6}$ | | |
| | | PPZ | $5.50*10^{-7}$ | $8.25*10^{-6}$ | | |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (1825d) | $Q^*_{leach,\ time\ 2}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $1.93*10^{-8}$ | $2.90*10^{-7}$ | | |
| | | TBZ | $1.85*10^{-5}$ | $2.78*10^{-4}$ | | |
| | | PPZ | $2.43*10^{-5}$ | $3.64*10^{-4}$ | | |
| Duration of the initial assessment period | TIME1 | | 30 | | [d] | D |
| Duration of the long-term assessment period | TIME2 | | 1825 | | [d] | D |
| Water volume under bridge | $V_{water}$ | | 1000 | | [$m^3$] | D |

D = default, A = based on information of applicant

The local emissions into surface water (*i.e*. the cumulative quantity of substance leached over 30 days and 5 years, $Q_{leach,time}$) are calculated according to the equations 4.61 and 4.62 from the revised ESD PT08 as following:
Equation 4.61: $Q_{leach,\ time1} = AREA_{bridge} * Q^*_{leach,\ time1}$
Equation 4.62: $Q_{leach,\ time2} = AREA_{bridge} * Q^*_{leach,\ time2}$

The local concentrations into surface water are calculated according to the equations 4.63 and 4.64 from the revised ESD PT08 as following:
Equation 4.63: $Clocal_{water,leach,\ time1} = Q_{leach,\ time1} / V_{water}$
Equation 4.64: $Clocal_{water,leach,\ time2} = Q_{leach,\ time2} / V_{water}$

The results are presented in the following tables.

**Table 3.3.2.2.2-2: Local emissions into surface water – service life, bridge over pond scenario**

| Active substance | Local emission into surface water due to leaching after 30 days [kg] | Local emission into surface water due to leaching after 5 years [kg] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $8.13*10^{-8}$ | $1.93*10^{-7}$ |
| Tebuconazole | $6.55*10^{-6}$ | $1.85*10^{-4}$ |
| Propiconazole | $5.50*10^{-6}$ | $2.43*10^{-4}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $1.22*10^{-6}$ | $2.90*10^{-6}$ |
| Tebuconazole | $9.82*10^{-5}$ | $2.78*10^{-3}$ |

| | | |
|---|---|---|
| Propiconazole | $8.25*10^{-5}$ | $3.64*10^{-3}$ |

**Table 3.3.2.2.2-3: Resulting concentrations into surface water – service life, bridge over pond scenario**

| Active substance | Local concentration into surface water after 30 days [mg/L] | Local concentration into surface water after 5 years [mg/L] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $8.13*10^{-8}$ | $1.93*10^{-7}$ |
| Tebuconazole | $6.55*10^{-6}$ | $1.85*10^{-4}$ |
| Propiconazole | $5.50*10^{-6}$ | $2.43*10^{-4}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $1.22*10^{-6}$ | $2.90*10^{-6}$ |
| Tebuconazole | $9.82*10^{-5}$ | $2.78*10^{-3}$ |
| Propiconazole | $8.25*10^{-5}$ | $3.64*10^{-3}$ |

**FR-CA box 12 - Calculations of emissions into the surface water according to the bridge scenario during service life of UC-3 wood**

According to the intended uses and considering the section 4.3 of the PT18-ESD on the emission estimation for treated wood in service, the bridge over pond scenario has been applied to calculate the emissions into the water for each active substance by considering emissions due to:

- Preventive treatment (200 g product/m²) during the wood in service period only;
- Curative treatment (300 g product/m²) during the wood in service period only;
- Injection treatment (150 g product/m²) followed by a curative surface treatment (300 g product/m²) during the wood in service period only, which is equivalent as a worst case to a surface application of 450 $g.m^{-2}$.

**BRIDGE - Preventive treatment (200 $g.m^{-2}$) – treated wood in service only**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Leachable wood area | $AREA_{bridge}$ | 10 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 4.37E-01 Propiconazole: 3.65E-01 Cypermethrin: 5.25E-03 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.24E+01 Propiconazole: 1.55E+01 Cypermethrin: 5.04E-02 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |

| | | | | |
|---|---|---|---|---|

| ***Outputs:*** | | | |
|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 4.37E+00<br>Propiconazole: 3.65E+00<br>Cypermethrin: 5.25E-02 | [mg] |
| Cumulative quantity of substance, leached over a longer assessment period | $Q_{leach,TIME2}$ | Tebuconazole: 1.24E+02<br>Propiconazole: 1.55E+02<br>Cypermethrin: 5.04E-01 | [mg] |

**BRIDGE - Curative treatment (300 g.m$^{-2}$) – treated wood in service only**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Leachable wood area | $AREA_{bridge}$ | 10 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 6.56E-01<br>Propiconazole: 5.48E-01<br>Cypermethrin: 7.88E-03 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.86E+01<br>Propiconazole: 2.33E+01<br>Cypermethrin: 7.56E-02 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |

| ***Outputs:*** | | | |
|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 6.56E+00<br>Propiconazole: 5.48E+00<br>Cypermethrin: 7.88E-02 | [mg] |
| Cumulative quantity of substance, leached over a longer assessment period | $Q_{leach,TIME2}$ | Tebuconazole: 1.86E+02<br>Propiconazole: 2.33E+02 | [mg] |

| | | | |
|---|---|---|---|
| | | Cypermethrin: 7.56E-01 | |

**BRIDGE - Injection treatment (eq. to 450 g.m$^{-2}$) – treated wood in service only**

| ***Inputs:*** | | | | |
|---|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| Leachable wood area | $AREA_{bridge}$ | 10 | [m²] | D |
| Duration of the initial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 9.83E-01 Propiconazole: 8.21E-01 Cypermethrin: 1.18E-02 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 2.79E+01 Propiconazole: 3.49E+01 Cypermethrin: 1.13E-01 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |

| ***Outputs:*** | | | |
|---|---|---|---|
| **Parameter/variable** | **Symbol** | **Value** | **Unit** |
| Cumulative quantity of substance, leached over the initial assessment period | $Q_{leach,TIME1}$ | Tebuconazole: 9.83E+00 Propiconazole: 8.21E+00 Cypermethrin: 1.18E-01 | [mg] |
| Cumulative quantity of substance, leached over a longer assessment period | $Q_{leach,TIME2}$ | Tebuconazole: 2.79E+02 Propiconazole: 3.49E+02 Cypermethrin: 1.13E+00 | [mg] |

2.2.8.4.1.6 Calculations of emissions into the STP according to the noise barrier scenario

The noise barrier scenario describes a noise barrier that is made of poles with planks in between. The medium size of a noise barrier in an urbanised area is assumed to be 1000 m long and 3 m high. It is assumed that 30% of the emissions of active substances due to leaching end up directly in the adjacent soil and 70% of the emissions are collected in the gutter and sewer, and finally enter a municipal STP. As emissions into the soil have already been assessed in the house scenario, which represents a worst case regarding the soil compartment, only emissions into the STP are calculated here.

The input parameters for calculating the local emission into the STP following leaching are presented in the following table.

**Table 3.3.2.2.3-1: Input parameters for calculating the local emission into the STP – Service life, noise barrier scenario**

| Parameter | Nomenclature | | Value | | Unit | Origin |
|---|---|---|---|---|---|---|
| Leachable wood area | $AREA_{noise\text{-}barrier}$ | | 3000 | | [$m^2$] | D |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the initial assessment period (30d) | $Q^*_{leach,\ time\ 1}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $8.13*10^{-9}$ | $1.22*10^{-7}$ | | |
| | | TBZ | $6.55*10^{-7}$ | $9.82*10^{-6}$ | | |
| | | PPZ | $5.50*10^{-7}$ | $8.25*10^{-6}$ | | |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (1825d) | $Q^*_{leach,\ time\ 2}$ | | After a treatment at 300 g/m² | After a treatment at 450 g/m² | [kg/m²] | A |
| | | Cyper | $1.93*10^{-8}$ | $2.90*10^{-7}$ | | |
| | | TBZ | $1.85*10^{-5}$ | $2.78*10^{-4}$ | | |
| | | PPZ | $2.43*10^{-5}$ | $3.64*10^{-4}$ | | |
| Duration of the initial assessment period | TIME1 | | 30 | | [d] | D |
| Duration of the long-term assessment period | TIME2 | | 1825 | | [d] | D |
| Fraction released to the STP | $F_{STP}$ | | 0.7 | | [-] | D |

D = default, A = based on information of applicant

The local daily emissions into the STP are calculated according to the equations 4.55 and 4.56 from the revised ESD PT08 as following:
Equation 4.55: $E_{STP,\ time1} = (AREA_{noise\text{-}barrier} * F_{STP} * Q^*_{leach,time1}) / TIME1$
Equation 4.56: $E_{STP,\ time2} = (AREA_{noise\text{-}barrier} * F_{STP} * Q^*_{leach,time2}) / TIME2$

The results are presented in the following tables.

**Table 3.3.2.2.3-2: Local emissions into the STP – service life, noise barrier scenario**

| **Active substance** | **Local emission into STP due to leaching during the first 30 days [kg/d]** | **Local emission into STP due to leaching during 5 years [kg/d]** |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $5.69*10^{-7}$ | $2.22*10^{-8}$ |
| Tebuconazole | $4.59*10^{-5}$ | $2.13*10^{-5}$ |
| Propiconazole | $3.85*10^{-5}$ | $2.80*10^{-5}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $8.54*10^{-6}$ | $3.34*10^{-7}$ |
| Tebuconazole | $6.87*10^{-4}$ | $3.20*10^{-4}$ |
| Propiconazole | $5.78*10^{-4}$ | $4.19*10^{-4}$ |

**FR-CA box 13 - Calculations of emissions into the STP according to the noise barrier scenario during service life of UC-3 wood**

FR-CA recalculate the local emissions into the STP using the noise barrier scenario during service life by modifying the inputs $Q^*_{Leach,TIME1}$ and $Q^*_{leach,TIME2}$ according to FR-CA box 10, for the following uses:

- Preventive treatment (200 g product/m²);
- Curative treatment (300 g product/m²);
- Injection treatment (150 g product/m²) followed by a curative surface treatment (300 g product/m²), which is equivalent as a worst case to a surface application of 450 $g.m^{-2}$.

**NOISE BARRIER - Preventive treatment (200 $g.m^{-2}$) – treated wood in service only**

| Parameter/Variable | Symbol | Value | Unit | Origin |
|---|---|---|---|---|
| ***Inputs for preventive treatment – 200 g product/m²:*** | | | | |
| Leachable wood area | $AREA_{noise-barrier}$ | 3000 | [m²] | D |
| Duration of the intitial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long-term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of substance leached out of 1m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 4.37E-01<br>Propiconazole: 3.65E-01<br>Cypermethrin: 5.25E-03 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.24E+01<br>Propiconazole: 1.55E+01<br>Cypermethrin: 5.04E-02 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |
| Fraction released to the STP | $F_{STP}$ | 0.7 | [-] | D |
| ***Outputs for preventive treatment – 200 g product/m²:*** | | | | |
| Local daily emission rate to the STP following leaching from treated wood during the initial assessment period - $E_{STP,TIME1}$ [$kg.d^{-1}$] | | | | |
| Tebuconazole | 3.06E-05 | | | |
| Propiconazole | 2.56E-05 | | | |
| Cypermethrin | 3.68E-07 | | | |
| Local daily emission rate to the STP following leaching from treated wood during a longer assessment period - $E_{STP,TIME2}$ [$kg.d^{-1}$] | | | | |
| Tebuconazole | 1.43E-05 | | | |
| Propiconazole | 1.78E-05 | | | |
| Cypermethrin | 5.80E-08 | | | |

**NOISE BARRIER - Curative treatment (300 g.m$^{-2}$) – treated wood in service only**

| Parameter/Variable | Symbol | Value | Unit | Origin |
|---|---|---|---|---|
| ***Inputs for curative treatment – 300 g product/m²:*** | | | | |
| Leachable wood area | $AREA_{noise-barrier}$ | 3000 | [m²] | D |
| Duration of the intitial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long-term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of substance leached out of 1m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 6.56E-01<br>Propiconazole: 5.48E-01<br>Cypermethrin: 7.88E-03 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 1.86E+01<br>Propiconazole: 2.33E+01<br>Cypermethrin: 7.56E-02 | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |
| Fraction released to the STP | $F_{STP}$ | 0.7 | [-] | D |
| ***Outputs for curative treatment – 300 g product/m²:*** | | | | |
| Local daily emission rate to the STP following leaching from treated wood during the initial assessment period - $E_{STP,TIME1}$ [kg.d$^{-1}$] | | | | |
| Tebuconazole | 4.59E-05 | | | |
| Propiconazole | 3.84E-05 | | | |
| Cypermethrin | 5.52E-07 | | | |
| Local daily emission rate to the STP following leaching from treated wood during a longer assessment period - $E_{STP,TIME2}$ [kg.d$^{-1}$] | | | | |
| Tebuconazole | 2.14E-05 | | | |
| Propiconazole | 2.68E-05 | | | |
| Cypermethrin | 8.70E-08 | | | |

**NOISE BARRIER - Injection treatment (eq. to 450 g.m$^{-2}$) – treated wood in service only**

| Parameter/Variable | Symbol | Value | Unit | Origin |
|---|---|---|---|---|
| ***Inputs for injection followed by a curative surface treatment– eq. to 450 g product/m²:*** | | | | |
| Leachable wood area | $AREA_{noise-barrier}$ | 3000 | [m²] | D |
| Duration of the intitial assessment period | TIME1 | 30 | [d] | D |
| Duration of the long-term assessment period | TIME2 | 1825 | [d] | D |
| Cumulative quantity of substance leached out of 1m² of treated wood over the initial assessment period | $Q^*_{leach,TIME1}$ | Tebuconazole: 9.83E-01<br>Propiconazole: 8.21E-01<br>Cypermethrin: | [mg.m$^{-2}$] | S – *c.f.* FR-CA box 10 |

| | | | | |
|---|---|---|---|---|
| | | 1.18E-02 | | |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | $Q^*_{leach,TIME2}$ | Tebuconazole: 2.79E+01<br>Propiconazole: 3.49E+01<br>Cypermethrin: 1.13E-01 | [$mg.m^{-2}$] | S – *c.f.* FR-CA box 10 |
| Fraction released to the STP | $F_{STP}$ | 0.7 | [-] | D |
| ***Outputs for injection followed by a curative surface treatment– eq. to 450 g product/m²:*** | | | | |
| Local daily emission rate to the STP following leaching from treated wood during the initial assessment period - $E_{STP,TIME1}$ [$kg.d^{-1}$] | | | | |
| Tebuconazole | 6.88E-05 | | | |
| Propiconazole | 5.75E-05 | | | |
| Cypermethrin | 8.26E-07 | | | |
| Local daily emission rate to the STP following leaching from treated wood during a longer assessment period - $E_{STP,TIME2}$ [$kg.d^{-1}$] | | | | |
| Tebuconazole | 3.21E-05 | | | |
| Propiconazole | 4.02E-05 | | | |
| Cypermethrin | 1.30E-07 | | | |

## 2.2.8.5 Local PECs

### *2.2.8.5.1 PEC*s *in STP*

* Consequently to the environmental risk assessment performed for the soil for the application phase (see sections 3.3.2.1 and 3.3.3.3 of this document and Document IIC, section 2.2.3.1), it is recommended on the label to cover the soil during the application by brushing, spraying or injection. Then, no emissions into the STP can occur during the application.

* Emissions of active substances into the STP may occur during service life of the treated wood following leaching due to rainfall. Daily emissions have been calculated according to the noise barrier scenario and results are reported in the Table 3.3.2.2.3-2. Daily emissions during the first 30 days assessment period are higher than daily emissions during the second assessment period of 5 years. Daily emissions during the 30 days assessment period are therefore used as worst case for calculating the PEC in the STP in EUSES v2.1.2

Results are reported in the following table.

**Table 3.3.3.1-1: Predicted concentrations in the STP – service life, noise barrier scenario**

| Active substance | PEC in STP [mg/L] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $2.60*10^{-8}$ |
| Tebuconazole | $2.04*10^{-5}$ |
| Propiconazole | $1.72*10^{-5}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $3.91*10^{-7}$ |
| Tebuconazole | $3.06*10^{-4}$ |
| Propiconazole | $2.59*10^{-4}$ |

**FR-CA box 14 – Calulcation of $PEC_{STP}$ (noise barrier scenario)**

*The PECSTP was recalculated by FR-CA, considering the noise barrier scenario and the* local daily emission rates to the STP following leaching from treated wood calculated in FR-CA box 13 according to the equations 32, 33, and 38 of the ECHA guidance, vol.IV, part B (2015).

| | | | | | |
|---|---|---|---|---|---|
| ***Fraction of emission directed to water by STP – $F_{STP,water}$*** | | | | | |
| ***Tebuconazole*** | *8.9E-01* | | | *[-]* | *S* – c.f. FR-CA box 2 |
| ***Propiconazole*** | *9.0E-01* | | | | |
| ***Cypermethrin*** | *9.1E-02* | | | | |
| **Outputs:** | | | | | |
| | **Preventive treatment (200 $g.m^{-2}$)** | **Curative treatment (300 $g.m^{-2}$)** | **Injection (150 $g.m^{-2}$) followed by curative (300 $g.m^{-2}$)** | | |
| ***$PEC_{STP,TIME1}$*** | | | | | |
| ***Tebuconazole*** | *1.36E-05* | *2.05E-05* | *3.07E-05* | *[$mg.L^{-1}$]* | *O* |
| ***Propiconazole*** | *1.15E-05* | *1.73E-05* | *2.59E-05* | | |
| ***Cypermethrin*** | *1.68E-08* | *2.52E-08* | *3.78E-08* | | |
| ***$PEC_{STP,TIME2}$*** | | | | | |
| ***Tebuconazole*** | *6.36E-06* | *9.53E-06* | *1.43E-05* | *[$mg.L^{-1}$]* | *O* |
| ***Propiconazole*** | *8.03E-06* | *1.21E-05* | *1.81E-05* | | |
| ***Cypermethrin*** | *2.65E-09* | *3.98E-09* | *5.95E-09* | | |

#### *2.2.8.5.2 PECs in surface water and sediment*

* As the product is only used to treat house pieces such as shutters, doors, siding, fences, gates, awnings, roof overhangs and is not used to treat commodities such as bridge over water bodies, the contamination of the surface water during application by brushing, spraying or injection is considered as negligible.
Indeed, as mentioned in the document Technical Agreement of Biocides, when it is not an intended use, the bridge over pond scenario does not need to be evaluated for the application phase:
***"Should the bridge over pond scenario for UC3 be included in the CAR even if this is not proposed as an intended use by the applicant?***
*(TM V 2007, TM IV 2012, TM I 2013)*
*The bridge over pond scenario* ***is not used to evaluate the application phase*** *but the use phase, in order to describe the emission pathway into open water bodies, and should therefore be included in the CAR".*

Surface water and sediment may be contaminated during the service life of the treated wood due to leaching of the active substances out of the wood. Surface water may be contaminated directly or indirectly *via* STP effluents.

* Direct emissions and resulting local concentrations are calculated according to the bridge over pond scenario in the section 3.3.2.2.2. These calculations don't take into account the degradation processes.
In a second tier, surface water concentrations taking into account the degradation of active substances are calculated using equations 3.16 and 3.17 described in section 3.4.2.1 of the revised ESD. It has to be pointed out that these equations do not take into account removal from the water column due to adsorption onto suspended matter and onto sediment. The resulting calculated concentrations can therefore be considered as a worst case.

For each active substance, the $DT50_{water}$ at 12°C is used to calculate the rate constant for removal from water (k) according to the following equation: $k = \ln 2 / DT50_{water}$. The following values of $DT50_{water}$ and k are used for the calculations:

**Table 3.3.3.2-1: $DT50_{water}$ and rate constant for removal from water values**

| Active substance | $DT50_{water}$ at 12°C [d] | k [$d^{-1}$] |
|---|---|---|
| Cypermethrin | 18.5 | 0.0375 |
| Tebuconazole | 198 | $3.50*10^{-3}$ |
| Propiconazole | 1206 | $5.75*10^{-4}$ |

The concentrations in surface water taking into account degradation are reported in the following table.

**Table 3.3.3.2-2: Predicted concentrations in surface water – service life, bridge over pond scenario, with degradation**

| Active substance | PEC in surface water, with degradation, over 30 days [mg/L] | PEC in surface water, with degradation, over 5 years [mg/L] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $2.89*10^{-8}$ | $2.78*10^{-9}$ |
| Tebuconazole | $3.16*10^{-6}$ | $2.44*10^{-5}$ |
| Propiconazole | $2.73*10^{-6}$ | $8.82*10^{-5}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $4.34*10^{-7}$ | $4.18*10^{-8}$ |
| Tebuconazole | $4.74*10^{-5}$ | $3.67*10^{-4}$ |
| Propiconazole | $4.10*10^{-5}$ | $1.32*10^{-3}$ |

The concentrations in sediment ($PEC_{sediment}$) are calculated according to the equilibrium partitioning method (equation 50 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0) based on $PEC_{water}$ calculated according to equations 3.16 and 3.17 of the revised ESD (*i.e.* taking into account degradation).

$PEC_{sediment} = K_{susp\text{-}water} / RHO_{susp} * PEC_{water} * 1000$

where:

$PEC_{sediment}$: Predicted Environmental Concentration in sediment [$mg/kg_{wwt}$]

$K_{susp\text{-}water}$: Partition coefficient suspended matter-water. Calculated according to equations 23 and 24 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0, see detailed calculation below.

$RHO_{susp}$: Bulk density of wet suspended matter [1150 $kg/m^3$]

$PEC_{water:}$ Predicted environmental concentration in water [mg/L]

Detailed calculation of $K_{susp\text{-}water}$:

- Equation 24 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0:

$K_{susp\text{-}water} = Fwater_{susp} + [Fsolid_{susp} * (Kp_{susp}/1000) * RHOsolid]$

where:

$K_{susp\text{-}water}$: suspended matter-water partitioning coefficient [$m^3.m^{-3}$]

$Fwater_{susp}$: fraction water in suspended matter [0.9 $m^3.m^{-3}$]

$Fsolid_{susp}$: fraction solids in suspended matter [0.1 $m^3.m^{-3}$]

$Kp_{susp}$: solids-water partitioning coefficient in suspended matter [$L.kg^{-1}$] (calculated according to equation 23)
RHOsolid: density of the solid phase [2500 $kg.m^{-3}$]

- Equation 23 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0:

$Kp_{susp} = Foc_{susp} * K_{oc}$

where:

$Kp_{susp}$: solids-water partitioning coefficient in suspended matter [$L.kg^{-1}$]
$Foc_{susp}$: weight fraction of organic carbon in suspended matter [0.1 $kg.kg^{-1}$]
$K_{oc}$: partition coefficient organic carbon-water [$L.kg^{-1}$]

$K_{oc}$ values used for the calculations and resulting $K_{susp\text{-}water}$ are reported for the 3 active substances in the following table.

**Table 3.3.3.2-3: $K_{oc}$ values and resulting $K_{susp\text{-}water}$ used for the calculations of the $PEC_{sediment}$**

| Active substance | $K_{oc}$ [L/kg] | $K_{susp\text{-}water}$ |
|---|---|---|
| Cypermethrin | 574 360 | 14 360 |
| Tebuconazole | 992 | 25.7 |
| Propiconazole | 944 | 24.5 |

The concentrations in sediment taking into account degradation calculated as described above are reported in the following table.

**Table 3.3.3.2-4: Predicted concentrations in sediment – service life, bridge over pond scenario, with degradation**

| Active substance | PEC in sediment, with degradation, over 30 days [$mg/kg_{wwt}$] | PEC in sediment, with degradation, over 5 years [$mg/kg_{wwt}$] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $3.61*10^{-4}$ | $3.47*10^{-5}$ |
| Tebuconazole | $7.07*10^{-5}$ | $5.46*10^{-4}$ |
| Propiconazole | $5.83*10^{-5}$ | $1.88*10^{-3}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $5.41*10^{-3}$ | $5.22*10^{-4}$ |
| Tebuconazole | $1.06*10^{-3}$ | $8.20*10^{-3}$ |
| Propiconazole | $8.74*10^{-4}$ | $2.81*10^{-2}$ |

* Indirect emissions *via* STP effluents and resulting concentrations in surface water and sediment are calculated in EUSES v2.1.2 using the daily quantities of active substances emitted in the STP calculated in section 3.3.2.2.3 according to the noise barrier scenario. Daily emissions during the first 30 days assessment period are higher than daily emissions during the second assessment period of 5 years. Daily emissions during the 30 days assessment period are therefore used as worst case for calculating the PEC in the surface water and sediment.

The concentrations in surface water and sediment calculated in EUSES v2.1.2 are reported in the following tables.

**Table 3.3.3.2-5: Predicted concentrations in surface water – service life, noise barrier scenario**

| Active substance | PEC in surface water over 30 days [mg/L] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $1.40*10^{-9}$ |
| Tebuconazole | $2.04*10^{-6}$ |
| Propiconazole | $1.72*10^{-6}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $2.10*10^{-8}$ |
| Tebuconazole | $3.06*10^{-5}$ |
| Propiconazole | $2.58*10^{-5}$ |

**Table 3.3.3.2-6: Predicted concentrations in sediment – service life, noise barrier scenario**

| Active substance | PEC in sediment over 30 days [$mg/kg_{wwt}$] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $1.75*10^{-5}$ |
| Tebuconazole | $4.56*10^{-5}$ |
| Propiconazole | $3.67*10^{-5}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $2.62*10^{-4}$ |
| Tebuconazole | $6.83*10^{-4}$ |
| Propiconazole | $5.50*10^{-4}$ |

**FR-CA box 15 – Calculation of $PEC_{water}$ and $PEC_{sediment}$.**

**1. Direct emission to the aquatic compartment - Bridge over the pond scenario**

The emissions in local water were calculated as described in FR-CA box 6 for the outdoor application phase, and in FR-CA box 12 for the service life of treated wood phase.

The initial concentrations in water were defined on the day of application for the application phase (PT08-ESD eq. 4.42). For service-life, concentrations were calculated over the assessment periods (*i.e.* 30 days for TIME1 and 1825 days for the TIME2), with the dissipation half-life from water ($DT50_{water}$) of each active substance in order to take into account degradation and adsorption processes (*c.f.* FR-CA box 2) using equations 3.16 and 3.17 for static water bodies. Application and service-life were calculated separately.

The concentrations in sediment were calculated using the equation 50 of the ECHA GUIDANCE vol.IV,Part B (2015). For service-life, concentrations in local water were calculated using the degradation half-life of each active substances (eq. 3.16 and 3.17) in the whole water-sediment system ($DT50_{whole\ system}$) or for degradation only in surface water (tebuconazole), and the partition coefficient organic carbon-water ($K_{oc}$) mentioned in the FR-CA box 2 were used.

**Direct emissions during outdoor application:**

| Application - Bridge over the pond - Preventive treatment by brushing (200 $g.m^{-2}$) | | |
|---|---|---|
| Initial concentration in local water after application [$\mu g.L^{-1}$] | | |
| | Professional | Non-professional |

| | | |
|---|---|---|
| Tebuconazole | 9.00E-02 | 1.50E-01 |
| Propiconazole | 8.40E-02 | 1.40E-01 |
| Cypermethrin | 1.08E-01 | 1.80E-01 |
| Initial concentration in local sediment after application [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 2.01E-03 | 3.35E-03 |
| Propiconazole | 1.79E-03 | 2.98E-03 |
| Cypermethrin | 1.35E+00 | 2.25E+00 |

| **Application - Bridge over the pond - Preventive treatment by spraying (200 g.m$^{-2}$)** | |
|---|---|
| Initial concentration in local water after application [µg.L$^{-1}$] | |
| Tebuconazole | 9.00E-01 |
| Propiconazole | 8.40E-01 |
| Cypermethrin | 1.08E+00 |
| Initial concentration in local sediment after application [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 2.01E-02 |
| Propiconazole | 1.79E-02 |
| Cypermethrin | 1.35E+01 |

| **Application - Bridge over the pond - Curative treatment by brushing (300 g.m$^{-2}$)** | | |
|---|---|---|
| Initial concentration in local water after application [µg.L$^{-1}$] | | |
| | Professional | Non-professional |
| Tebuconazole | 1.35E-01 | 2.25E-01 |
| Propiconazole | 1.26E-01 | 2.10E-01 |
| Cypermethrin | 1.62E-01 | 2.70E-01 |
| Initial concentration in local sediment after application [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 3.02E-03 | 5.03E-03 |
| Propiconazole | 2.68E-03 | 4.47E-03 |
| Cypermethrin | 2.03E+00 | 3.38E+00 |

| **Application - Bridge over the pond - Curative treatment by spraying (300 g.m$^{-2}$)** | |
|---|---|
| Initial concentration in local water after application [µg.L$^{-1}$] | |
| Tebuconazole | 1.35E+00 |
| Propiconazole | 1.26E+00 |
| Cypermethrin | 1.62E+00 |
| Initial concentration in local sediment after application [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 3.02E-02 |
| Propiconazole | 2.68E-02 |
| Cypermethrin | 2.03E+01 |

| **Application - Bridge over the pond - Curative treatment by injection (150 g.m$^{-2}$) followed by brushing (300 g.m$^{-2}$)** | | |
|---|---|---|
| Initial concentration in local water after application [µg.L$^{-1}$] | | |
| | Professional | Non-professional |
| Tebuconazole | 2.48E-01 | 3.38E-01 |
| Propiconazole | 2.31E-01 | 3.15E-01 |
| Cypermethrin | 2.97E-01 | 4.05E-01 |
| Initial concentration in local sediment after application [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 5.53E-03 | 7.54E-03 |
| Propiconazole | 4.92E-03 | 6.71E-03 |
| Cypermethrin | 3.71E+00 | 5.06E+00 |

| **Application - Bridge over the pond - Curative treatment by injection (150 g.m$^{-2}$) followed by spraying (300 g.m$^{-2}$)** |
|---|

| Initial concentration in local water after application [µg.L$^{-1}$] | |
|---|---|
| Tebuconazole | 1.46E+00 |
| Propiconazole | 1.37E+00 |
| Cypermethrin | 1.76E+00 |
| Initial concentration in local sediment after application mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 3.27E-02 |
| Propiconazole | 2.91E-02 |
| Cypermethrin | 2.19E+01 |

**Direct emissions during service life:**

| **Wood-in-service - Bridge over the pond - Preventive surface treatment (200 g.m$^{-2}$) – Treated wood in service only** | |
|---|---|
| TWA concentration in local water over the TIME1 assessment period (30 days) [µg.L$^{-1}$] | |
| Tebuconazole | 1.87E-03 |
| Propiconazole | 1.10E-03 |
| Cypermethrine | 2.29E-06 |
| Local concentration in sediment over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 4.72E-05 |
| Propiconazole | 3.86E-05 |
| Cypermethrine | 2.33E-04 |
| TWA concentration in local water over the TIME2 assessment period [µg.L$^{-1}$] | |
| Tebuconazole | 4.06E-03 |
| Propiconazole | 1.45E-03 |
| Cypermethrin | 3.78E-07 |
| Local concentration in sediment over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 3.66E-04 |
| Propiconazole | 1.20E-03 |
| Cypermethrine | 9.08E-05 |

| **Wood-in-service - Bridge over the pond - Curative surface treatment (300 g.m$^{-2}$)– Treated wood in service only** | |
|---|---|
| TWA concentration in local water over the TIME1 assessment period (30 days) [µg.L$^{-1}$] | |
| Tebuconazole | 2.80E-03 |
| Propiconazole | 1.66E-03 |
| Cypermethrine | 3.44E-06 |
| Local concentration in sediment over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 7.08E-05 |
| Propiconazole | 5.79E-05 |
| Cypermethrine | 3.50E-04 |
| TWA concentration in local water over the TIME2 assessment period – [µg.L$^{-1}$] | |
| Tebuconazole | 6.09E-03 |
| Propiconazole | 2.18E-03 |
| Cypermethrin | 5.67E-07 |
| Local concentration in sediment over the TIME2 assessment period – [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 5.49E-04 |
| Propiconazole | 1.80E-03 |
| Cypermethrine | 1.36E-04 |

| Wood-in-service - Bridge over the pond - Injection followed by curative surface treatment (eq. to 450 $g.m^{-2}$) – Treated wood in service only | |
|---|---|
| TWA concentration in local water over the TIME1 assessment period (30 days) – $Clocal_{water.surface.TWA\ TIME1}$ [$\mu g.L^{-1}$] | |
| Tebuconazole | 4.20E-03 |
| Propiconazole | 2.48E-03 |
| Cypermethrine | 5.14E-06 |
| Local concentration in sediment over the TIME1 assessment period (30 days) – [$mg.kg^{-1}_{wwt}$] | |
| Tebuconazole | 1.06E-04 |
| Propiconazole | 8.68E-05 |
| Cypermethrine | 5.25E-04 |
| TWA concentration in local water over the TIME2 assessment period [$\mu g.L^{-1}$] | |
| Tebuconazole | 9.14E-03 |
| Propiconazole | 3.27E-03 |
| Cypermethrin | 8.48E-07 |
| Local concentration in sediment over the TIME2 assessment period [$mg.kg^{-1}_{wwt}$] | |
| Tebuconazole | 8.23E-04 |
| Propiconazole | 2.69E-03 |
| Cypermethrine | 2.04E-04 |

**2. Indirect emissions via the STP - Noise barrier scenario:**

Indirect emissions to surface water and sediment via the STP were calculated on results described in FR-CA box 14, and according to the equations 45 and 50 of the ECHA Guidance Vol.IV, par B (2015).

| Wood-in-service – Noise barrier - Preventive treatment (200 $g.m^{-2}$) – Treated wood in service only | | |
|---|---|---|
| **$PEC_{water\ via\ STP}$ [$\mu g.L^{-1}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 1.36E-03 | 6.35E-04 |
| Propiconazole | 1.15E-03 | 8.01E-04 |
| Cypermethrine | 9.03E-07 | 1.42E-07 |
| **$PEC_{sediment\ via\ STP}$ [$mg.kg^{-1}_{wwt}$]** | | |
| Tebuconazole | 3.04E-05 | 1.42E-05 |
| Propiconazole | 2.45E-05 | 1.71E-05 |
| Cypermethrine | 1.13E-05 | 1.78E-06 |

| Wood-in-service – Noise barrier - Curative treatment (300 $g.m^{-2}$) – Treated wood in service only | | |
|---|---|---|
| **$PEC_{water\ via\ STP}$ [$\mu g.L^{-1}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 2.04E-03 | 9.52E-04 |
| Propiconazole | 1.72E-03 | 1.20E-03 |
| Cypermethrine | 1.35E-06 | 2.14E-07 |
| **$PEC_{sediment\ via\ STP}$ [$mg.kg^{-1}_{wwt}$]** | | |
| Tebuconazole | 4.56E-05 | 2.13E-05 |
| Propiconazole | 3.67E-05 | 2.57E-05 |
| Cypermethrine | 1.69E-05 | 2.67E-06 |

| Wood-in-service – Noise barrier - Injection followed by curative surface treatment (eq. to 450 $g.m^{-2}$) – Treated wood in service only | | |
|---|---|---|
| **$PEC_{water\ via\ STP}$ [$\mu g.L^{-1}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 3.06E-03 | 1.43E-03 |
| Propiconazole | 2.58E-03 | 1.80E-03 |
| Cypermethrine | 2.03E-06 | 3.19E-07 |

| $PEC_{sediment\_via\_STP}$ [$mg.kg^{-1}_{wwt}$] | | |
|---|---|---|
| Tebuconazole | 6.84E-05 | 3.19E-05 |
| Propiconazole | 5.50E-05 | 3.84E-05 |
| Cypermethrine | 2.54E-05 | 3.99E-06 |

#### *2.2.8.5.3 PECs in soil*

The soil may be contaminated directly during the application of the product 06LBCEOL20/2PT and during the service life of the treated wood due to leaching of the active substances out of the wood. The agricultural soil may also be contaminated indirectly *via* sewage sludge applications.
PECs in soil are calculated for these 3 ways of contamination.

* Direct emissions into the soil during the application by brushing, spraying or injection and the resulting concentrations in soil are calculated in the section 3.3.2.1.2.

**Table 3.3.3.3-1: Predicted concentrations into the soil – *in situ* brushing**

| Active substance | PECs in soil [$kg/kg_{wwt}$] |
|---|---|
| **Application dose: 200 g/m² (preventive treatment)** | |
| Cypermethrin | $9.62*10^{-8}$ |
| Tebuconazole | $7.92*10^{-8}$ |
| Propiconazole | $7.35*10^{-8}$ |
| **Application dose: 300 g/m² (curative treatment)** | |
| Cypermethrin | $1.44*10^{-7}$ |
| Tebuconazole | $1.19*10^{-7}$ |
| Propiconazole | $1.10*10^{-7}$ |

**Table 3.3.3.3-2: Predicted concentrations into the soil – *in situ* spraying**

| Active substance | PEC in a band of soil of 50 cm width adjacent to the house (tier 1) [$kg/kg_{wwt}$] | PEC in a band of soil of 50 cm width at a distance between 1 m and 1.5 m from the house wall (tier 2) [$kg/kg_{wwt}$] |
|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | |
| Cypermethrin | $5.77*10^{-7}$ | $5.50*10^{-8}$ |
| Tebuconazole | $4.75*10^{-7}$ | $4.53*10^{-8}$ |
| Propiconazole | $4.41*10^{-7}$ | $4.21*10^{-8}$ |
| **Application dose = 300 g/m² (curative treatment)** | | |
| Cypermethrin | $8.65*10^{-7}$ | $8.25*10^{-8}$ |
| Tebuconazole | $7.13*10^{-7}$ | $6.79*10^{-8}$ |
| Propiconazole | $6.62*10^{-7}$ | $6.31*10^{-8}$ |

**Table 3.3.3.3-3: Predicted concentrations into the soil – *in situ* injection**

| Active substance | PEC in soil [$kg/kg_{wwt}$] |
|---|---|
| **Application dose = 150 g/m²** | |
| Cypermethrin | $1.13*10^{-8}$ |
| Tebuconazole | $9.26*10^{-9}$ |
| Propiconazole | $8.60*10^{-9}$ |

* Direct emissions into the soil during the service life of the treated wood and the resulting concentrations in soil are calculated in the section 3.3.2.2.1. These calculations don't take into account degradation processes.
In a second tier, soil concentrations were calculated taking into account degradation of the substances, using the model described in section 3.4.1.2 of the revised ESD (equations 3.11 and 3.12).
The $DT50_{soil}$ at 12°C is used to calculate the rate constant for removal from soil (k) according to the following equation: $k = ln2 / DT50_{soil}$. The following values of $DT50_{soil}$ and k are used for the calculations:

**Table 3.3.3.3-4: $DT50_{water}$ and rate constant for removal from water values**

| Active substance | $DT50_{soil}$ at 12°C [d] | k [$d^{-1}$] |
|---|---|---|
| Cypermethrin | 17.2 | 0.0403 |
| Tebuconazole | 77 | $9.00*10^{-3}$ |
| Propiconazole | 129 | $5.37*10^{-3}$ |

The concentrations in soil taking into account degradation are reported in the following table.

**Table 3.3.3.3-5: Predicted concentrations in soil – service life, house scenario, with degradation**

| Active substance | PEC in soil, with degradation, over 30 days [$kg/kg_{wwt}$] | PEC in soil, with degradation, over 5 years [$kg/kg_{wwt}$] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $2.67*10^{-11}$ | $1.48*10^{-12}$ |
| Tebuconazole | $3.25*10^{-9}$ | $6.37*10^{-9}$ |
| Propiconazole | $2.87*10^{-9}$ | $1.40*10^{-8}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $6.25*10^{-11}$ | $3.48*10^{-12}$ |
| Tebuconazole | $7.59*10^{-9}$ | $1.49*10^{-8}$ |
| Propiconazole | $6.72*10^{-9}$ | $3.28*10^{-8}$ |

* Indirect emissions into agricultural soil *via* sewage sludge applications and resulting concentrations in soil are calculated in EUSES v2.1.2 using the quantities of active substance emitted in the STP calculated in section 3.3.2.2.3 according to the noise barrier scenario. Daily emissions during the first 30 days assessment period are higher than daily emissions during the second assessment period of 5 years. Daily emissions during the 30 days assessment period are therefore used as worst case for calculating the PEC in agricultural soil.

The concentrations in agricultural soil calculated in EUSES v2.1.2 are reported in the following tables.

**Table 3.3.3.3-6: Predicted concentrations in agricultural soil – service life, noise barrier scenario**

| Active substance | PEC in agricultural soil over 30 days [$kg/kg_{wwt}$] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $5.58*10^{-13}$ |
| Tebuconazole | $8.49*10^{-12}$ |
| Propiconazole | $8.02*10^{-12}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $8.38*10^{-12}$ |
| Tebuconazole | $1.27*10^{-10}$ |
| Propiconazole | $1.20*10^{-10}$ |

**FR-CA box 16 – Calulcation of $PEC_{soil}$.**

1. Direct emissions to soil – House scenario

For direct releases to soil, the concentrations in local soil were calculated using emission values as described in FR-CA box 7 for the outdoor application phase, and in FR-CA box 11 for the service life of treated wood phase. For application, initial concentrations are presented (eq. 4.38 for brush, 4.120 for spray Tier 1 and 4.121 for spray Tier 2 of the PT08 ESD). For service-life, twa concentrations are calculated (with eq. 3.7 and 3.8 of the PT08 ESD) taking into account the degradation process with the half-life in soil ($DT50_{soil}$) described in FR-CA box 2.

**Direct emissions during outdoor application:**

| **Application – House -Preventive treatment by brushing (200 $g.m^{-2}$)** | | |
|---|---|---|
| Initial concentrations in local soil [$mg.kg^{-1}_{wwt}$] | | |
| | Professional | Non-professional |
| Tebuconazole | 5.09E-02 | 8.48E-02 |
| Propiconazole | 4.75E-02 | 7.92E-02 |
| Cypermethrin | 6.11E-02 | 1.02E-01 |

| **Application – House -Preventive treatment by spraying (200 $g.m^{-2}$)** | | |
|---|---|---|
| Initial concentrations in local soil [$mg.kg^{-1}_{wwt}$] | | |
| | Tier1 (Runoff + Drift) | Tier 2 (Drift) |
| Tebuconazole | 5.09E-01 | 4.85E-02 |
| Propiconazole | 4.75E-01 | 4.53E-02 |
| Cypermethrin | 6.11E-01 | 5.82E-02 |

| **Application – House - Curative treatment by brushing (300 $g.m^{-2}$)** | | |
|---|---|---|
| Initial concentrations in local soil [$mg.kg^{-1}_{wwt}$] | | |
| | Professional | Non-professional |
| Tebuconazole | 7.64E-02 | 1.27E-01 |
| Propiconazole | 7.13E-02 | 1.19E-01 |
| Cypermethrin | 9.16E-02 | 1.53E-01 |

| **Application – House - Curative treatment by spraying (300 $g.m^{-2}$)** | | |
|---|---|---|
| Initial concentrations in local soil [$mg.kg^{-1}_{wwt}$] | | |
| | Tier1 (Runoff + Drift) | Tier 2 (Drift) |
| Tebuconazole | 7.64E-01 | 7.28E-02 |
| Propiconazole | 7.13E-01 | 6.79E-02 |
| Cypermethrin | 9.16E-01 | 8.74E-02 |

| Application – House - Curative treatment by injection (150 g.m$^{-2}$) | |
|---|---|
| Initial concentrations in local soil [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 6.36E-02 |
| Propiconazole | 5.94E-02 |
| Cypermethrin | 7.64E-02 |

**Direct emissions during service life of treated wood:**

| Wood-inservice – House - Preventive treatment (200 g.m$^{-2}$) – Treated wood in service only | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 1.13E-03 |
| Propiconazole | 9.50E-04 |
| Cypermethrine | 1.03E-05 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 4.14E-03 |
| Propiconazole | 5.43E-03 |
| Cypermethrin | 4.06E-06 |

| Wood-inservice – House - Preventive treatment (200 g.m$^{-2}$) – Brush application + Treated wood in service | | |
|---|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | | |
| | Professional | Non professional |
| Tebuconazole | 4.57E-02 | 7.55E-02 |
| Propiconazole | 4.29E-02 | 7.09E-02 |
| Cypermethrine | 3.55E-02 | 5.91E-02 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 6.51E-03 | 8.08E-03 |
| Propiconazole | 7.82E-03 | 9.42E-03 |
| Cypermethrin | 2.52E-04 | 4.17E-04 |

| Wood-inservice – House - Preventive treatment (200 g.m$^{-2}$) – Spray application + Treated wood in service | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| | Tier1 (Runoff + Drift) |
| Tebuconazole | 4.47E-01 |
| Propiconazole | 4.21E-01 |
| Cypermethrine | 3.54E-01 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 2.78E-02 |
| Propiconazole | 2.93E-02 |
| Cypermethrin | 2.48E-03 |

| Wood-inservice – House - Curative treatment (300 g.m$^{-2}$)– Treated wood in service only | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 1.70E-03 |
| Propiconazole | 1.43E-03 |
| Cypermethrine | 1.55E-05 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 6.21E-03 |

| | |
|---|---|
| Propiconazole | 8.17E-03 |
| Cypermethrin | 6.09E-06 |

| **Wood-inservice – House - Curative treatment (300 g.m$^{-2}$) – Brush application + Treated wood in service** | | |
|---|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | | |
| | Professional | Non professional |
| Tebuconazole | 6.86E-02 | 1.13E-01 |
| Propiconazole | 6.44E-02 | 1.06E-01 |
| Cypermethrine | 5.32E-02 | 8.86E-02 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 9.76E-03 | 1.21E-02 |
| Propiconazole | 1.18E-02 | 1.41E-02 |
| Cypermethrin | 3.78E-04 | 6.26E-04 |

| **Wood-inservice – House - Curative treatment (300 g.m$^{-2}$) – Spray application + Treated wood in service** | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| | Tier1 (Runoff + Drift) |
| Tebuconazole | 6.71E-01 |
| Propiconazole | 6.31E-01 |
| Cypermethrine | 5.32E-01 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 4.17E-02 |
| Propiconazole | 4.40E-02 |
| Cypermethrin | 3.73E-03 |

| **Wood-inservice – House - Injection followed curative surface application treatment (eq. to 450 g.m$^{-2}$) – Treated wood in service only** | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 2.55E-03 |
| Propiconazole | 2.14E-03 |
| Cypermethrine | 2.32E-05 |
| 1,2,4-triazole | 2.44E-04 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 9.32E-03 |
| Propiconazole | 1.22E-02 |
| Cypermethrin | 9.10E-06 |
| 1,2,4-triazole | 1.73E-03 |

| **Wood-in service – House - Injection followed curative surface application treatment (eq. to 450 g.m$^{-2}$) – Injection followed by brush application + Treated wood in service** | | |
|---|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | | |
| | Professional | Non professional |
| Tebuconazole | 1.24E-01 | 1.69E-01 |
| Propiconazole | 1.18E-01 | 1.60E-01 |
| Cypermethrine | 9.76E-02 | 1.33E-01 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | | |
| Tebuconazole | 1.58E-02 | 1.82E-02 |
| Propiconazole | 1.88E-02 | 2.12E-02 |

| | | |
|---|---|---|
| Cypermethrin | 6.91E-04 | 9.39E-04 |

| **Wood-in service – House - Injection followed curative surface application treatment (eq. to 450 g.m$^{-2}$) – Injection followed by spray application + Treated wood in service** | |
|---|---|
| TWA concentration in local soil over the TIME1 assessment period (30 days) [mg.kg$^{-1}_{wwt}$] | |
| | Tier1 (Runoff + Drift) |
| Tebuconazole | 7.28E-01 |
| Propiconazole | 6.84E-01 |
| Cypermethrine | 5.76E-01 |
| TWA concentration in local soil over the TIME2 assessment period [mg.kg$^{-1}_{wwt}$] | |
| Tebuconazole | 4.78E-02 |
| Propiconazole | 5.11E-02 |
| Cypermethrin | 4.04E-03 |

**2. Indirect emissions via the STP - Noise barrier scenario:**

Indirect emissions to soil via spreading of STP sludge onto soil was calculated based on results described in FR-CA box 13, and according to the equations of the ECHA Guidance Vol.IV, par B (2015), with the following inputs. As the Noise barrier scenario has been requested to the applicant to cover releases to STP in urban area, only this indirect emission pathway to soil was assessed.

| Variable/Parameter | Value | Unit | Origin |
|---|---|---|---|
| Estp,TIME1 | c.f. FR-CA box 13 | [kg.d-1] | S |
| Estp,TIME2 | | | |
| $K_{oc}$ | *c.f.* FR-CA box 2 | [L.kg-1] | S |
| $DT50_{soil}$ | | [L.kg$^{-1}$] | S |
| $Fstp_{sludge}$ | | [-] | S |
| SLUDGERATE | 790 | [kg.d$^{-1}$] | D |

| **Wood-in-service – Noise barrier- Preventive treatment (200 g.m$^{-2}$) – Treated wood in service only** | | |
|---|---|---|
| **$PEC_{soil\_via\_STP}$ [mg.kg$^{-1}_{wwt}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 5.64E-06 | 2.63E-06 |
| Propiconazole | 4.39E-06 | 3.06E-06 |
| Cypermethrine | 3.61E-07 | 5.69E-08 |

| **Wood-in-service – Noise barrier- Curative treatment (300 g.m$^{-2}$) – Treated wood in service only** | | |
|---|---|---|
| **$PEC_{soil\_via\_STP}$ [mg.kg$^{-1}_{wwt}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 8.46E-06 | 3.94E-06 |
| Propiconazole | 6.59E-06 | 4.61E-06 |
| Cypermethrine | 5.42E-07 | 8.54E-08 |

| **Wood-in-service – Noise barrier- Injection followed curative surface application treatment (eq. to 450 g.m$^{-2}$) – Treated wood in service only** | | |
|---|---|---|
| **$PEC_{soil\_via\_STP}$ [mg.kg$^{-1}_{wwt}$]** | **TIME1** | **TIME 2** |
| Tebuconazole | 1.27E-05 | 5.92E-06 |
| Propiconazole | 9.88E-06 | 6.90E-06 |
| Cypermethrine | 8.11E-07 | 1.28E-07 |

#### *2.2.8.5.4 PECs in groundwater*

When the soil is contaminated, the active substances may leach into the soil and reach the groundwater.
Consequently to the environmental risk assessment performed for the application phase (see sections 3.3.2.1 and 3.3.3.3 of this document and Document IIC, section 2.2.3.1), it is recommended on the label to cover the soil during the application by brushing, spraying or injection. Then, no emission into the soil occurs during the application. Therefore, only emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.
During the service life of the treated wood, the soil may be contaminated directly due to leaching and the agricultural soil may also be contaminated indirectly *via* sewage sludge applications.
Concentrations in groundwater are therefore estimated for these 2 ways of contamination of the soil.

<u>* Calculations for direct contamination of the soil</u>
As an indication for potential groundwater contamination, the concentration in pore water is calculated from the $PEC_{soil}$ calculated in section 3.3.3.3 according to the following formula (equations 3.9 and 3.10 of the revised ESD for PT08). It has to be noted that this calculation is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

$PEClocal_{porewater,\ time} = [Clocal_{soil,\ time} * RHO_{soil} / K_{soil\text{-}water}] / 1000$

where:
$PEClocal_{porewater,\ time}$: Local PEC in pore water over the assessment period [kg/L]
$Clocal_{soil,\ time}$: Concentration in local soil taking into account degradation over the assessment period [$kg/kg_{wwt}$]
$RHO_{soil}$: Bulk density of wet soil [1700 $kg/m^3$]
$K_{soil\text{-}water}$: Soil-water partitioning coefficient [$m^3/m^3$] (see detailed calculation below).

$K_{soil\text{-}water}$ is calculated according to equation 24 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0 based on the $K_{oc}$ and Henry's law constant of each active substance.

$K_{soil\text{-}water} = Fair_{soil} * K_{air\text{-}water} + Fwater_{soil} + [Fsolid_{soil} * (Kp_{soil}/1000) * RHOsolid]$
where:
$K_{soil\text{-}water}$: soil-water partitioning coefficient [$m^3.m^{-3}$]
$Fair_{soil}$ fraction of air in soil [0.2 $m^3.m^{-3}$]
$K_{air\text{-}water}$ air-water partitioning coefficient [-] calculated according to equation 22
$Fwater_{soil}$: fraction of water in soil [0.2 $m^3.m^{-3}$]
$Fsolid_{soil}$: fraction of solids in soil [0.6 $m^3.m^{-3}$]
$Kp_{soil}$: solids-water partitioning coefficient in soil [$L.kg^{-1}$] calculated according to equation 23
RHOsolid: density of the solid phase [2500 $kg.m^{-3}$]

- Equation 22 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0:
$K_{air\text{-}water} = HENRY / (R * TEMP)$
where:
HENRY: Henry's law constant [$Pa.m^3.mol^{-1}$]
R: gas constant [8.314 $Pa.m^3.mol^{-1}.k^{-1}$]
TEMP: temperature at the air-water interface [285 K]

- Equation 23 of the Guidance on the BPR, Volume IV Environment – Part B Risk assessment (active substances), April 2015, version 1.0:
$Kp_{soil} = Foc_{soil} * K_{oc}$
where:
$Kp_{soil:}$ partition coefficient solid-water in soil [$L.kg^{-1}$]

$Foc_{soil}$: weight fraction of organic carbon in soil [0.02 $kg.kg^{-1}$]
$K_{oc}$: partition coefficient organic carbon-water [$L.kg^{-1}$]

Henry's law constant and $K_{oc}$ values used for the calculations and resulting $K_{air\text{-}water}$ and $K_{soil\text{-}water}$ are reported for the 3 active substances in the following tables.

**Table 3.3.3.4-1: Henry's law constant values and resulting $K_{air\text{-}water}$ used for the calculations of the $PEC_{pore\text{-}water}$**

| Active substance | Henry's law constant [$Pa.m^3.mol^{-1}$] | $K_{air\text{-}water}$ |
|---|---|---|
| Cypermethrin | 0.0240 | $1.01*10^{-5}$ |
| Tebuconazole | $1.00*10^{-5}$ | $4.22*10^{-9}$ |
| Propiconazole | $9.20*10^{-5}$ | $3.88*10^{-8}$ |

**Table 3.3.3.4-2: $K_{oc}$ values and resulting $K_{soil\text{-}water}$ used for the calculations of the $PEC_{pore\text{-}water}$**

| Active substance | $K_{oc}$ [L/kg] | $K_{soil\text{-}water}$ |
|---|---|---|
| Cypermethrin | 574 360 | 17 231 |
| Tebuconazole | 992 | 29.96 |
| Propiconazole | 944 | 28.52 |

The concentrations in pore water are reported in the following table.

**Table 3.3.3.4-3: Predicted concentrations in pore water – service life, house scenario, with degradation**

| Active substance | PEC in pore water, with degradation, over 30 days [µg/L] | PEC in pore water, with degradation, over 5 years [µg/L] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $2.63*10^{-6}$ | $1.46*10^{-7}$ |
| Tebuconazole | 0.184 | 0.361 |
| Propiconazole | 0.171 | 0.835 |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $6.16*10^{-6}$ | $3.43*10^{-7}$ |
| Tebuconazole | 0.431 | 0.847 |
| Propiconazole | 0.401 | 1.95 |

* Calculation for indirect contamination of the soil
Concentration in pore water following indirect contamination of the soil *via* sewage sludge application are calculated in EUSES v2.1.2 and reported in the following table.

**Table 3.3.3.4-4: Predicted concentrations in pore water – service life, noise barrier scenario**

| Active substance | PEC in pore water of agricultural soil [µg/L] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $1.31*10^{-8}$ |
| Tebuconazole | $2.71*10^{-4}$ |
| Propiconazole | $3.30*10^{-4}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $1.96*10^{-7}$ |
| Tebuconazole | $4.06*10^{-3}$ |
| Propiconazole | $4.95*10^{-3}$ |

**FR-CA box 17 - Estimations of releases of active substances, and their relevant degradation products for the groundwater compartment**

The estimations of releases of active substances, and their relevant degradation products for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

According to the paragraph 578 of the PT08-ESD (2013), the estimation of releases to groundwater is relevant for susbstance with:

- $K_{oc}$ < 500 $L.kg^{-1}$ and
- $DT50_{soil}$ > 21 d**.**

Considering that:

| Substance | $K_{oc}$ [$L.kg^{-1}$] | $DT50_{soil,12°C}$ [d] | Origin |
|---|---|---|---|
| Tebuconazole | 992 | 77 | S - PT07-CAR of tebuconazole |
| Propiconazole | 944 | 82 | S - PT07-CAR of propiconazole |
| 1,2,4-triazole (*) | 89 | 114.7 (**) | S - PT07-CAR of propiconazole / PT07-CAR of tebuconazole |
| Cypermethrin | 575000 | 17.2 | S - PT08-CAR of cypermethrin |

(*) – Relevant degradation product of tebuconazole and propiconazole in soil, with a maximum of 9% and 43.23% of applied radioactivity, respectively.
(**) – Calculated according to the arrhenius equation with a $DT_{50}$ at 20°C of 60.5 days.

Estimations of releases to groundwater is considered relevant by FR-CA for the following substances: tebuconazole, propiconazole, and 1,2,4-triazole.

According to the paragraph 580 of the PT08-ESD (2013), a groundwater assessement is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD was applied for injection followed curative surface application treatment (eq. to 450 $g.m^{-2}$) as a worst case, based on leaching values calculated in the FR-CA box 10, and summarized below:

| Extrapolated leaching values for a surface application at 450 g/m² with topcoat | |
|---|---|
| Active substance | Q*leach, TIME2 (5y) [$mg.m^{-2}$] |
| Tebuconazole | 2.79E+01 |
| Propiconazole | 3.49E+01 |

Other inputs are:

***Inputs:***

| Parameter | Value | Origin |
|---|---|---|
| Q*leach, TIME2(5y) [mg.m$^{-2}$] | *C.f.* FR-CA box 10 | S |
| Total leachable area per hectare [m².ha$^{-1}$] | 2000 (corresponding to 16 houses) | D – PT08-ESD, appendix 4 |
| Fraction of house surface exposed to weather – $F_{weatherside}$ [-] | 0.5 | D – PT08-ESD, appendix 4 |
| Service life for surface applicaton [d] | 1825 | D – PT08-ESD |
| Fraction of house surface exposed to weather ($F_{weatherside}$) | 0.5 | D – PT08-ESD, appendix 4 |
| Number of equal applications per annum | 10 | D – PT08-ESD, appendix 4 |
| Application scheme | 10.01<br>15.02<br>24.03<br>29.04<br>05.06<br>11.07<br>17.08<br>22.09<br>29.10<br>04.12 | D – PT08-ESD, appendix 4 |
| Scenarios to be calculated | All 9 scenarios | D – PT08-ESD, appendix 4 |
| Crop setting | "grassland" scenario | D – PT08-ESD, appendix 4 |
| Additional assumptions | - No interception<br>- Fallow soil<br>- No plant uptake<br>- Assessment of standard 26 years | D – PT08-ESD, appendix 4 |
| Freundlich exponent | 1 | D |

The results are listed in the table below.

| Model | Scenario | Tebuconazole [µg.L$^{-1}$] | Propiconazole [µg.L$^{-1}$] | 1,2,4-triazole (*) [µg.L$^{-1}$] |
|---|---|---|---|---|
| PEARL 4.4.4 | CHATEAUDUN | < 0.001 | < 0.001 | 0.05 |
| | HAMBURG | < 0.001 | < 0.001 | 0.08 |
| | JOIKIONEN | < 0.001 | < 0.001 | 0.07 |
| | KREMSMUENSTER | < 0.001 | < 0.001 | 0.05 |
| | OKEHAMPTON | < 0.001 | < 0.001 | 0.07 |
| | PIACENZA | < 0.001 | < 0.001 | 0.05 |
| | PORTO | < 0.001 | < 0.001 | 0.04 |
| | SEVILLA | < 0.001 | < 0.001 | 0.02 |
| | THIVA | < 0.001 | < 0.001 | 0.03 |
| (*) – Values are the sum of 1,2,4-triazole from the degradation of tebuconazole and propiconazole in soil. | | | | |

#### *2.2.8.5.5 PEC in air*

The vapour pressure of cypermethrin, tebuconazole and propiconazole are very low ($2.3*10^{-7}$ Pa at 20°C, $1.7*10^{-6}$ Pa at 20°C and $5.6*10^{-5}$ Pa at 25°C, respectively), therefore emissions and PECs in air are considered as negligible for the three active substances.

#### *2.2.8.5.6 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)*

*- Cypermethrin*
As cypermethrin has a log $K_{ow}$ > 3 (log $K_{ow}$ = 5.45) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm estimated in EUSES as 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

The concentration of cypermethrin in food *(i.e.* in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) is calculated in EUSES v2.1.2.

The concentration in fish is calculated using the worst case concentration in surface water (*i.e.* the concentration of $2.90*10^{-6}$ mg/L obtained with the bridge over pond scenario, without degradation for the application dose of 450 g/m², see Table 3.3.2.2.2-2). The calculated concentration in fishes can therefore be considered as a worst case.

The concentration in earthworm is calculated using the worst case concentration in soil (*i.e.* the concentration of $2.56*10^{-10}$ $kg/kg_{wwt}$ obtained with the house scenario without degradation adapted for injection treatment, see Table 3.3.2.2.1-3). The calculated concentration in earthworms can therefore be considered as a worst case.

**Table 3.3.4-1 PEC of cypermethrin in fish and earthworm**

| | Concentration in fish | Concentration in earthworm |
|---|---|---|
| Cypermethrin | $6.05*10^{-4}$ $mg/kg_{wet\ fish}$ | $5.14*10^{-5}$ $mg/kg_{wet\ earthworm}$ |

*- Tebuconazole*
According to the BCF in earthworm equal to 28, tebuconazole is not expected to bioaccumulate to terrestrial organisms. Therefore, even if tebuconazole has a potential to cause toxic effects in higher organism since it is classified as toxic for the reproduction, category 2 (H361d), an assessment of secondary poisoning doesn't need to be performed.

*- Propiconazole*
Log $K_{ow}$ of propiconazole is 3.7 implying slight bioaccumulation potential. However, based on the estimation of BCF for terrestrial organisms (BCF = 64) propiconazole is not bioaccumulative to terrestrial organisms. Moreover, propiconazole is not classified as STOT RE 1 or 2 (H372 or H373, equivalent to R48), and is not classified as reprotoxic category 1 or 2 (H360f, H360d, H361f, H361d or H362, equivalent to R60, R61, R62, R63 and R64). Therefore, there is no need to perform an assessment of secondary poisoning for propiconazole.

**FR-CA box 18 – Secondary poisoning for cypermethrin**

FR-CA agreed with the applicant for considering that secondary poisoning is relevant only for the active substance cypermethrin. As a consequence, the secondary poisoning was assessed for the TIME2 assessment period of service life considering as a worst case:

- for the aquatic food chain**,** the scenario "injection followed by curative surface treatment (eq. to 450 $g.m^{-2}$) – treated wood in service only" with a $Clocal_{water,TWA\ TIME2}$ of 8.48E-07 $\mu g.L^{-1}$ (*c.f.* FR-CA box 15);

- for the terrestrial food chain, the scenario “curative treatment – Injection followed by spray application (Tier1 – runoff + drift) + treated wood in service” with a $Clocal_{soil,TWA\ TIME2}$ of 4.04E-03 $mg.kg^{-1}_{wwt}$ (*c.f.* FR-CA box 16).

In accordance with the equations of the ECHA guidance vol.IV, part B (2015), $PEC_{oral,predator}$ for both food chain were calculated as followed:

| Parameter / variable | Symbol | Unit | Value | Origin |
|---|---|---|---|---|
| ***Aquatic food chain:*** | | | | |
| Predicted environmental concentration during episode | $PEC_{local,water}$ | $[mg.L^{-1}]$ | 8.48E-10 | S - FR-CA box 15 |
| Bioconcentration factor for fish on wet weight basis | $BCF_{fish}$ | $[L.kg^{-1}_{wet\ fish}]$ | 417 | S |
| Biomagnification factor in fish | BMF | [-] | 2 | S - table 24 of ECHA guidance vol.IV, part B (2015) |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **$PEC_{oral,predator}$** | **$[mg.kg^{-1}_{wet\ fish}]$** | **3.54E-07** | **Eq. 76 - ECHA guidance vol.IV, part B (2015)** |
| ***Terrestrial food chain :*** | | | | |
| log of partition coefficient n-octanol-water | Log $K_{ow}$ | [-] | 5.45 | S |
| Bioconcentration factor for earthworm on wet weight basis | $BCF_{earthworm}$ | $[L.kg^{-1}_{wet\ earthworm}]$ | 3.38E+03 | Eq. 82d - ECHA guidance vol.IV, part B (2015) |
| Concentration in porewater | $C_{porewater}$ | $[mg.L^{-1}]$ | 3.98E-07 | Eq. 67 - ECHA guidance vol.IV, part B (2015) |
| Concentration in soil | $C_{soil}$ | $[mg.kg^{-1}_{wwt}]$ | 4.04E-03 | S - FR-CA box 16 |
| Fraction of gut loading in worm | $F_{gut}$ | $[kg_{dwt}.kg^{-1}_{wwt}]$ | 0.1 | D |
| Conversion factor for soil concentration wet-dry weight soil | $CONV_{soil}$ | $[kg_{wwt}.kg^{-1}_{dwt}]$ | 1.13 | Eq. 82b - ECHA guidance vol.IV, part B (2015) |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **$PEC_{oral,predator}$** | **$[mg.kg^{-1}_{wet\ earthworm}]$** | **8.10E-04** | **Eq. 80 - ECHA guidance vol.IV, part B (2015)** |

### 2.2.8.6 Risk characterisation for the environment

The risk characterisation presented below is based on estimated concentrations in the different compartments calculated for amateur use which is a worst case and covers the professional use. The calculated concentrations take into account the application of a topcoat after the treatment with the product 06LBCEOL20/2PT (see Document IIB).
For the service life, the application rates assessed are 300 g/m² (corresponding to a curative treatment by brushing or spraying) and 450 g/m² (corresponding to a curative treatment by injection at 150 g/m² followed by a treatment by brushing or spraying at 300 g/m²). The risk assessment for the service life after a treatment at

200 g/m² (corresponding to a preventive treatment by brushing or spraying) is not presented as it is covered by the assessment performed for the highest application doses of 300 or 450 g/m².

According to the screening step for mixture ecotoxicity assessment, a mixture assessment is needed for the product 06LBCEOL20/PT. The mixture assessment is conducted according to the tiered assessment scheme described in the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment of May 2014.
The risk quotients of the product are estimated in a first tier by the sum of PEC/PNEC ratios according to equation 4:

$$RQ_{\text{Product}} = \sum_{i=1}^{n} \left( \frac{PEC}{PNEC} \right)_i$$

**FR-CA box 19**

The risk characterisation presented below by FR-CA is based on estimated concentrations in the different compartments calculated for the scenarios corresponding to the following applicant's intended uses:

- Preventive treatment by surface application (200 g product/m² by brushing and spraying) by professional and non-professional;
- Curative treatment:
  - by surface application (300 g product/m² by brushing and spraying) by professional and non-professional;
  - by injection (150 g product/m²) followed by surface application (300 g product/m² by brushing and spraying) by professional and non-professional.

As mentioned by the applicant the mixture ecotoxicity assessment was conducted in accordance with the first Tier of the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment of May 2014.

#### *2.2.8.6.1 Risk characterisation for the Sewage Treatment Plant*

Emissions of active substances into the STP may occur during the service life of the treated wood following leaching due to rainfall. Daily emissions into the STP have been calculated according to the noise barrier scenario.
Concentrations in the STP are calculated in EUSES v2.1.2, using the daily emission during the first 30 days assessment period which is a worst case as compared to daily emission during the second assessment period of 5 years.
PECs and risk ratios for the STP are presented in the following table.

**Table 2.2.1-1: PECs and risk ratios for the STP – service life, noise barrier scenario**

| Active substance | PEC in STP [mg/L] | RCR for the STP |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin ($PNEC_{STP}$ = 1.63 mg/L) | $2.60*10^{-8}$ | $1.60*10^{-8}$ |
| Tebuconazole ($PNEC_{STP}$ = 0.320 mg/L) | $2.04*10^{-5}$ | $6.39*10^{-5}$ |
| Propiconazole ($PNEC_{STP}$ = 100 mg/L) | $1.72*10^{-5}$ | $1.72*10^{-7}$ |
| Cumulated RCR | | **$6.41*10^{-5}$** |

| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
|---|---|---|
| Cypermethrin ($PNEC_{STP}$ = 1.63 mg/L) | $3.91*10^{-7}$ | $2.40*10^{-7}$ |
| Tebuconazole ($PNEC_{STP}$ = 0.320 mg/L) | $3.06*10^{-4}$ | $9.57*10^{-4}$ |
| Propiconazole ($PNEC_{STP}$ = 100 mg/L) | $2.59*10^{-4}$ | $2.59*10^{-6}$ |
| Cumulated RCR | | **$9.60*10^{-4}$** |

The individual risk characterisation ratios for each active substance and the cumulated RCR are below 1 for the application doses of 300 and 450 g/m².
Therefore, the risk for the STP is acceptable when using the product 06LBCEOL20/2PT at the doses of 200 g/m² (preventive treatment by brushing or spraying), 300 g/m² (curative treatment by brushing and spraying) and 450 g/m² (curative treatment by injection at 150 g/m² followed by a treatment by brushing or spraying at 300 g/m²) according to the label recommendations.

**FR-CA box 20 – Risk characterisation for the STP**

The risk characterisation for the STP has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD as described in the FR-CA box 14, and compared to $PNEC_{STP}$ of each active substance for the service life of treated wood.

| | | Preventive treatment (200 g.m$^{-2}$) | | Curative surface treatment (300 g.m$^{-2}$) | | Injection treatment (eq. to 450 g.m-2) | |
|---|---|---|---|---|---|---|---|
| | | PEC [mg.L$^{-1}$] | PEC/PNEC | PEC [mg.L$^{-1}$] | PEC/PNEC | PEC [mg.L$^{-1}$] | PEC/PNEC |
| TIME1 | Tebuconazole | 1.36E-05 | 4.25E-05 | 2.05E-05 | 6.41E-05 | 3.07E-05 | 9.59E-05 |
| | Propiconazole | 1.15E-05 | 1.15E-07 | 1.73E-05 | 1.73E-07 | 2.59E-05 | 2.59E-07 |
| | Cypermethrin | 1.68E-08 | 1.03E-08 | 2.52E-08 | 1.55E-08 | 3.78E-08 | 2.32E-08 |
| | ΣPEC/PNEC | | 4.26E-05 | | 6.43E-05 | | 9.62E-05 |
| TIME2 | Tebuconazole | 6.36E-06 | 1.99E-05 | 9.53E-06 | 2.98E-05 | 1.43E-05 | 4.47E-05 |
| | Propiconazole | 8.03E-06 | 8.03E-08 | 1.21E-05 | 1.21E-07 | 1.81E-05 | 1.81E-07 |
| | Cypermethrin | 2.65E-09 | 1.63E-09 | 3.98E-09 | 2.44E-09 | 5.95E-09 | 3.65E-09 |
| | ΣPEC/PNEC | | 2.00E-05 | | 2.99E-05 | | 4.49E-05 |

Considering that all PEC/PNEC ratios and aggregated PEC/PNEC ratios for STP are below 1, the risk for the STP is considered acceptable for preventive and curative treatment with the product.

#### *2.2.8.6.2 Risk characterisation for the aquatic compartment including sediment*

2.2.8.6.2.1 Risk characterisation for the application *phase*

As the product is only used to treat house pieces such as shutters, doors, siding, fences, gates, awnings, roof overhangs and is not used to treat commodities such as bridge over water bodies, the contamination of the surface water during application by brushing, spraying or injection is considered as negligible.
Indeed, as mentioned in the document Technical Agreement of Biocides, when it is not an intended use, the bridge over pond scenario does not need to be evaluated for the application phase:
***"Should the bridge over pond scenario for UC3 be included in the CAR even if this is not proposed as an intended use by the applicant?***
*(TM V 2007, TM IV 2012, TM I 2013)*
*The bridge over pond scenario is not used to evaluate the application phase but the use phase, in order to describe the emission pathway into open water bodies, and should therefore be included in the CAR."*

The risk for the aquatic compartment is therefore acceptable when applying the product 06LBCEOL20/2PT according to the label recommendations.

**FR-CA box 21 – Outdoor application phase - Risk characterisation for the aquatic compartment including sediment**

For the application phase, the risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge over pond scenario of the PT08-ESD as described in the FR-CA box 15, and compared to $PNEC_{water}$ and $PNEC_{sediment}$ of each active substance for the application phase of preventive and curative treatment. Agreggated ratios are also presented.

**BRIDGE OVER POND - BRUSHING APPLICATION – SURFACE WATER [µg.L$^{-1}$]**

| | Preventive treatment (200 g.m$^{-2}$) | | | | Curative treatment (300 g.m$^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|
| | Professional | | Non-professional | | Professional | | Non-professional | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 9.00E-02 | 9.00E-02 | 1.50E-01 | 1.50E-01 | 1.35E-01 | 1.35E-01 | 2.25E-01 | 2.25E-01 |
| Propiconazole | 8.40E-02 | 1.24E-02 | 1.40E-01 | 2.06E-02 | 1.26E-01 | 1.85E-02 | 2.10E-01 | 3.09E-02 |
| Cypermethrin | 1.08E-01 | 108 | 1.80E-01 | **180** | 1.62E-01 | **162** | 2.70E-01 | **270** |
| **ΣPEC/ PNEC** | | **108** | | **180** | | **162** | | **270** |

**BRIDGE OVER POND - BRUSHING APPLICATION – SEDIMENT [mg.kg$^{-1}_{wwt}$]**

| | Preventive treatment (200 g.m$^{-2}$) | | | | Curative treatment (300 g.m$^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|
| | Professional | | Non-professional | | Professional | | Non-professional | |
| | PEC | PEC/PNEC | PEC | PEC/PNEC | PEC | PEC/PNEC | PEC | PEC/PNEC |
| Tebuconazole | 2.01E-03 | 3.66E-03 | 3.35E-03 | 6.09E-03 | 3.02E-03 | 5.49E-03 | 5.03E-03 | 9.14E-03 |
| Propiconazole | 1.79E-03 | 3.31E-02 | 2.98E-03 | 5.52E-02 | 2.68E-03 | 4.97E-02 | 4.47E-03 | 8.29E-02 |
| Cypermethrin* | 1.35E+00 | **108** | 2.25E+00 | **180** | 2.03E+00 | **162** | 3.38E+00 | **270** |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **ΣPEC/ PNEC** | | **108.04** | | **180.06** | | **162.06** | | **270.09** |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

| **BRIDGE OVER POND - SPRAYING APPLICATION – SURFACE WATER [µg.L$^{-1}$]** | | | | |
|---|---|---|---|---|
| | **Preventive treatment** | | **Curative treatment** | |
| | **PEC** | **PEC/ PNEC** | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 9.00E-01 | 9.00E-01 | 1.35E+00 | **1.35E+00** |
| Propiconazole | 8.40E-01 | 1.24E-01 | 1.26E+00 | 1.85E-01 |
| Cypermethrin | 1.08E+00 | **1080** | 1.62E+00 | **1620** |
| **ΣPEC/ PNEC** | | **1081** | | **1621** |

| **BRIDGE OVER POND - SPRAYING APPLICATION – SEDIMENT [mg.kg$^{-1}_{wwt}$]** | | | | |
|---|---|---|---|---|
| | **Preventive treatment** | | **Curative treatment** | |
| | **PEC** | **PEC/ PNEC** | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 2.01E-02 | 3.66E-02 | 3.02E-02 | 5.49E-02 |
| Propiconazole | 1.79E-02 | 3.31E-01 | 2.68E-02 | 4.97E-01 |
| Cypermethrin* | 1.35E+01 | **1080** | 2.03E+01 | **1620** |
| **PEC/ PNEC** | | **1080** | | **1620** |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

| **BRIDGE OVER POND - INJECTION (150 g.m$^{-2}$) FOLLOWED BY BRUSHING (300 g.m$^{-2}$) – SURFACE WATER [µg.L$^{-1}$]** | | | | |
|---|---|---|---|---|
| | **Curative treatment** | | | |
| | **Professional** | | **Non-professional** | |
| | **PEC** | **PEC/ PNEC** | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 2.48E-01 | 2.48E-01 | 3.38E-01 | 3.38E-01 |
| Propiconazole | 2.31E-01 | 3.40E-02 | 3.15E-01 | 4.63E-02 |
| Cypermethrin | 2.97E-01 | **297** | 4.05E-01 | **405** |
| **ΣPEC/ PNEC** | | **297.28** | | **405.38** |

| **BRIDGE OVER POND - INJECTION (150 g.m$^{-2}$) FOLLOWED BY BRUSHING (300 g.m$^{-2}$) – SEDIMENT [mg.kg$^{-1}_{wwt}$]** | | | | |
|---|---|---|---|---|
| | **Curative treatment** | | | |
| | **Professional** | | **Non-professional** | |
| | **PEC** | **PEC/ PNEC** | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 5.53E-03 | 1.01E-02 | 7.54E-03 | 1.37E-02 |
| Propiconazole | 4.92E-03 | 9.11E-02 | 6.71E-03 | 1.24E-01 |
| Cypermethrin* | 3.71E+00 | **297** | 5.06E+00 | **405** |
| **ΣPEC/ PNEC** | | **297.10** | | **405.14** |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

| BRIDGE OVER POND - INJECTION (150 g.m$^{-2}$) FOLLOWED BY SPRAYING (300 g.m$^{-2}$) – SURFACE WATER [µg.L$^{-1}$] | | |
|---|---|---|
| | Curative treatment | |
| | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 1.46E+00 | **1.46E+00** |
| Propiconazole | 1.37E+00 | 2.01E-01 |
| Cypermethrin | 1.76E+00 | **1755** |
| **ΣPEC/ PNEC** | | **1756.66** |

| BRIDGE OVER POND - INJECTION (150 g.m$^{-2}$) FOLLOWED BY SPRAYING (300 g.m$^{-2}$) – SEDIMENT [mg.kg$^{-1}_{wwt}$] | | |
|---|---|---|
| | Curative treatment | |
| | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 3.27E-02 | 5.94E-02 |
| Propiconazole | 2.91E-02 | 5.39E-01 |
| Cypermethrin* | 2.19E+01 | **1755** |
| **ΣPEC/ PNEC** | | **1755.6** |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

Whatever the application method (brushing, spraying, and injection) and the application rate, all the calculated sums of PEC/PNEC ratios are above 1 for surface water and sediment.

Therefore, the application phase by brushing, spraying or injection near surface water is cause of concern for the aquatic compartment (including sediment) and should be prevented.

2.2.8.6.2.2 Risk characterisation *for the service life*

Surface water and sediment may be contaminated during the service life of the treated wood due to leaching of the active substances out of the wood. Surface water may be contaminated directly or indirectly *via* the STP effluents. The risk assessment is performed for these 2 ways of contamination and is presented below.

* Concentrations in surface water and sediment resulting from direct emissions into surface water due to leaching have been calculated in the document IIB, section 3.3.3.2 according to the bridge over pond scenario. The degradation of the active substances is taken into account. PECs and risk ratios for surface water and sediment are summarised in the following tables.

**Table 2.2.2.2-1: PECs and risk ratios for surface water – service life, bridge over pond scenario, with degradation**

| Active substance | PEC in surface water, with degradation, over 30 days [mg/L] | RCR for surface water, over 30 days | PEC in surface water, with degradation, over 5 years [mg/L] | RCR for surface water, over 5 years |
|---|---|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | | | |
| Cypermethrin (PNECsw = 1.00*10$^{-6}$ mg/L) | 2.89*10$^{-8}$ | 0.0289 | 2.78*10$^{-9}$ | 2.78*10$^{-3}$ |
| Tebuconazole | 3.16*10$^{-6}$ | 3.16*10$^{-3}$ | 2.44*10$^{-5}$ | 0.0244 |

| | | | | |
|---|---|---|---|---|
| (PNECsw = 1.00*10$^{-3}$ mg/L) | | | | |
| Propiconazole (PNECsw = 6.80*10$^{-3}$ mg/L) | 2.73*10$^{-6}$ | 4.02*10$^{-4}$ | 8.82*10$^{-5}$ | 0.0130 |
| Cumulated RCR | | **0.0325** | | **0.0402** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | | | |
| Cypermethrin (PNECsw = 1.00*10$^{-6}$ mg/L) | 4.34*10$^{-7}$ | 0.434 | 4.18*10$^{-8}$ | 0.0418 |
| Tebuconazole (PNECsw = 1.00*10$^{-3}$ mg/L) | 4.74*10$^{-5}$ | 0.0474 | 3.67*10$^{-4}$ | 0.367 |
| Propiconazole (PNECsw = 6.80*10$^{-3}$ mg/L) | 4.10*10$^{-5}$ | 6.03*10-3 | 1.32*10$^{-3}$ | 0.194 |
| Cumulated RCR | | **0.487** | | **0.603** |

**Table 2.2.2.2-2: PECs and risk ratios for sediment – service life, bridge over pond scenario, with degradation**

| **Active substance** | **PEC in sediment, with degradation, over 30 days [mg/kg$_{wwt}$]** | **RCR for sediment, over 30 days** | **PEC in sediment, with degradation, over 5 years [mg/kg$_{wwt}$]** | **RCR for sediment, over 5 years** |
|---|---|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | | | |
| Cypermethrin (PNECsed = 0.125 mg/kg$_{wwt}$) | 3.61*10$^{-4}$ | 2.89*10$^{-3}$ | 3.47*10$^{-5}$ | 2.78*10$^{-4}$ |
| Tebuconazole (PNECsed = 0.55 mg/kg$_{wwt}$) | 7.07*10$^{-5}$ | 1.29*10$^{-4}$ | 5.46*10$^{-4}$ | 9.93*10$^{-4}$ |
| Propiconazole (PNECsed = 0.054 mg/kg$_{wwt}$) | 5.83*10$^{-5}$ | 1.08*10$^{-3}$ | 1.88*10$^{-3}$ | 0.0348 |
| Cumulated RCR | | **4.10*10$^{-3}$** | | **0.0361** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | | | |
| Cypermethrin (PNECsed = 0.125 mg/kg$_{wwt}$) | 5.41*10$^{-3}$ | 0.0433 | 5.22*10$^{-4}$ | 4.17*10$^{-3}$ |
| Tebuconazole (PNECsed = 0.55 mg/kg$_{wwt}$) | 1.06*10$^{-3}$ | 1.93*10$^{-3}$ | 8.20*10$^{-3}$ | 0.0149 |
| Propiconazole (PNECsed = 0.054 mg/kg$_{wwt}$) | 8.74*10$^{-4}$ | 0.0162 | 2.81*10$^{-2}$ | 0.521 |
| Cumulated RCR | | **0.0614** | | **0.540** |

**FR-CA box 22 – Service Life of treated wood - Risk characterisation for direct releases to the aquatic compartment including sediment**

The risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge scenario as described in the FR-CA box 15, and compared to $PNEC_{water}$ and $PNEC_{sediment}$ of each active substance for the service life of the treated wood.

**BRIDGE OVER POND - SERVICE LIFE OF TREATED WOOD – SURFACE WATER [µg.L$^{-1}$]**

| | Preventive treatment (200 g.m$^{-2}$) | | | | Curative treatment (300 g.m$^{-2}$) | | | | Injection followed by curative surface treatment (eq. to 450 g.m$^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 1.87E-03 | 1.87E-03 | 4.06E-03 | 4.06E-03 | 2.80E-03 | 2.80E-03 | 6.09E-03 | 6.09E-03 | 4.20E-03 | 4.20E-03 | 9.14E-03 | 9.14E-03 |
| Propiconazole | 1.10E-03 | 1.62E-04 | 1.45E-03 | 2.13E-04 | 1.66E-03 | 2.44E-04 | 2.18E-03 | 3.21E-04 | 2.48E-03 | 3.65E-04 | 3.27E-03 | 4.81E-04 |
| Cypermethrin | 2.29E-06 | 2.29E-03 | 3.78E-07 | 3.78E-04 | 3.44E-06 | 3.44E-03 | 5.67E-07 | 5.67E-04 | 5.14E-06 | 5.14E-03 | 8.48E-07 | 8.48E-04 |
| **ΣPEC/ PNEC** | | 4.32E-03 | | 4.65E-03 | | 6.48E-03 | | 6.98E-03 | | 9.71E-03 | | 1.05E-02 |

**BRIDGE OVER POND - SERVICE LIFE OF TREATED WOOD – SEDIMENT [mg.kg$^{-1}_{wwt}$]**

| | Preventive treatment (200 g.m$^{-2}$) | | | | Curative treatment (300 g.m$^{-2}$) | | | | Injection followed by curative surface treatment (eq. to 450 g.m$^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 4.72E-05 | 8.58E-05 | 3.66E-04 | 6.65E-04 | 7.08E-05 | 1.29E-04 | 5.49E-04 | 9.98E-04 | 1.06E-04 | 1.93E-04 | 8.23E-04 | 1.50E-03 |
| Propiconazole | 3.86E-05 | 7.15E-04 | 1.20E-03 | 2.22E-02 | 5.79E-05 | 1.07E-03 | 1.80E-03 | 3.33E-02 | 8.68E-05 | 1.61E-03 | 2.69E-03 | 4.98E-02 |
| Cypermethrin* | 2.33E-04 | 1.87E-02 | 9.08E-05 | 7.26E-03 | 3.50E-04 | 2.80E-02 | 1.36E-04 | 1.09E-02 | 5.25E-04 | 4.20E-02 | 2.04E-04 | 1.63E-02 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **ΣPEC/ PNEC** | | 1.95E-02 | | 3.01E-02 | | 2.92E-02 | | 4.52E-02 | | 4.38E-02 | | 6.76E-02 |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

Considering that all PEC/PNEC ratios for surface water and sediment are below 1, as well as the aggregated values, the risk for the aquatic compartment (including sediment) exposed to direct releases is considered acceptable during the service life of treated wood, whatever the treatment type. Nevertheless the application phase of the product above or near water leads to unacceptable risk to the aquatic compartment; no treatment above or near water is allowed.
As leaching rates have been derived from semi-field studies using treated wood also protected with a top coat, the labelling will demand the systematic application of a top coat after wood preservation, as intended by the applicant.

* Concentrations in surface water and sediment resulting from indirect emissions *via* STP effluents have been calculated in EUSES v2.1.2 using the daily quantities of active substance emitted in the STP calculated according to the noise barrier scenario (see document IIB, section 3.3.3.2). The daily emission during the first 30 days assessment period is a worst case as compared to daily emission during the second assessment period of 5 years and is therefore used to calculate PEC in surface water and sediments.
PECs and risk ratios for surface water and sediment are summarised in the following tables.

**Table 2.2.2.2-3: PECs and risk ratios for surface water – service life, noise barrier scenario**

| Active substance | PEC in surface water [mg/L] | RCR for surface water |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin (PNECsw = $1.00*10^{-6}$ mg/L) | $1.40*10^{-9}$ | $1.40*10^{-3}$ |
| Tebuconazole (PNECsw = $1.00*10^{-3}$ mg/L) | $2.04*10^{-6}$ | $2.04*10^{-3}$ |
| Propiconazole (PNECsw = $6.80*10^{-3}$ mg/L) | $1.72*10^{-6}$ | $2.53*10^{-4}$ |
| Cumulated RCR | | **$3.69*10^{-3}$** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin (PNECsw = $1.00*10^{-6}$ mg/L) | $2.10*10^{-8}$ | 0.0210 |
| Tebuconazole (PNECsw = $1.00*10^{-3}$ mg/L) | $3.06*10^{-5}$ | 0.0306 |
| Propiconazole (PNECsw = $6.80*10^{-3}$ mg/L) | $2.58*10^{-5}$ | $3.80*10^{-3}$ |
| Cumulated RCR | | **0.0554** |

**Table 2.2.2.2-4: PECs and risk ratios for sediment – service life, noise barrier scenario**

| Active substance | PEC in sediment [mg/$kg_{wwt}$] | RCR for sediment |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin (PNECsed = 0.125 mg/$kg_{wwt}$) | $1.75*10^{-5}$ | $1.40*10^{-4}$ |
| Tebuconazole (PNECsed = 0.55 mg/$kg_{wwt}$) | $4.56*10^{-5}$ | $8.29*10^{-5}$ |
| Propiconazole (PNECsed = 0.054 mg/$kg_{wwt}$) | $3.67*10^{-5}$ | $6.79*10^{-4}$ |
| Cumulated RCR | | **$9.02*10^{-4}$** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin (PNECsed = 0.125 mg/$kg_{wwt}$) | $2.62*10^{-4}$ | $2.10*10^{-3}$ |
| Tebuconazole (PNECsed = 0.55 mg/$kg_{wwt}$) | $6.83*10^{-4}$ | $1.24*10^{-3}$ |
| Propiconazole (PNECsed = 0.054 mg/$kg_{wwt}$) | $5.50*10^{-4}$ | 0.0102 |
| Cumulated RCR | | **0.0135** |

For the both scenarios, the individual risk characterisation ratios for each active substance and the cumulated RCR are below 1 for the application doses of 300 and 450 g/m².
Therefore, the risk for the surface water and sediment is acceptable when using the product 06LBCEOL20/2PT at the doses of 200 g/m² (preventive treatment by brushing or spraying), 300 g/m² (curative treatment by brushing and spraying) and 450 g/m² (curative treatment by injection at 150 g/m² followed by a treatment by brushing or spraying at 300 g/m²) according to the label recommendations.

**FR-CA box 23 – Service Life of treated wood - Risk characterisation for indirect releases (*via* STP) to the aquatic compartment including sediment.**

The risk characterisation for indirect releases via STP to the aquatic compartment including sediment has been performed considering PEC calculated for the noise barrier scenario as described in the FR-CA box 15, and compared to $PNEC_{water}$ and $PNEC_{sediment}$ of each active substance for the service life of the treated wood.

**NOISE BARRIER - SERVICE LIFE OF TREATED WOOD – SURFACE WATER VIA STP [µg.$L^{-1}$]**

| | Preventive treatment (200 g.$m^{-2}$) | | | | Curative treatment (300 g.$m^{-2}$) | | | | Injection followed by curative surface treatment (eq. to 450 g.$m^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 1.36E-03 | 1.36E-03 | 6.35E-04 | 6.35E-04 | 2.04E-03 | 2.04E-03 | 9.52E-04 | 9.52E-04 | 3.06E-03 | 3.06E-03 | 1.43E-03 | 1.43E-03 |
| Propiconazole | 1.15E-03 | 1.69E-04 | 8.01E-04 | 1.18E-04 | 1.72E-03 | 2.53E-04 | 1.20E-03 | 1.76E-04 | 2.58E-03 | 3.79E-04 | 1.80E-03 | 2.65E-04 |
| Cypermethrin | 9.03E-07 | 9.03E-04 | 1.42E-07 | 1.42E-04 | 1.35E-06 | 1.35E-03 | 2.14E-07 | 2.14E-04 | 2.03E-06 | 2.03E-03 | 3.19E-07 | 3.19E-04 |
| **ΣPEC/ PNEC** | | 2.43E-03 | | 8.95E-04 | | 3.64E-03 | | 1.34E-03 | | 5.47E-03 | | 2.01E-03 |

**NOISE BARRIER - SERVICE LIFE OF TREATED WOOD – SEDIMENT VIA STP [mg.$kg^{-1}_{wwt}$]**

| | Preventive treatment (200 g.$m^{-2}$) | | | | Curative treatment (300 g.$m^{-2}$) | | | | Injection followed by curative surface treatment (eq. to 450 g.$m^{-2}$) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 3.04E-05 | 5.53E-05 | 1.42E-05 | 2.58E-05 | 4.56E-05 | 8.29E-05 | 2.13E-05 | 3.87E-05 | 6.84E-05 | 1.24E-04 | 3.19E-05 | 5.80E-05 |
| Propiconazole | 2.45E-05 | 4.54E-04 | 1.71E-05 | 3.17E-04 | 3.67E-05 | 6.80E-04 | 2.57E-05 | 4.76E-04 | 5.50E-05 | 1.02E-03 | 3.84E-05 | 7.11E-04 |
| Cypermethrin* | 1.13E-05 | 9.04E-04 | 1.78E-06 | 1.42E-04 | 1.69E-05 | 1.35E-03 | 2.67E-06 | 2.14E-04 | 2.54E-05 | 2.03E-03 | 3.99E-06 | 3.19E-04 |
| **ΣPEC/ PNEC** | | 1.41E-03 | | 4.85E-04 | | 2.11E-03 | | 7.29E-04 | | 3.17E-03 | | 1.09E-03 |

* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

Considering that all PEC/PNEC ratios for surface water and sediment are below 1, as well as the aggregated values, the risk for the aquatic compartment (including sediment) exposed to indirect releases via the STP is considered acceptable during the service life of treated wood with the product.
As leaching rates have been derived from semi-field studies using treated wood also protected with a top coat, the labelling will demand the systematic application of a top coat after wood preservation, as intended by the applicant.

2.2.8.6.2.3 Risk characterisation for the metabolites

In surface water and sediments, three major metabolites of cypermethrin were identified: 3-phenoxybenzoic acid (21% AR in water and 11% in sediment), TDCVC (44% AR in water and 20% in sediment) and CDCVC (22% AR in water and 15% in sediment). A further unknown metabolite was identified up to 14% of AR in the units dosed with the cyclopropyl label.
The two main degradation products TDCVC and CDCVC have to be considered as persistent with typical $DT_{50}$ values > 40 days.
However, no data on the ecotoxicity of these major metabolites is available and no environmental risk assessment has been performed for the metabolites in the assessment report of cypermethrin.
Therefore, it is not possible to perform a risk assessment for the metabolites of cypermethrin in surface and sediment.

No major metabolites were found in water/sediment systems for tebuconazole and propiconazole.

### *2.2.8.6.3 Risk characterisation for the terrestrial compartment*

2.2.8.6.3.1 Risk characterisation for the application phase

The soil may be contaminated during the application of the product 06LBCEOL20/2PT by brushing, spraying or injection.
Emissions into the soil following application of the product 06LBCEOL20/2PT and resulting concentrations in soil have been calculated in the Document IIB, section 3.3.2.1.2.
PECs and risk ratios for the soil are summarised in the following tables.

**Table 2.2.3.1-1: PECs and risk ratios for soil – *in situ* brushing**

| Active substance | PEC in soil [$kg/kg_{wwt}$] | RCR for soil |
|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $9.62*10^{-8}$ | 1.05 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $7.92*10^{-8}$ | 0.792 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $7.35*10^{-8}$ | 0.735 |
| Cumulated RCR | | **2.58** |
| **Application dose = 300 g/m² (curative treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $1.44*10^{-7}$ | 1.57 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $1.19*10^{-7}$ | 1.19 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $1.10*10^{-7}$ | 1.10 |
| Cumulated RCR | | **3.86** |

The cumulated RCR are above the trigger value of 1. Therefore, the risk for the soil is unacceptable when applying the product 06LBCEOL20/2PT by brushing.
Therefore, it is recommended to cover the soil during the application by brushing. This is stated on the label.

**Table 2.2.3.1-2: PECs and RCR in soil – *in situ* spraying, tier 1**

| Active substance | PEC in a band of soil of 50 cm width adjacent to the house (tier 1) [$kg/kg_{wwt}$] | RCR for soil (tier 1) |
|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $5.77*10^{-7}$ | 6.28 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $4.75*10^{-7}$ | 4.75 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $4.41*10^{-7}$ | 4.41 |
| Cumulated RCR | | **15.4** |
| **Application dose = 300 g/m² (curative treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $8.65*10^{-7}$ | 9.43 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $7.13*10^{-7}$ | 7.13 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $6.62*10^{-7}$ | 6.62 |
| Cumulated RCR | | **23.2** |

**Table 2.2.3.1-3: PECs and RCR in soil – *in situ* spraying, tier 2**

| Active substance | PEC in a band of soil of 50 cm width at a distance between 1 m and 1.5 m from the house wall (tier 2) [$kg/kg_{wwt}$] | RCR for soil (tier 2) |
|---|---|---|
| **Application dose = 200 g/m² (preventive treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $5.50*10^{-8}$ | 0.599 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $4.53*10^{-8}$ | 0.453 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $4.21*10^{-8}$ | 0.421 |
| Cumulated RCR | | **1.47** |
| **Application dose = 300 g/m² (curative treatment)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $8.25*10^{-8}$ | 0.899 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $6.79*10^{-8}$ | 0.679 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $6.31*10^{-8}$ | 0.631 |
| Cumulated RCR | | **2.21** |

The cumulated RCR are above the trigger value of 1 for both tiers. Therefore, the risk for the band of soil of 1.5 m width adjacent to the house is unacceptable when applying the product 06LBCEOL20/2PT by spraying.

Therefore, it is recommended to cover the soil up to 1.5 m from the house walls during the application by spraying.

**Table 2.2.3.1-4: PECs and RCR in soil – *in situ* injection at 150 g/m²**

| Active substance | PEC in soil [$kg/kg_{wwt}$] | RCR for soil |
|---|---|---|
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $1.13*10^{-8}$ | 0.123 |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $9.26*10^{-9}$ | 0.0926 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $8.60*10^{-9}$ | 0.0860 |
| Cumulated RCR | | **0.301** |

The cumulated RCR is below the trigger value of 1. Therefore, the risk for the soil is acceptable when applying the product 06LBCEOL20/2PT by injection.

**FR-CA box 24 - Risk characterisation for the terrestrial compartment for outdoor application**

The risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD as described in the FR-CA box 16, and compared to $PNEC_{soil}$ of each active substance for the application phase of preventive and curative treatment.

| HOUSE - BRUSHING APPLICATION – SOIL [$mg.kg^{-1}_{wwt}$] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Preventive treatment (200 $g.m^{-2}$) | | | | Curative treatment (300 $g.m^{-2}$) | | | |
| | Professional | | Non-professional | | Professional | | Non-professional | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 5.09E-02 | 5.09E-01 | 8.48E-02 | 8.48E-01 | 7.64E-02 | 7.64E-01 | 1.27E-01 | **1.27E+00** |
| Propiconazole | 4.75E-02 | 4.75E-01 | 7.92E-02 | 7.92E-01 | 7.13E-02 | 7.13E-01 | 1.19E-01 | **1.19E+00** |
| Cypermethrin | 6.11E-02 | 6.65E-01 | 1.02E-01 | 1.11E+00 | 9.16E-02 | 9.98E-01 | 1.53E-01 | **1.66E+00** |
| **ΣPEC/ PNEC** | | **1.65E+00** | | **2.75E+00** | | **2.48E+00** | | **4.12E+00** |

Considering that calculated ΣPEC/PNEC ratio for are above 1 for soil, brushing application phase is cause of concern for the terrestrial compartment, unless direct releases to soil is prevented by covering the soil during application.

As a consequence, the risk for the application phase by brushing is considered acceptable for the terrestrial compartment only if the soil is covered during the application, in order to prevent direct releases to soil.

| HOUSE - SPRAYING APPLICATION – SOIL [$mg.kg^{-1}_{wwt}$] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Preventive treatment (200 $g.m^{-2}$) | | | | Curative treatment (300 $g.m^{-2}$) | | | |
| | TIER1 (runoff + drift) | | TIER 2 (drift) | | TIER1 (runoff + drift) | | TIER 2 (drift) | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 5.09E-01 | **5.09E+00** | 4.85E- | 4.85E-01 | 7.64E-01 | **7.64E+00** | 7.28E- | 7.28E-01 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 02 | | | | 02 | |
| Propiconazole | 4.75E-01 | **4.75E+00** | 4.53E-02 | 4.53E-01 | 7.13E-01 | **7.13E+00** | 6.79E-02 | 6.79E-01 |
| Cypermethrin | 6.11E-01 | **6.65E+00** | 5.82E-02 | 6.34E-01 | 9.16E-01 | **9.98E+00** | 8.74E-02 | 9.52E-01 |
| **ΣPEC/ PNEC** | | **1.65E+01** | | **1.57E+00** | | **2.48E+01** | | **2.36E+00** |

For the terrestrial compartment and considering releases due to run off and drift (TIER1) on soil adjacent to the treated surface (0 to 1m), PEC/PNEC ratios for tebuconazole, propiconazole, and cypermethrin are above 1 for preventive and curative treatment by spraying.
For the terrestrial compartment and considering releases due to drift only (TIER 2) on soil distant form the treated surface (1 to 1.5m), ΣPEC/PNEC ratios for tebuconazole, propiconazole, and cypermethrin are also above 1 for preventive and curative treatment by spraying.

As a consequence, the risk for the terrestrial compartment induced by application by spraying is considered acceptable only if the soil is covered during the application, in order to prevent all direct releases to soil *via* run-off and drift.

| **HOUSE INJECTION (150 g.m$^{-2}$) – SOIL [mg.kg$^{-1}_{wwt}$]** | | |
|---|---|---|
| | **Curative treatment** | |
| | **PEC** | **PEC/ PNEC** |
| Tebuconazole | 6.36E-02 | 6.36E-01 |
| Propiconazole | 5.94E-02 | 5.94E-01 |
| Cypermethrin | 7.64E-02 | 8.33E-01 |
| **ΣPEC/ PNEC** | | **2.06E+00** |

Considering that aggregated PEC/PNEC ratio are above 1, the application by injection alone is cause of concern for the terrestrial compartment, unless direct releases to soil is prevented by covering the soil during application.

As a consequence, the risk for the application phase by injection is considered acceptable for the terrestrial compartment only if the soil is covered during the application, in order to preventdirect releases to soil.

2.2.8.6.3.2 Risk characterisation for the service life phase

The soil may be contaminated during the service life of the treated wood due to leaching of the active substances out of the wood. The soil may be contaminated directly or indirectly *via* sewage sludge application on agricultural soil. The risk assessment is performed for these 2 ways of contamination and is presented below.

* Concentrations in soil resulting of direct emissions into soil due to leaching have been calculated in the document IIB, section 3.3.3.3 according to the house scenario. The degradation of the active substances is taken into account. PECs and risk ratios for the soil are summarised in the following table.

**Table 2.2.3.2-1: PECs and risk ratios for the soil – service life, house scenario, with degradation**

| Active substance | PEC in soil, with degradation, over 30 days [$kg/kg_{wwt}$] | RCR for soil | PEC in soil, with degradation, over 5 years [$kg/kg_{wwt}$] | RCR for soil |
|---|---|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $2.67*10^{-11}$ | $2.91*10^{-4}$ | $1.48*10^{-12}$ | $1.62*10^{-5}$ |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $3.25*10^{-9}$ | 0.0325 | $6.37*10^{-9}$ | 0.0637 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $2.87*10^{-9}$ | 0.0287 | $1.40*10^{-8}$ | 0.140 |
| Cumulated RCR | | **0.0615** | | **0.204** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $6.25*10^{-11}$ | $6.80*10^{-4}$ | $3.48*10^{-12}$ | $3.79*10^{-5}$ |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $7.59*10^{-9}$ | 0.0759 | $1.49*10^{-8}$ | 0.149 |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $6.72*10^{-9}$ | 0.0672 | $3.28*10^{-8}$ | 0.328 |
| Cumulated RCR | | **0.144** | | **0.477** |

The individual risk characterisation ratios for each active substance and the cumulated RCR are below 1. Therefore, the risk for the soil is acceptable when using the product 06LBCEOL20/2PT at the doses of 200 g/m² (preventive treatment by brushing or spraying), 300 g/m² (curative treatment by brushing and spraying) and 450 g/m² (curative treatment by injection and by brushing or spraying**)**.

**FR-CA box 25 - Risk characterisation for the terrestrial compartment during the service life of treated wood**

Concerning the service-life phase of treated wood, the risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD as described in the FR-CA box 16, and compared to $PNEC_{soil}$ of each active substance for the service life of the treated wood.

Considering the unacceptable risk for the terrestrial compartment calculated for all intended type of application (c.f. FR-CA box 24), the risk characterisation for the terrestrial compartment during the service life of treated wood taking into account also the application phase was not calculated.

| HOUSE - SERVICE LIFE OF TREATED WOOD – SOIL [$mg.kg^{-1}_{wwt}$] | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Preventive surface treatment (200 $g.m^{-2}$) | | | | Curative surface treatment (300 $g.m^{-2}$) | | | | Injection followed curative surface treatment (eq. to 450 $g.m^{-2}$) | | | |
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 1.13E-03 | 1.13E-02 | 4.14E-03 | 4.14E-02 | 1.70E-03 | 1.70E-02 | 6.21E-03 | 6.21E-02 | 2.55E-03 | 2.55E-02 | 9.32E-03 | 9.32E-02 |
| Propiconazole | 9.50E-04 | 9.50E-03 | 5.43E-03 | 5.43E-02 | 1.43E-03 | 1.43E-02 | 8.17E-03 | 8.17E-02 | 2.14E-03 | 2.14E-02 | 1.22E-02 | 1.22E-01 |
| Cypermethrin | 1.03E-05 | 1.12E-04 | 4.06E-06 | 4.42E-05 | 1.55E-05 | 1.69E-04 | 6.09E-06 | 6.63E-05 | 2.32E-05 | 2.52E-04 | 9.10E-06 | 9.91E-05 |
| 1,2,4-triazole | - | - | - | - | - | - | - | - | 2.44E-04 | 2.97E-02 | 1.73E-03 | 2.11E-01 |
| **ΣPEC/ PNEC** | | 2.09E-02 | | 9.57E-02 | | 3.14E-02 | | 1.44E-01 | | 7.69E-02 | | 4.26E-01 |

Considering that all PEC/PNEC ratios for terrestrial compartment are below 1 regarding the parent compounds, the risk is considered acceptable during the service life of treated wood (also considering that application phases lead to no release to the terrestrial compartment with the application of appropriate risk mitigation measure.

The risk assessment for the metabolite 1,2,4-triazole has been conducted with the highest emission rate (injection + curative) covering all the scenarios. Risks are also acceptable considering this metabolite.

As leaching rates have been derived from semi-field studies using treated wood also protected with a top coat, the labelling will demand the systematic application of a top coat after wood preservation, as intended by the applicant.

* Concentrations in agricultural soil resulting from indirect emissions *via* sewage sludge application have been calculated in EUSES v2.1.2 using the daily quantities of active substance emitted in the STP calculated according to the noise barrier scenario (see document IIB, section 3.3.3.2).
The daily emission during the first 30 days assessment period is a worst case as compared to daily emission during the second assessment period of 5 years and is therefore used to calculate PEC in agricultural soil.
PECs and risk ratios for agricultural soil are summarised in the following tables

**Table 2.2.3.2-2: PECs and risk ratios for the soil – service life, noise barrier scenario**

| Active substance | PEC in agricultural soil [$mg/kg_{wwt}$] | RCR for agricultural soil |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $5.58*10^{-13}$ | $6.09*10^{-6}$ |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $8.49*10^{-12}$ | $8.49*10^{-5}$ |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $8.02*10^{-12}$ | $8.02*10^{-5}$ |
| Cumulated RCR | | **$1.71*10^{-4}$** |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin ($PNEC_{soil}$ = $9.18*10^{-8}$ $kg/kg_{wwt}$) | $8.38*10^{-12}$ | $9.13*10^{-5}$ |
| Tebuconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $1.27*10^{-10}$ | $1.26*10^{-3}$ |
| Propiconazole ($PNEC_{soil}$ = $1.00*10^{-7}$ $kg/kg_{wwt}$) | $1.20*10^{-10}$ | $1.21*10^{-3}$ |
| Cumulated RCR | | **$2.56*10^{-3}$** |

The individual risk characterisation ratios for each active substance and the cumulated RCR are below 1 for the application doses of 300 and 450 g/m².
Therefore, the risk for the agricultural soil is acceptable when using the product 06LBCEOL20/2PT at the doses of 200 g/m² (preventive treatment by brushing or spraying), 300 g/m² (curative treatment by brushing and spraying) and 450 g/m² (curative treatment by injection at 150 g/m² followed by a treatment by brushing or spraying at 300 g/m²) according to the label recommendations.

**FR-CA box 26 - Risk characterisation for indirect releases via STP (*i.e.* spreading of STP sludge on soil) to the terrestrial compartment**

Concerning the service-life of treated wood, the risk characterisation for indirect releases via STP (*i.e.* spreading of STP sludge on soil) to the terrestrial compartment has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD as described in the FR-CA box 16, and compared to $PNEC_{soil}$ of each active substance for the service life of the treated wood.

| NOISE BARRIER - SERVICE LIFE OF TREATED WOOD – SOIL VIA STP [$mg.kg^{-1}_{wwt}$] | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Preventive treatment (200 $g.m^{-2}$) | | | | Curative treatment (300 $g.m^{-2}$) | | | | Injection followed curative surface application treatment (eq. to 450 $g.m^{-2}$) | | | |
| | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | | TIME 1 | | TIME 2 | |
| | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC | PEC | PEC/ PNEC |
| Tebuconazole | 5.64E-06 | 5.64E-05 | 2.63E-06 | 2.63E-05 | 8.46E-06 | 8.46E-05 | 3.94E-06 | 3.94E-05 | 1.27E-05 | 1.27E-04 | 5.92E-06 | 5.92E-05 |
| Propiconazole | 4.39E-06 | 4.39E-05 | 3.06E-06 | 3.06E-05 | 6.59E-06 | 6.59E-05 | 4.61E-06 | 4.61E-05 | 9.88E-06 | 9.88E-05 | 6.90E-06 | 6.90E-05 |
| Cypermethrin | 3.61E-07 | 3.93E-06 | 5.69E-08 | 6.20E-07 | 5.42E-07 | 5.90E-06 | 8.54E-08 | 9.30E-07 | 8.11E-07 | 8.83E-06 | 1.28E-07 | 1.36E-06 |
| **ΣPEC/ PNEC** | | 1.04E-04 | | 5.75E-05 | | 1.56E-04 | | 8.64E-05 | | 2.35E-04 | | 1.30E-04 |

Considering that all PEC/PNEC ratios for terrestrial compartment are below 1 regarding the parent compounds, the risk for the terrestrial compartment is considered acceptable during the service life of treated wood following indirect emissions *via* the STP.

For the metabolite 1,2,4-triazole, the risk assessment conducted for the house scenario covers the noise barrier emissions. Therefore the risks considering this metabolite are also acceptable for indirect releases *via* the STP.

As leaching rates have been derived from semi-field studies using treated wood also protected with a top coat, the labelling will demand the systematic application of a top coat after wood preservation, as intended by the applicant.

2.2.8.6.3.3 Risk characterisation for the metabolites

In soil in aerobic conditions, two major metabolites of cypermethrin were identified: 3-phenoxybenzoic acid (10.2% Applied Radioactivity, AR at day 7) and TDCVC (13.6% of AR at day 7). Further metabolism of these metabolites lead to bound residues and mineralisation to carbon dioxide. A risk assessment for these 2 metabolites is not necessary. Concentrations of cypermethrin in soil can be used as a worst-case assumption in the risk assessment of these degradation products.
1,2,4-triazole was identified as a major metabolite of tebuconazole (9% of AR) and propiconazole (24 – 43% of AR) in soil. Due to the considerably shorter half-life of 1,2,4-triazole in soil compared to that of tebuconazole (10 days *versus* 77 days) and propiconazole (10 days *versus* 129 days), 1,2,4-triazole can be regarded as a transient metabolite. Moreover, the ecotoxicity for the terrestrial environment of the metabolite is significantly lower than found for tebuconazole and propiconazole (see Document IIB, point 5.3). Therefore, the risk assessment of the parent compounds tebuconazole and propiconazole will cover the risk assessment of the metabolite 1,2,4-triazole.
CGA 118 245 was also identified as a main degradation product of propiconazole in soil. This metabolite is also biodegraded in soil faster than propiconazole and is less toxic than the parent compound (see Document IIB, point 5.3). The concentrations of CGA 118 245 is not assumed to exceed the one of propiconazole in soil. Therefore, concentrations of propiconazole in soil can be used as the worst case assumption in the risk assessment of this degradation product.
Based on these considerations it can be concluded that none of the major metabolites will pose an unacceptable risk to the soil compartment following the use of the product 06LBCEOL20/2PT according to the label recommendations.

**FR-CA box 27 – Risk chracterisation for the relevant metabolites**

1,2,4-triazole has been considered relevant for the risk assessment for the terrestrial and the groundwater compartments. The assessment of 1,2,4-triazole was proposed only for groundwater and soil at the highest level of environmental exposure during service-life, as described in FR-CA box 16, FR-CA box 17, FR-CA box 25, and FR-CA box 26.

2.2.8.6.3.4 Risk characterisation for the groundwater compartment

When the soil is contaminated, the active substances may leach into the soil and reach the groundwater. The soil may be contaminated during the service life of the treated wood due to leaching of the active substances out of the wood. The soil may be contaminated directly or indirectly *via* sewage sludge application on agricultural soil. The risk assessment is performed for these 2 ways of contamination and is presented below.

As an indication for potential groundwater concentrations, the concentrations in pore water have been calculated. These concentrations are calculated based on concentrations in soil taking into account the degradation of the substances. The Predicted concentrations in pore water are compared to the threshold value of 0.1 µg/L, the maximum permissible concentration for drinking water laid down by Directive 98/83/EC.

**Table 2.2.4-1 Predicted concentrations in pore water – service life, house scenario, with degradation**

| Active substance | PEC in pore water, with degradation, over 30 days [µg/L] | PEC in pore water, with degradation, over 5 years [µg/L] |
|---|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | | |
| Cypermethrin | $2.63*10^{-6}$ | $1.46*10^{-7}$ |
| Tebuconazole | 0.184 | 0.361 |
| Propiconazole | 0.171 | 0.835 |

| | | |
|---|---|---|
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | | |
| Cypermethrin | $6.16*10^{-6}$ | $3.43*10^{-7}$ |
| Tebuconazole | 0.431 | 0.847 |
| Propiconazole | 0.401 | 1.95 |

**Table 2.2.4-2: Predicted concentrations in pore water – service life, noise barrier scenario**

| Active substance | PEC in pore water of agricultural soil [µg/L] |
|---|---|
| **Application dose = 300 g/m² (curative treatment by brushing or spraying)** | |
| Cypermethrin | $1.31*10^{-8}$ |
| Tebuconazole | $2.71*10^{-4}$ |
| Propiconazole | $3.30*10^{-4}$ |
| **Application dose = 450 g/m² (curative treatment by injection and by brushing or spraying)** | |
| Cypermethrin | $1.96*10^{-7}$ |
| Tebuconazole | $4.06*10^{-3}$ |
| Propiconazole | $4.95*10^{-3}$ |

Cypermethrin $PEC_{porewater}$ is below the threshold value for drinking water of 0.1 µg/L in both scenarios.
Therefore, cypermethrin will not reach the groundwater in unacceptable amounts following the use of the product 06LBCEOL20/2PT according to the label recommendations.

For tebuconazole and propiconazole, the PECs are below 0.1 µg/L in the noise barrier scenario but are above 0.1 µg/L at both times in the house scenario.

However, it has to be noted that this calculation is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.
Moreover, the fate and behaviour of tebuconazole and propiconazole suggest that it is not expected to reach groundwater since these compounds have a low mobility in soil ($K_{oc}$ = 992 L/kg for tebuconazole and 944 L/kg for propiconazole). Furthermore, at the active substance's authorisation stage, the leaching potential of tebuconazole from wood in service was evaluated using the leaching model PEARL 3.3.3. The results show that tebuconazole is not expected to leach to groundwater in unacceptable amounts. Regarding propiconazole, the groundwater concentrations were also calculated at active substance evaluation stage, using FOCUS-PEARL 3.3.3 simulation in nine different FOCUS scenarios with the assumption of 35 houses of treated wood per hectare. None of these concentrations exceeded the maximum permissible concentration of 0.1 µg/L.

Therefore, it can be concluded that a higher tier assessment is not necessary and that tebuconazole and propiconazole are not expected to reach groundwater in unacceptable amounts following the use of the product 06LBCEOL20/2PT according to the label recommendations.

**FR-CA box 28**

The estimated concentrations of active substances, and their relevant degradation products, in the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software, as described in the FR-CA box 17.

The calculated $PEC_{groudwater}$ have been compared to the drinking water standard for pesticides (set at 0.1 µg/L) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/L.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

#### *2.2.8.6.4 Risk characterisation for the atmospheric compartment*

The vapour pressures of cypermethrin, tebuconazole and propiconazole are very low ($2.3*10^{-7}$ Pa at 20°C, $1.7*10^{-6}$ Pa at 20°C and $5.6*10^{-5}$ Pa at 25°C, respectively), thus emissions and PECs in air are considered as negligible for the three active substances.
Therefore, it can be concluded that the use of the product 06LBCEOL20/2PT will not pose a significant risk to the atmospheric compartment.

#### *2.2.8.6.5 Risk characterisation for non-compartmental-specific exposure relevant to the food chain (secondary poisoning)*

*- Cypermethrin*

As cypermethrin has a log $K_{ow}$ > 3 (log $K_{ow}$ = 5.45) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm estimated in EUSES as 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.
The concentration of cypermethrin in food (*i.e.* in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) is calculated in the Document IIB, section 3.3.3.6 taking into account the worst case concentrations in surface water and soil. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

**Table 2.2.6-1: PEC and risk ratios for secondary poisoning**

| **Concentration in freshwater or soil** | **$PEC_{oral\ predator}$** | **$PEC/PNEC_{birds}$** ($PNEC_{oral,bird}$ =33.3 mg/kg food) | **$PEC/PNEC_{mammals}$** ($PNEC_{oral,small\ mammal}$ = 3.33 mg/kg food) |
|---|---|---|---|
| $PEC_{freshwater}$ = $2.90*10^{-6}$ mg/L | $6.05*10^{-4}$ $mg/kg_{wet\ fish}$ | **$1.82*10^{-5}$** | **$1.82*10^{-4}$** |
| $PEC_{soil}$ = $2.56*10^{-10}$ $kg/kg_{wwt}$ | $5.14*10^{-5}$ $mg/kg_{wet\ earthworm}$ | **$1.54*10^{-6}$** | **$1.54*10^{-5}$** |

The RCR are below 1 for the birds and for mammals.
Therefore, the risk of secondary poisoning is acceptable when using the product 06LBCEOL20/2PT at the doses of 200 g/m² (preventive treatment by brushing or spraying), 300 g/m² (curative treatment by brushing and spraying) and 450 g/m² (curative treatment by injection at 150 g/m² followed by a treatment by brushing or spraying at 300 g/m²) according to the label recommendations.

*- Tebuconazole*

According to the BCF in earthworm equal to 28, tebuconazole is not expected to bioaccumulate to terrestrial organisms. Therefore, even if tebuconazole has a potential to cause toxic effects in higher organism since it is classified as toxic for the reproduction, category 2 (H361d), an assessment of secondary poisoning doesn't need to be performed.

*- Propiconazole*

Log $K_{ow}$ of propiconazole is 3.7 implying slight bioaccumulation potential. However, based on the estimation of BCF for terrestrial organisms (BCF = 64) propiconazole is not bioaccumulative to terrestrial organisms. Moreover, propiconazole is not classified as STOT RE 1 or 2 (H372 or H373, equivalent to R48), and is not classified as reprotoxic category 1 or 2 (H360f, H360d, H361f, H361d or H362, equivalent to R60, R61, R62, R63 and R64). Therefore, there is no need to perform an assessment of secondary poisoning for propiconazole.

Based on these considerations, it can be concluded that the use of the product 06LBCEOL20/2PT according to the label recommendations will not pose a significant risk to the top predators.

**FR-CA box 29 – Risk characterisation for secondary poisonning.**

FR-CA agreed with the applicant for considering that secondary poisoning is relevant only for the active substance cypermethrin. As a consequence, the secondary poisoning was assessed for the TIME2 assessment period of the service life for wood treated by injection and surface treatment, considered as a worst case, as described in the FR-CA box 18. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

| **$PEC_{oral\ predator}$** | **$PEC/PNEC_{birds}$** ($PNEC_{oral.bird}$ = 33.3 mg/kg food) | **$PEC/PNEC_{mammals}$** ($PNEC_{oral.small\ mammal}$ = 3.33 mg/kg food) |
|---|---|---|
| 3.54E-07 $mg/kg_{wet\ fish}$ | 1.06E-8 | 1.06E-07 |
| 8.10E-04 $mg/kg_{wet\ earthworm}$ | 2.43E-05 | 2.43E-04 |

Based on these PEC/PNEC ratios, it can be concluded that the use of the product will not pose a significant risk to the top predators.

### 2.2.8.7 Conclusions

| Treatment | Phase | Type of application / uses | Direct releases to the environment | | | Indirect releases to the environment (via STP) | | | | Secondary poisoning |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | House scenario (direct releases to soil) | | Bridge scenario (direct releases to surface water) | Noise barrier scenario | | | | |
| | | | Soil | Groundwater | Surface water and sediment | STP | Surface water and sediment | Soil | Groundwater | |
| Preventive | Application | Brush | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | | Spray | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | Wood in service | Use Class 1 and 2 | Not relevant (releases to the environment not expected) | | | | | | | |
| | | Use Class 3 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable (2) |
| Curative | Application | Brush | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | | Spray | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | | Injection + Brush | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | | Injection + Spray | Acceptable (1) | Acceptable | **Unacceptable** | n.r. | n.r. | n.r. | n.r. | n.r. |
| | Wood in service | Use Class 1 and 2 | Not relevant (releases to the environment not expected) | | | | | | | |
| | | Use Class 3 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable (2) |

(1) Only if soil is covered during the product application, in order to prevent direct releases to soil.
(2) For aquatic and terrestrial food chain.
n.r. – not relevant

For use classes 1 and 2, emissions are considered negligible according to PT08 ESD. The risks for the application phase and service life are therefore considered acceptable for treatment in classes 1 and 2.

For the application phase for wood in class 3, risks are only acceptable if emissions to the aquatic and terrestrial compartments are prevented whatever the type of treatment. As a consequence, no application above or near surface water is allowed to protect the aquatic compartment and the ground has to be covered with an appropriate plastic sheet to prevent any emission to the terrestrial compartment.

For the service-life phase of treated wood, considering that no emissions occurs during application with the use of appropriate risk mitigation measures and considering the systematic application of a top-coat after the wood treatment, risks can be considered acceptable for all the compartments whatever the type of treatment.

The risks are also acceptable for the service-life phase using the bridge over pond and noise barrier scenarios, which covers urban direct and indirect releases to the aquatic compartment.

Proposed risk mitigation measures are detailed in the table below.

| **Specific instructions for use and risk mitigation measures** | **Context / Remark** |
|---|---|
| **Use classes 1 and 2** | |
| None | |
| **Use class 3** | |
| For outdoor treatment, do not apply under rainfall or when rainfall is expected during the next 24 hours. | General risk mitigation |
| For outdoor treatment, cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment | **Risk mitigation measure mandatory to insure acceptable risks to the terrestrial compartment during outdoor application** |
| Do not apply where the product can reach surface water during outdoor application | **Risk mitigation measure mandatory to insure acceptable risks to the aquatic compartment during outdoor application** |
| The outdoor use of treated wood is allowed only if wood preservation is followed by the application of a top-coat which does not contain biocides. This top-coat has to be stable under the standard EN 927-2 in order to limit biocide leaching all along the service-life of wood. | **Risk mitigation measure mandatory to insure acceptable risks to the aquatic compartment and terrestrial compartment during outdoor use of treated wood** |

| **Instructions for safe disposal of the product and its packaging** | **Context / Remark** |
|---|---|
| Dispose of unused product, its packaging and all other waste (i.e. plastic sheet) in accordance with local regulations. | General risk mitigation |

| | |
|---|---|
| Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. | General risk mitigation |

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

*See Summary of Product Characteristics (SPC)*

### *2.2.10 Comparative assessment*

Taking into account that only one product is authorized for the same uses, Anses concludes that there is no adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since tebuconazole does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point. The comparative assessment for V33 TRAITEMENT MULTI-USAGES can be finalised at the screening stage and the product can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

## Annex 2: List of studies reviewed

***List of <u>new data</u>[16] submitted in support of the evaluation of the active substance***

No new data has been sumitted.

***List of <u>new data</u> submitted in support of the evaluation of the biocidal product***

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Yes | No | Yes | No |
| **2.3.2.2** | Legay S. | 2015 | Physico chemical properties, technical characteristics and chemical analyse of the bioicidal product 06LBCEOL20/2P 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)<br>Final report No.402/14/1207F/abcde-e<br>Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex.<br>GLP | V33 | ☐ | ☒ | ☒ | ☐ |
| **2.3.2.2** | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product 06LBCEOL20/2PT<br>final report No.402/14/1207F/ fgh-e<br>Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex.<br>GLP | V33 | ☐ | ☒ | ☒ | ☐ |

16 Data which have not been already submitted for the purpose of the Annex I inclusion.

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| **2.3.2.2** | Legay S. | 2015 | Analyse chimique des matières actives déclarées dans le produit de traitement 06LBCEOL20PT Rapport final n°402/09/1046F/a Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex. GLP | V33 | ☐ | ☒ | ☒ | ☐ |
| **2.3.2.2** | Legay S. | 2015 | Physico-chemical testing on wood preservative 06LBCEO20PT, storage stability at ambient temperature Draft report N°402/09/1046F/b-e Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex. GLP | V33 | ☐ | ☒ | ☒ | ☐ |
| **2.3.2.2** | Legay S. | 2015 | Analyse chimique sur la formulation 06LBCEO20PT (n°lot: 02021120/2PT) Rapport final n°402/11/1003F/a Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex. GLP | V33 | ☐ | ☒ | ☒ | ☐ |
| **2.3.2.2** | Legay S. | 2013 | Chemical analysis of the test item ready to use 06LBCEO20PT (batch n°26031320/2PT) Final report n°402/13/1030F/a-e Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex. GLP | V33 | ☐ | ☒ | ☒ | ☐ |

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| **2.3.2.2** | Legay S. | 2013 | Chemical analysis of the test item ready to use 06LBCEO20PT/2PT (batch n°26031320/2PT)<br>Final report n°402/13/1030F/a-e<br>Laboratoire de Chimie Ecotoxicologie FCBA, Pôle des laboratoires Bois, Allée de Boutaut – BP 227, 33028 Bordeaux cédex.<br>GLP | V33 | ☐ | ☒ | ☒ | ☐ |
| **2.3.2.4** | Legay S. | 2016 | 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 | V33 | ☐ | ☒ | ☒ | ☐ |
| | | | | | | | | |
| 2.2.7.1.7.2 | [redacted] | 2014 | 06LBCEOL20/2PT Assessment of eye irritation Study No.: IO-OCDE-PH-14/0423 | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.2.7.1.7.3 | [redacted] | 2014 | 06LBCEOL20/2PT Assessment of the skin sensitisation potential in the mouse using the LLNA (LLNA: BrdU) | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.2.7.1.4 | J. Bernal | 2016 | In-vitro human skin penetration on 14C-propiconazole in 06LBCEOL20/2PT test item, in accordance to the guideline OECD No.428 | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.2.7.1.4 | J. Bernal | 2015 | In-vitro human skin penetration on 14C-cypermethrine in 06LBCEOL20/2PT test item, in accordance to the guideline OECD No.428 | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.2.7.1.4 | J. Bernal | 2015 | In-vitro human skin penetration on 14C-tebuconazole in 06LBCEOL20/2PT test item, in accordance to the guideline OECD No.428 | V33 | ☐ | ☒ | ☒ | ☐ |

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| 2.1.8.1 | Gabille M. and Le Bayon I. | 2010 | NF EN 113. Determination of the protective effectiveness of a wood preservative against wood-destroying basidiomycetes. Accelerated ageing prior to biological testing: evaporation test (EN 73). | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Le Bayon I. | 2009 | NF EN 113. Determination of the protective effectiveness of a wood preservative against wood-destroying basidiomycetes. Accelerated ageing prior to biological testing: leaching procedure (EN 84). | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Arana M., Arancon J. and Munné O. | 2012 | Determination of preventive action against Reticulitermes species according to EN 118 (2005). | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Arana M., Arancon J. and Munné O. | 2012 | Determination of preventive action against Reticulitermes species according to EN 118 (2005). | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Ansard D. and Paulmier I. | 2015 | Efficacité preventive contre les termites du genre Heterotermes, selon NF EN118 adaptée avec NF EN 73. | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Ansard D. and Paulmier I. | 2015 | Efficacité preventive contre les termites du genre Heterotermes, selon NF EN118 adaptée avec NF EN 84. | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Arana M., Arancon J. and Munné O. | 2012 | Determination of preventive action against Hylotrupes bajulus (Linnaeus) - Part 1: larvicidal effect according to EN 46-1 (2009) | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Arana M., Arancon J. and Munné O. | 2012 | Determination of preventive action against Hylotrupes bajulus (Linnaeus) - Part 1: larvicidal effect according to EN 46-1 (2009) | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Brunet C.and Paulmier I. | 2015 | Détermination de l'efficacité protectrice vis-à-vis de Lyctus brunneus selon NF EN 20-1 | V33 | ☐ | ☒ | ☒ | ☐ |

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| 2.1.8.1 | Brunet C.and Paulmier I. | 2016 | Efficacité protectrice contre Anobium punctatum selon NF EN 49-1 avec épreuves d'usure. | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Brunet C.and Paulmier I. | 2015 | Efficacité protectrice contre Lyctus brunneus selon NF EN 20-1 | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Brunet C. and Paulmier I. | 2011 | 06LBCEOL20/2PT. Eradicant efficacy against Hylotrupes bajulus according to EN 1390. | V33 | ☐ | ☒ | ☒ | ☐ |
| 2.1.8.1 | Schumacher P. and Fennert E.-M. | 2010 | 06LBCEOL20/2PT. Determination of the eradicant efficacy in preventing hatching of Anobium punctatum (De Geer) according to EN 370 (05/1993) in combination with evaporative ageing procedure according to EN 73 (04/90). | V33 | ☐ | ☒ | ☒ | ☐ |

## Annex 4: Toxicology and metabolism –active substance

**<Cypermethrin>**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | SF |
| AEL long-term | 0.022 | 2 years rat | 100 |
| AEL medium-term | 0.055 | 90 days dog | 100 |
| AEL acute | 0.088 | Neurotoxicity rat | 100 |

| | |
|---|---|
| Inhalative absorption | 100% |
| Oral absorption | 57% |
| Dermal absorption | 2% |

| **Classification** | |
|---|---|
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 3 – H301<br>STOT SE 3 – H335<br>STOT RE 2 – H 373 |

**<Propiconazole>**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | SF |
| AEL long-term | 0.04 | 2 years rat | 100 |
| AEL medium-term | 0.08 | Fertility rat | 100 |
| AEL acute | 0.3 | Developmental rat | 100 |

| | |
|---|---|
| Inhalative absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | 3% |

| **Classification** | |
|---|---|
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302<br>Skin Sens 1 – H317 |

**<Tebuconazole>**

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | SF |
| AEL long-term | 0.03 | 1 year dog | 100 |
| AEL medium-term | 0.03 | 1 year dog | 100 |
| AEL acute | 0.03 | 1 year dog | 100 |

| | |
|---|---|
| Inhalative absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | 6% |

| **Classification** | |
|---|---|
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302<br>Repr 2 – H361d |

## Annex 5: Toxicology – biocidal product

**<V33 TRAITEMENT MULTI USAGES>**

Date: 26/07/2016

**General information**

| | |
|---|---|
| Formulation Type | RTU |
| Active substance(s) (incl. content) | Cypermethrin 0.18%<br>Propiconazole 0.14%<br>Tebuconazole 0.15% |

| **Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)** | |
|---|---|
| Rat LD50 oral (OECD 420) | n.a |
| Rat LD50 dermal (OECD 402) | n.a |
| Rat LC50 inhalation (OECD 403) | n.a |
| Skin irritation (OECD 404) | n.a |
| Eye irritation (OECD 405) | Non irritant to eyes |
| Skin sensitisation (OECD 429; LLNA) | Non skin sensitizer |

| **Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)** | |
|---|---|
| Short-term toxicity studies | n.a |
| Toxicological data on active substance(s) (not tested with the preparation) | n.a<br>n.a |
| Toxicological data on non-active substance(s) (not tested with the preparation) | n.a<br>n.a |
| Further toxicological information | n.a |

| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
|---|---|
| Regulation 1272/2008/EC | EUH 208: Contains propiconazole and 2-methyl-3(2H)-isothiazolone (MIT). May produce an allergic reaction. |

## Annex 6: Safety for professional operators

**<V33 TRAITEMENT MULTI USAGES>**

Date: 26/07/2016

**Exposure assessment**

Please refer to the Excel data sheet “Expo Pro – V33” attached to the PAR.
This file contains several excel data sheet for each exposure scenario, as follows:

Brush application: Excel data sheet “Expo IR – Brushing”;
Spray application: Excel data sheet “Expo IR – Spraying”;
Brush application + injection: Excel data sheet “Expo IR – Injecting (1);
Spray application + injection: Excel data sheet “Expo IR – Injecting (2);

**Risk assessment**

Please see the tables presented in the document section 2.2.7.3.1.1

# Annex 7: Safety for non-professional operators and the general public

**<V33 TRAITEMENT MULTI USAGES>**

Date:26/07/2016

**Exposure assessment for Non-professionals**

Please refer to the Excel data sheet “Expo Non Pro – V33” attached to the PAR.
This file contains several excel data sheet for each exposure scenario, as follows:

Brush application: Excel data sheet “Expo IR – Brushing”;
Spray application: Excel data sheet “Expo IR – Spraying”;
Brush application + injection: Excel data sheet “Expo IR – Injecting (1);
Spray application + injection: Excel data sheet “Expo IR – Injecting (2);

**Risk assessment for Non-professionals**

Please see the tables presented in the document section 2.2.7.3.1.2.

**Exposure assessment for General public (secondary exposure)**

Please refer to the Excel data sheet “Expo Pro – V33” attached to the PAR.
This file contains 2 excel data sheet for secondary exposure scenario, as follows:

Acute exposure scenario: Excel data sheet “Expo IIR - Acute”;
Chronic exposure scenario: Excel data sheet “Expo IIR - Chronic”.

**Risk assessment for General public (secondary exposure)**

Please see the tables presented in the document section 2.2.7.3.2.

## Annex 8: Residue behaviour

**cypermethrine, tebuconazole, propiconazole**

Date: 07/07/2016

Intended Use (critical application): preventive and curative treatment of interior woods especially in wet situation (beams, frames, wood in cellars, basements and bathrooms) and exterior woods (shutters, doors, siding, fences, gates, awnings, roof overhangs).
Active substance(s): cypermethrin, tebuconazole, propiconazole
Formulation of biocidal product: EW (emulsion, oil in water)
Place of treatment: indoor and outdoor
Target organisms: wood rotting basidiomycetes, wood boring insects, termites
Superficial application/ spray treatment at 300 g product/m² and by injection (in combination with superficial application) at 150 g product/m².

The intended use descriptions of the cypermethrin, tebuconazole, propiconazole 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 and exterior woods that does not come in direct contact with food and feedstuff. No further data are required concerning the residue behaviour.

## Annex 9: Efficacy of the active substance from its use in the biocidal product (*)

| 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 | 06LBCEOL20/2PT concentrate[1] | *C. puteana*<br>*G.trabeum*<br>*P.placenta*<br>*C.versicolor* | EN 113 after EN 73 (evaporation) | Following the recommendation of the standard:<br>On scots pine blocks, the targeted concentrations to be tested were 0.0, 3.7, 4.6, 5.8, 7.2 and 9.0 kg of product/m3 of wood.<br>On beech blocks, the targeted concentrations to be tested were 0.0, 6.3, 8.0, 10.0, 12.6 and 15.9 kg of product/$m^3$ of wood.<br>The product was applied by vacuum impregnation<br>- 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine. *C. versicolor* is tested on beech replicates<br>- Number of replicates: 6 replicates for each treatment and each fungal strain.<br>CONTROLS<br>- Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.<br><br>The effects investigated is mass loss of the test blocks, induced by the fungal development<br>The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.<br>- Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains. | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)<br><br>Mid toxic values of the test product 06LBCEOL20/2 PT concentrate:<br>- cannot be determined for *C. puteana*, *G. trabeum* and *C. versicolor*, but the toxic values were lower than 3.7, 3.8 and 6.4 kg/$m^3$ respectively.<br>- against *P. placenta*: 6.6 kg/$m^3$ or 13.2 g/$m^2$.<br><br>**Thus, the biological reference value of the test product 06LBCEOL20/2PT concentrate for brown and white rot fungi, on softwoods and hardwoods, after evaporative ageing procedure, is 6.6 kg/$m^3$ or 160.25 g 06LBCEOL20/2PT / $m^2$ of wood.** | Gabille M. and Le Bayon I., 2010<br><br>401/09/047F/1/b/e<br><br>IC 2 |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT concentrate[1] | *C. puteana*<br>*G.trabeum*<br>*P.placenta*<br>*C.versicolor* | EN 113 After EN 84 (leaching) | Following the recommendation of the standard:<br>On scots pine blocks, the targeted concentrations to be tested were 0.0, 3.7, 4.6, 5.8, 7.2 and 9.0 kg of product/m3 of wood. | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)<br><br>**The study demonstrates the efficacy of the 06LBCEOL20/2PT** | Le Bayon I., 2009<br><br>401/09/047F/1/a/e<br><br>IC 1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | On beech blocks, the targeted concentrations to be tested were 0.0, 6.3, 8.0, 10.0, 12.6 and 15.9 kg of product/m3 of wood.<br>- 6 blocks tested for each treatment and each fungal strain. *C. puteana, G. trabeum* and *P. placenta* are tested on pine. C. versicolor is tested on beech replicates<br>The product was applied by vacuum impregnation<br>- Number of replicates: 6 replicates for each treatment and each fungal strain.<br>CONTROLS<br>- Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.<br><br>The effects investigated is mass loss of the test blocks, induced by the fungal development<br>The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.<br>- Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains. | **concentrate formulation is 4.2 kg/m$^3$ on *C. puteana, G. trabeum, P. placenta* and 7.2 kg/m$^3$ for *C. versicolor*. It corresponds to an application rate of 14.4 g/m² of concentrate product or 174.82 g of 06LBCEOL20/2PT / m² of wood.** | |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | Common furniture beetle | EN 49 + EN 73 (evaporation) | The ready to use product 06LBCEOL20/2PT is applied by dipping on oak test blocks and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 197.9 g/m² and 199.60 g/m² (mean 101.2 g/m²).<br>5 replicates for the treated block and for the control are performed.<br>The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.<br>The method for recording / scoring effects is the count of eggs laid, eggs hatched and alive larvae found. | The study is validated as more than 50 alive larvae in total are found in the control and as alive larvae are found in each control block<br><br>**This study demonstrated the efficacy of the product at 200 g of product / m² of wood against *Anobium punctatum*** | Brunet C.and Paulmier I., 2016<br><br>401/14/084F/a<br><br>IC1 |
| MG 02: preservatives | Wood preservative | 06LBCEOL20/2PT[2] | Common furniture beetle | EN 49 + EN 84 (leaching | The ready to use product 06LBCEOL20/2PT is applied by dipping | The study is validated as more than 50 alive larvae in total are found in | Brunet C.and Paulmier I., 2016 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Preventive treatment | | | | on oak test blocks and followed by an artificial weathering according to the EN 84 standard method (leaching).<br>The quantity really applied on each test block varied between 198.2 g/m² and 200.2 g/m² (mean 199.4 g/m²).<br>5 replicates for the treated block and for the control are performed.<br>The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.<br>The method for recording / scoring effects is the count of eggs laid, eggs hatched and alive larvae found. | the control and as alive larvae are found in each control block<br><br>**This study demonstrated the efficacy of the product at 200 g of product / m² of wood against *Anobium punctatum***| 401/14/084F/b<br><br>IC1 |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product 06LBCEOL20/2PT is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 100.80 g/m² and 101.60 g/m² (mean 101.2 g/m²).<br>10 recently hatched larvae of *H. bajulus* for each are used for each test block.<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The effect investigated is the mortality of insect's larvae.<br>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.<br>- Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (90%).<br>On the treated test block, 100 % or the larvae was dead and had not tunnelled.<br><br>**This study demonstrated the efficacy of the product at 100 g of product / m² of wood against *Hylotrupes bajulus* larvae** | Arana M., Arancon J. and Munné O., 2012<br><br>27378-1-a<br><br>IC2 |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 84 (leaching) | The ready to use product 06LBCEOL20/2PT is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).<br>The quantity really applied on each test block varied between 100.08 g/m² and 102.24 g/m² (mean 101.05 g/m²).<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The effect investigated is the mortality of | The study is validated as the survival rate in the control is higher than 70 % (90%).<br>On the treated test block, 100 % or the larvae was dead and had not tunnelled.<br><br>**This study demonstrated the efficacy of the product at 100 g of product / m² of wood against *Hylotrupes bajulus* larvae** | Arana M., Arancon J. and Munné O., 2012<br><br>27378-2-a<br><br>IC 1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | insect's larvae.<br>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.<br>- Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | | |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product 06LBCEOL20/2PT is applied by brushing on oak test blocks and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 194.7 g/m² and 197.3 g/m² (mean 196.0 g/m²).<br>10 recently hatched larvae of *L. bruneus* for each are used for each test block.<br>5 replicates for the treated block and 5 replicates for the control are performed.<br>The investigated effects are the mortality of the insects.<br>The method for recording / scoring effects is the recovery and the counting of the insects (alive/dead) and the number of drilled openings.<br>- Intervals of examination is one examination, 20 weeks after beginning of exposure of the adults. | The study is validated as:<br>- At least, for each control, 20 insects are found<br>- Adult emergence has started at the end test in the control and at least 85 % of the insects are found alive<br>In the treated blocks, a mortality of 100% is observed in each replicate. | Brunet C.and Paulmier I., 2015<br><br>401/14/084F/c |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | Subterranean termite: *Reticulitermes grassei* | EN 118 + EN 73 (evaporation) | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 198.45 mL/m² and 200.48 mL/m² (mean 199.66 mL/m²).<br>250 workers, 4 nymphs and 1 soldier termite were used for each test block.<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The investigated effects are the mortality of the insects.<br>Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs.<br>Calculation of the percentage of | The study is validated as the survival rate in the control is higher than 50 % (88 %) and the control test blocks are ranked 4.<br><br>**All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 06LBCEOL20/2PT at the application rate of 200 ml of product / m² of wood.** | Arana M., Arancon J. and Munné O., 2012<br><br>27378-3-a<br><br>IC 2 |

| | | | | | | | |
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| | | | | | 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).<br>- Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | | |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | European subterranean termite: *Reticulitermes grassei* | EN 118 + EN 84 (leaching) | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (Pinus sylvaticus) and followed by an artificial weathering according to the EN 84 standard method (leaching).<br>The quantity really applied on each test block varied between 198.89 mL/m² and 200.68 mL/m² (mean 199.50 mL/m²).<br>250 workers, 4 nymphs and 1 soldier termite were used for each test block.<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The investigated effects are the mortality of the insects.<br>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).<br>- Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (88 %) and the control test blocks are ranked 4.<br><br>**All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 06LBCEOL20/2PT at the application rate of 200 ml of product / m² of wood.** | Arana M., Arancon J. and Munné O., 2012<br><br>27378-4-a<br><br>IC 1 |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | Subterranean termite: *Heterotermes tenuis* | EN 118 + EN 73 | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 199.3 mL/m² and 202.6 mL/m² (mean 200.6 mL/m²)<br>250 workers, 4 nymphs and 1 soldier termite were used for each test block.<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The investigated effects are the mortality of the insects.<br>Method for recording / scoring effects: | The study is validated as the survival rate in the control is higher than 50 % (61.3 %) and the control test blocks are ranked 4.<br><br>**All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 06LBCEOL20/2PT at the application rate of 200 ml of product / m² of wood.** | Kutnik M., 2015<br><br>401/15/005F/b<br><br>IC 1 |

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| | | | | | 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).<br>- Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | | |
| MG 02: preservatives | Wood preservative Preventive treatment | 06LBCEOL20/2PT[2] | Subterranean termite: *Heterotermes tenuis* | EN 118 + EN 84 | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).<br>The quantity really applied on each test block varied between 199.1 mL/m² and 204.3 mL/m² (mean 201.6 mL/m²).<br>250 workers, 4 nymphs and 1 soldier termite were used for each test block.<br>6 replicates for the treated block and 3 replicates for the control are performed.<br>The investigated effects are the mortality of the insects.<br>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).<br>- 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 % (58.3 %) and the control test blocks are ranked 4.<br><br>**All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product 06LBCEOL20/2PT at the application rate of 200 ml of product / m² of wood.** | Ansard D and Paulmier I, 2015<br><br>401/15/005F/a<br><br>IC 1 |
| MG 02: preservatives | Wood preservative Curative treatment | 06LBCEOL20/2PT[2] | Common furniture beetle: *Anobium punctatum (L.)* | EN 370 + EN 73 | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).<br>The quantity really applied on each test block varied between 300.8 mL/m² and 301.7 mL/m² (mean 301.2 mL/m²).<br>12 larvae of *Anobium punctatum* were used per test blocks<br>6 replicates for the treated block and 6 replicates for the control are performed. | The study is validated at least 30 (37) larvae has emerged in the control<br>No emergence of adult is observed in the treated blocks and the proportion of alive imago is lower than in the control<br><br>**Then this study demonstrates the differed curative efficacy of the product 06LBCEOL20/2PT at the application rate of 300 ml product / m² of wood.** | Schumacher P. and Fennert E.-M., 2010<br><br>32/09/9289/01<br><br>IC 2 |

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| | | | | | The investigated effects is the mortality of the larvae and hatched beetles<br>- 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.<br>- Intervals of examination: one time, 6 weeks after beginning of the hatching in the control blocks. | | |
| MG 02: preservatives | Wood preservative Curative treatment | 06LBCEOL20/2PT[2] | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product 06LBCEOL20/2PT is applied by brushing on sapwood test blocks (*Pinus sylvestris*)<br>The quantity really applied on each test block varied between 299.3 mL/m² and 300.8 mL/m² (mean 300.1 mL/m²).<br>6 larvae of *Hylotrupes bajulus* were used for each test block.<br>10 replicates for the treated block and 2 replicates for the control are performed.<br>The investigated effects are the mortality of the larvae.<br>- Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.<br>- Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.<br>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 75 % (92%).<br><br>**The mortality observed in the treated block is higher than 80 % (86.4 %) which validated the low action efficacy of the product 06 LBCEOL 20/2 PT, at the application rate of 300 ml of product / m² of wood, 24 weeks after is application.** | Brunet C. and Paulmier I., 2011<br><br>401/10/096F/1/e<br><br>IC 1 |

*(*) fill in one table for each MG/PT and/or field of use envisage*